



September 02, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1614-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: CMS-1614-P—Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.

Dear Ms. Tavenner:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on the Proposed Rule that updates and makes revisions to the End Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2015, and sets forth requirements for the ESRD Quality Incentive Program (QIP) for payment years (PYs) 2017 and 2018.

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 In the final rule implementing the new ESRD PPS on January 1, 2011, CMS indicated that the new bundled payment would “encourage patient access to home dialysis,”² and, “make home dialysis economically feasible and available to the ESRD patient population.”³ To that end, data indicates that the ESRD PPS—which pays for home

¹ Neumann, Mark. "Some bright spots for home dialysis." *Nephrology News & Issues*. (July 13, 2012). Web. <http://www.nephrologynews.com/blogs/post/2012/07/13/Some-bright-spots-for-home-dialysis.aspx>

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

³ *Id.* at 49,060.

dialysis at the same rate as dialysis provided in the facility—has led to an increase in the utilization of home dialysis.⁴ 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.”⁵ Specifically, MedPAC reports “each year from January 2010 through June 2013, CMS reports that the share of beneficiaries dialyzing at home steadily increased from a monthly average of 8.3 percent to 8.9 percent, 9.5 percent, and 9.9 percent, respectively.”⁶

Additionally, an annual survey of the ten largest providers found that between 2010 and 2012, home patients represented about 20 percent of the growth in ESRD patients, largely attributed to the growth in PD.⁷ A recent update to the survey continues to show that “overall, the percentage of patients on home therapies has been growing steadily in this group since 2011.”⁸ This is significant given that in years prior there has been little growth in home dialysis. 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.

The Alliance is encouraged by the growth in PD as a result of the bundle and wishes to see it continue through CY 2015 and beyond. HHD has not had the same type of growth, but it is another important treatment option for patients that should be fully supported within the bundled payment environment.

Comments on ESRD PPS Proposed Rule for Calendar Year 2015

Section II. Calendar Year (CY) 2015 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

The Alliance supports a strong, stable Medicare payment system for dialysis to ensure that patients have access to all treatment modalities, including PD and HHD. It is important that the payment system is sustainable and structured to ensure that dialysis providers have the necessary resources to provide the full range of services, including training and equipment required to support patients receiving treatments in-center and within their home.

The Alliance commends CMS for restating its policy to allow patients with medical necessity to benefit from more frequent dialysis. Studies have demonstrated that more frequent

⁴ 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.

⁵ Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, March 2014.

⁶ *ibid*

⁷ Mark E. Neumann, “Has renewed interest in home therapies led to more patients going home?” Nephrology News Webinar (Jun. 28, 2012), available at <http://www.nephrologynews.com/assets/documents/NNI/HD%20-%20Next%20StepsMNeumann2.pdf>.

⁸ Mark E. Neumann, “A look back, and getting positioned for the future” Nephrology News (July 16, 2014), available at <http://www.nephrologynews.com/articles/110332-a-look-back-and-getting-positioned-for-the-future>.

hemodialysis results in faster recovery time after treatment with fewer side effects;⁹ improved cardiac status¹⁰ and survival rates;¹¹ and increased likelihood for transplantation¹² and opportunity for rehabilitation.¹³

The Alliance believes that any policy on payment for more frequent hemodialysis should be consistent with Congress' stated intent in the creation of the ESRD benefit that "the maximum practicable number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated."¹⁴

As such, the Alliance appreciates CMS's restatement of its current policy which recognizes that some patient conditions can benefit from more than three dialysis sessions per week and, importantly, allows Medicare Administrative Contractors (MACs) to determine whether additional treatments are medically necessary at the local level.

The Alliance shares CMS's commitment to ensuring the highest quality of care and access to life-sustaining dialysis treatments for all ESRD patients and offers the following recommendation for consideration:

1. CMS should provide for an appropriate and routine update of the self- and home dialysis training add-on adjustment.

The Alliance thanks CMS for the focus on self- and home dialysis training in last year's rule including the increase in the training add-on adjustment from \$33.44 to \$50.16. The Alliance was encouraged by CMS's recognition of the importance of training for home dialysis patients and hopes the Agency will continue to monitor and evaluate the impact of the training payment on access to home dialysis.

To that end, the Alliance believes one of the barriers to achieving appropriate utilization of self- and home dialysis is the up-front investment in nursing and other resources that are necessary to create and nurture a home dialysis 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.¹⁵ As stated earlier, only 10 percent of U.S. dialysis patients receive treatment at home, with less

⁹ 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.

¹⁰ Culleton, B et al. Effect of Frequent NHD vs.CHD on Left Ventricular Mass and Quality of Life. *JAMA* 2007;11

¹¹ 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.

¹² *ibid*

¹³ 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>.

¹⁴ Section 1881(c)(6) of the Social Security Act.

¹⁵ 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

than 2 percent of patients receiving HHD.¹⁶ Additionally, less than a quarter of dialysis centers are certified to offer HHD.¹⁷

Significant training is involved in preparing a dialysis patient to self-dialyze or 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 training service performed by RNs is 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.

Despite the important increase that occurred last year, there is still a significant disparity between the reimbursement that the facility receives for HHD training and the actual cost to provide a home dialysis training session. In a 2014 Moran Company analysis of 2012 CMS cost reports, the average cost of a HHD training session for all centers providing HHD services was \$500.57 (including treatment and training, exclusive of IV pharmaceuticals), and the cost for high volume facilities was slightly higher at \$504.08. Based on the average maintenance cost of a home dialysis session for high-volume providers in 2012 (\$185.84), the incremental cost for training across all high-volume home dialysis facilities was \$318.24. This added \$318.24 in cost is clearly in excess of the current add-on training payment of \$50.16. Additionally, the Moran Company reports, “in 2012, HHD training required more sessions on average, compared to PD training (14.7 HHD training sessions per patient compared to 5.6 PD training sessions). The number of training sessions for HHD has increased slightly from 2010 and has remained constant for PD training (13.35 HHD training sessions and 5.53 PD training sessions on average in 2010).”¹⁸

Training is a critical part of a patient’s success with self- and home dialysis and this payment, similar to other payments, should compensate fairly for the resources required to administer the service.

In order to ensure patient access to home dialysis modalities, CMS should consider using the best available information to update the dialysis training add-on payment in a way that more appropriately reflects the actual nursing and facility costs to provide this training service, and CMS should continue to refine this methodology overtime.

¹⁶ 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.

¹⁷ Dialysis Facility Compare <http://www.medicare.gov/Download/DownloaddbInterrim.asp>

¹⁸ The Moran Company, “Home Dialysis Cost Study: 2012 Medicare Cost Report Analysis Modality & Training Costs” May 2014. Analysis conducted for NxStage Medical, INC. A summary of the analysis is available upon request. These findings are consistent with a 2010 Moran Company Study of 2006 cost reports previously provided to the Agency, which found a per HHD training session cost of \$430.29 versus a per session HD cost of 208.82, representing \$221.47 in additional costs. It is also consistent with a 2012 Moran Company Study of 2010 cost reports previously provided to the Agency, which found the average cost of a HHD training session for all centers providing HHD services was \$438.17 (including treatment and training, exclusive of IV pharmaceuticals), representing \$251.75 in additional costs when compared to an average HD treatment without training at these centers (\$186.42, again, exclusive of IV pharmaceuticals).

Additionally, CMS should allow for an inflationary adjustment to the payment. A separate inflationary adjustment is necessary, as the training add-on payment is outside the bundled base rate and is not adjusted by the annual market basket update. Given that the “training add-on adjustment is directly related to nursing salaries,”¹⁹ and those salaries and staffing costs go up over time, the training add-on payment should be adjusted accordingly.

It is important to note that an update to the training add-on should be made in a manner as to not impact patients on other treatment modalities; and, as discussed below, the Alliance believes that an update can be accomplished in a non budget-neutral way. We understand that CMS chose to make a budget neutral update last year, but we continue to assert that the modest investment to update this payment could be done in a manner that does not impact any proposal for the CY 2015 PPS payment rate for providing ESRD services.

The Alliance believes that section 1881(b)(14) of the Social Security Act (SSA), as amended most recently by ATRA,²⁰ is silent as to whether a payment adjustment (whether new or a revision to the amount of a current adjustment) under the ESRD PPS for 2015 or a later year must be budget neutral, giving CMS the choice to have the change be budget neutral or not.

Therefore, 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. Requiring budget neutrality exacerbates the historical underfunding of the overall dialysis payment.

Section III. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

The Alliance believes that the ESRD QIP offers tremendous opportunities to drive improvements in the quality, safety, and efficacy of dialysis care. That is why it is critical that the 10 percent of ESRD patients who dialyze at home be assessed and included as appropriate in the QIP. The inclusion of this population in the QIP ensures that quality improvements extend to all modalities, not just in-center care.

As CMS facilitates, considers and implements new and existing quality measures, the Alliance encourages the Agency to include home dialysis-focused measures that are supported by data derived specifically from home dialysis patients and not from information that is extrapolated from in-center data. Additionally, in the development of these measures, CMS should recognize that PD and HHD are distinct from each other and from in-center dialysis. Thus, quality

¹⁹ 75 Fed. Reg. at 49,063.

²⁰ Pub. L. No. 112-240, § 632.

measures in the QIP should reflect the unique nature of each modality and should be developed based on data specific to that modality.

Metrics designed for in-center conventional dialysis may not capture the clinical and/or quality-of-life benefits of home dialysis and may impose additional burdens on facilities without enhancing the home dialysis patient's experience of care. CMS should work closely with ESRD stakeholders including providers, facilities, patients, organizations including the Alliance and other experts in home dialysis to consider QIP metrics that will achieve the overarching goals of right therapy, right place, and reduced cost at the highest level of patient experience. The Alliance continues to believe that patient involvement is critical in the development of quality measures to ensure they address issues that will lead to improved quality of life.

The Alliance looks forward to working with CMS on these issues and submits the following comments on the proposed ESRD QIP:

1. CMS should develop and adopt a validated patient experience instrument for assessing the home dialysis population.

The Alliance believes that patient experience is an important quality of care indicator. Home dialysis patients have historically demonstrated increased satisfaction with their care versus in-center HD patients. For instance, home dialysis allows for greater autonomy and flexibility over when a patient dialyzes and is more conducive for work—both of which can have a positive impact on quality of life. Yet experiences of home patients are not currently considered in the ESRD QIP. This is contrary to the intent of Congress which required CMS to adopt “to the extent feasible, such measure (or measures) of patient satisfaction.”²¹ This also significantly limits the ability to assess and improve the quality of care provided to home patients, and compare care across modalities and settings.

The Alliance was encouraged by the inclusion of measures in this Proposed Rule that focus on quality of life and patient well-being, but remains concerned that home dialysis patients are still not adequately represented in the current QIP.

For instance, the current In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) was designed for use only with in-center hemodialysis patients. In this rule, CMS is proposing to replace the ICH CAHPS reporting measure with a new clinical measure for PY 2018 and future payment years, but the Agency makes no mention of how it will meet the statutory requirement to measure patient satisfaction in the 10 percent of ESRD patients who dialyze at home. The Alliance strongly believes that CMS should not overlook this important patient population and that the experience of home dialysis patients should be included in the QIP.

Therefore, the Alliance urges CMS to facilitate the development and adoption of a patient experience instrument validated for assessing the home dialysis population. In developing this

²¹ See Section 153(c) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275), adding new Section 1881(h) of the Social Security Act.

tool, the Alliance encourages collaboration with stakeholders, particularly home dialysis patients, to ensure that the survey instrument is designed to capture the experience of home dialysis patients in all settings in a manner that is not overly burdensome for patients and providers.

Conclusion

The Alliance appreciates the opportunity to provide comments on the ESRD PPS for CY 2015 and the ESRD QIP for PYs 2017 and 2018. We look forward to working with CMS in the future to advance policies that support appropriate utilization of home dialysis.

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

Sincerely,

A handwritten signature in cursive script that reads "Stephanie Silverman". The signature is written in black ink and includes a long horizontal flourish at the end.

Stephanie Silverman
Executive Director



Participating Organizations (2014)

American Association of Kidney Patients

American Kidney Fund

American Nephrology Nurses Association

American Society of Nephrology

American Society of Pediatric Nephrology

Baxter

Cleveland Clinic

Dialysis Clinic, Inc.

Dialysis Patient Citizens

Fresenius Medical Care

Greenfield Health Systems

Home Dialysis Plus

Home Dialyzors United

Hortense and Louis Rubin Dialysis Center, Inc.

Medical Education Institute

National Kidney Foundation

National Renal Administrators Association

Northwest Kidney Centers

NxStage Medical

Renal Physicians Association

Renal Support Network

Satellite Healthcare

Southwest Kidney Institute

TNT Moborg International Ltd.