August 25, 2015

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1628-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: CMS-1628-P—Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program

Dear Acting Administrator Slavitt:

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) 2016 and to the ESRD Quality Incentive Program (QIP) for payment year (PY) 2019.

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

[1] United States Renal Data System (USRDS), 2014 Annual Data Report: Epidemiology of Kidney Disease in the United States, available at www.usrds.org/2014/view/Default.aspx

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 dialysis at the same rate as dialysis provided in the facility—has led to an increase in the utilization of home dialysis, particularly PD.[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]

The percentage of dialysis patients on home therapies has been growing steadily since 2011, largely attributed to the growth in PD. Between 2002 and 2012, home dialysis utilization increased by 35 percent, with a majority of that growth occurring between 2008 and 2012.[7] 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 2016 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.

The Alliance shares CMS' commitment to ensuring the highest quality of care and access to life-sustaining dialysis treatments for all ESRD patients. The Alliance is pleased to offer the following specific comments related to this year's Proposed Rule.

Section II. Calendar Year (CY) 2016 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.

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[2] 75 Fed. Reg. 49,030, 49,058 (Aug. 12, 2010).
[3] *Id*. at 49,060.
[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] United States Renal Data System (USRDS), 2014 Annual Data Report: Epidemiology of Kidney Disease in the United States, available at www.usrds.org/2014/view/Default.aspx

The Alliance commends CMS for clarifying in last year's Final Rule its policy to allow patients with medical necessity to benefit from more frequent dialysis. Studies have demonstrated that more frequent hemodialysis results in faster recovery time after treatment with fewer side effects;[8] improved cardiac status[9] and survival rates;[10] and increased likelihood for transplantation[11] and opportunity for rehabilitation.[12] As such, the Alliance appreciates CMS' recognition that some patient conditions can benefit from dialysis regimens of more than three dialysis sessions per week. However, the Alliance encourages CMS to be more consultative with Medicare Administrative Contractors (MACs) to ensure that access to medically appropriate home dialysis care is not discouraged, and that appropriate policies outlined in the Provider Integrity Manual and other relevant publications, such as the Local Coverage Determination process, are followed in the event of a MAC's intent to clarify its local coverage policies.

1. **When reassessing data through regression analysis, CMS should consider the self- and home dialysis training add-on adjustment.**

The Alliance was encouraged by CMS' recognition of the importance of training for home dialysis patients by increasing the training adjustment from $33.44 to $50.16 in its CY 2014 rule, and by its acknowledgement in last year's rule of the hundreds of stakeholder comments it received in support of an increase in this payment. However, we believe that the increased payment rate should not have taken funding from the ESRD PPS but rather should have been funded with new money.

Significant training is involved in preparing a dialysis patient to perform more frequent HHD, 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.

In addition, during HHD training, the RN is responsible for teaching both the training patient and a care partner in each session. Despite the increase that occurred two years ago, there is still a significant disparity between the reimbursement that the facility receives for HHD training and the actual cost to provide an HHD training session.

In this year's Proposed Rule, CMS performed a regression analysis to update certain payment multipliers. In doing so, "home dialysis training treatments, in which the proportion of training

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[8] 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.

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

[10] 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.

[11] ibid

[12] 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.

treatments furnished by the facility is specified," were held constant as a control variable. This was done "in order to remove any confounding cost effects of training on other independent variables included in the payment model, particularly the onset of dialysis within 4 months." Rather than being a confounding effect, training treatments are truly associated with the costs contained within the onset period.

Training is an essential gateway to a patient's ability to perform their own treatments safely and successfully and this payment, similar to other payments, should compensate fairly for the resources required to administer the service. This issue has comprised, year over year, a significant proportion of the comments submitted to CMS during the rulemaking period -- primarily from beneficiaries directly impacted by the policy.[13] Despite this level of concern, the issue remains unresolved. As CMS considers substantial changes to its case-mix payment adjustments, we urge the agency to factor the cost of training in a way that more appropriately reflects the actual nursing and facility costs to provide this training service when a patient successfully goes home.

Payment for HHD training supports the important policy purpose of encouraging home dialysis modalities (as mandated by Congress in Section 1881(c)(6) of the Social Security Act), and the costs of such training are reported and tied to training activity in the CMS cost reports. By reducing the payment multiplier for the onset of dialysis adjustor in the Proposed Rule, CMS in effect reduces payment for home patient training, as this adjustor is applied in lieu of the training payment for patients in the first 120 days of dialysis. This is in contrast to the derivation through regression used in other adjustors. The Alliance encourages CMS to establish in the Final Rule an appropriate payment for home dialysis training consistent with cost reports and reported time requirements in CMS' manuals. However, the funds required to establish this cannot come at the expense of the base rate that applies to all dialysis patients for the benefit of those limited number of patients who receive home dialysis training.

CMS has the authority to make reasonable payment for this add-on service in a non-budget neutral way. The law mandates budget neutrality in very specific circumstances which do not apply in this case. In order to enable the maximum reasonable number of patients to utilize home therapy, an adjustment to the current training payment must be reasonably applied.

2. CMS should allow for an inflationary adjustment to the training adjustment payment.

The Alliance believes that a separate inflationary adjustment to the training add-on payment is necessary, as it resides outside the bundled base rate and is not adjusted by the annual market basket update. We continue to believe that the 1.5 hours used by CMS as proxy to establish

[13] For the CY 2012 rulemaking, 27 (26%) of the 105 comments on ESRD discussed training, even though it was not mentioned in the proposed rule; for the CY 2013 rulemaking, 15 direct comments (25%) of the 60 comments on ESRD discussed training; for the CY 2014 rulemaking, 365 (37%) of the 967 comments on ESRD discussed training; and for the CY 2015 rulemaking, 392 (94%) of the 417 comments on ESRD discussed training, and CMS referenced in its Final Rule a petition with thousands of signatures calling for the training payment to be addressed. These comment counts were pulled from regulations.gov and/or specific mentions in the Final Rules.

the training payment significantly underestimates the amount of time needed to train a patient properly. However, given that the "training add-on adjustment is directly related to nursing salaries,"[14] and those salaries and staffing costs go up over time, the training add-on payment should be adjusted accordingly.

Again, 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 we have articulated before, 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 for CY 2014, 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 2016 PPS payment rate for providing ESRD services.

3. **CMS should minimize administrative burdens for facilities providing drugs for home use.**

The Proposed Rule states that, per section 20.3.C of the updated Medicare Benefits Policy Manual, ESRD facilities should report one line item per prescription for ESRD-related oral or other forms of drugs that are filled at the pharmacy for home use, but only for the quantity of the drug expected to be taken during the claim billing period, which is typically one month. While the Alliance understands CMS' efforts to ensure accurate claims information, this practice places a substantial administrative burden on dialysis facilities to compute the amount of pills prescribed to a patient within a claim billing period. This burden is felt most strongly by smaller facilities, whose limited resources make this type of data manipulation all the more arduous. Resources used in this way are resources diverted from patient care.

The Alliance believes that CMS could alleviate this burden and ensure that facilities of all sizes are able to focus on patient care by managing the reconciliation function within the agency.

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. Also, 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 measures in

[14] 75 Fed. Reg. at 49,063.

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 ESRD QIP is the first Medicare program linking payments to any provider or facility to certain performance measures. These measures are important indicators of patient outcomes, as failure to meet clinical QIP measures can result in poor health outcomes and avoidable hospitalizations.

The Alliance strongly supports the QIP program, and the central role that patient experience plays in assessing care. Home dialysis patients have historically experienced unique and important quality of life benefits, including more autonomy and flexibility over when they dialyze and greater ability to maintain employment. Unfortunately, experiences of home patients are not currently considered in the ESRD QIP. The Alliance believes such exclusion is contrary to the intent of Congress, which required CMS to adopt "to the extent feasible, such measure (or measures) of patient satisfaction."[15] This also significantly limits the ability to assess and improve the quality of care provided to home patients, and to compare care across modalities and settings.

CMS proposes to expand the consideration of the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS), which was designed for use only with in-center hemodialysis patients, as both a reporting and clinical measure for PY 2018 and future payment years. However, 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.

[15] 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.

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 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.

2. **The proposal to aggregate the "Dialysis Adequacy" measure could decrease accountability for home patients.**

The Alliance thanks CMS for its dedication to ensuring that its QIP clinical measurements capture a broad array of patients' experiences. However, we are concerned that by bundling the four existing dialysis adequacy measures into a single "Dialysis Adequacy" measure, CMS' proposal may have the unintended consequence of diluting the experience of home dialysis patients by grouping them with a larger population of in-center patients. Because those HHD patients dialyzing either more or less than three times per week are already excluded from the existing measures, we fear that this change could further reduce accountability for the quality of care provided to all home patients.

3. **The proposal to add a new "Ultrafiltration Rate" reporting measure appropriately includes home dialysis.**

Along with dialysis adequacy (Kt/V), ultrafiltration rates are a critical tool for managing patient health while on dialysis. Excessive ultrafiltration rates can lead to decreased blood flow to the heart and loss of consciousness, and are one of the major sources of morbidity and mortality for dialysis patients. The Alliance thanks CMS for incentivizing greater oversight of patient health by proposing an ultrafiltration measure for the QIP. One of the ways to manage ultrafiltration rates is through longer or more frequent dialysis treatments, and decreasing the amount of fluid taken with ultrafiltration, which is often the case with home dialysis.

While the Alliance applauds CMS for identifying clinically-meaningful measures that hold significance for patients, we encourage the agency to ensure that the measures ultimately adopted are supported by evidence and validated by clinical experts. Measures should be put through a vigorous validation process, such as that used by the National Quality Forum (NQF).

The Alliance appreciates the opportunity to provide comments on the ESRD PPS for CY 2016 and the ESRD QIP for PY 2019. We look forward to working with CMS in the future to advance policies that support appropriate utilization of home dialysis. Please contact Elizabeth Brooks at 202-466-8700 if you have any questions.

Sincerely,

Stephanie Silverman
Executive Director

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