



August 31, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1352-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: CMS-1352-P—Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for all Medicare Providers

Dear Ms. Tavenner:

The Alliance for Home Dialysis 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 2013; sets forth requirements for the ESRD Quality Incentive Program (QIP), including for payment year 2015 and beyond; and implements changes to bad debt reimbursement for all Medicare providers, suppliers, and other entities to receive bad debt.

The Alliance for Home Dialysis is a coalition of kidney dialysis stakeholders, representing patients, clinicians, providers and industry, that came together following the first-ever National Summit on Home Dialysis Policy held in March of 2012 in Washington, D.C., to promote activities and policies that will facilitate treatment choice in dialysis care while identifying and addressing systematic barriers that limit access for patients and their families to the many benefits of home dialysis therapy.

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% of U.S. dialysis patients receive treatment at home. 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”¹ and “make home dialysis economically feasible and available to the ESRD patient population.”² To that end, the most recent data available indicates that the ESRD PPS—which pays for home dialysis at the same rate as dialysis provided in the facility—has led

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

² *Id.* at 49,060.

to an increase in the utilization of PD.³ In fact, an annual survey of the ten largest providers found that between 2010-2012, home patients represented about 20% of the growth in ESRD patients, largely attributed to the growth in PD.⁴

Comments on ESRD PPS Proposed Rule for Calendar Year 2013

Section II. Calendar Year (CY) 2013 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

The Alliance is encouraged by the impact of the ESRD PPS on utilization of PD, but data suggests that barriers still remain for optimizing the availability and utilization of HHD. In order to ensure that Congress' 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"⁵ is fulfilled, the Alliance offers the following recommendations:

1. CMS should provide for an appropriate and routine update of the training add-on payment.

The ESRD PPS proposed rule for calendar year 2013 describes how the base rate for the ESRD PPS is calculated and adjusted for various factors, including training payments (if applicable).⁶

The one-on-one home dialysis training service performed by registered nurses is essential to supporting home patients. The Alliance believes that the home dialysis training add-on payment should be adjusted to reflect the costs that the one-on-one home dialysis training service represents and should allow for an inflationary adjustment to the training add-on payment. A separate inflationary adjustment is necessary, as the training add-on payment is outside the bundled base rate and is not captured in the annual market basket update methodology. Given that the "training-add on adjustment is directly related to nursing salaries,"⁷ and those salaries and staffing costs go up over time, the training add-on payment should be adjusted accordingly.

In addition, we believe that it would be appropriate to rebase the home dialysis training add-on payment to reflect the actual costs of providing this resource-intensive service. In the ESRD PPS Final Rule for CY 2011, CMS described a methodology for calculating the training add-on payment based upon "one hour of nursing time to conduct one-on-one training with a patient for either hemodialysis or PD."⁸ For HHD, this assumption does not begin to reflect actual

³ 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.

⁴ 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>.

⁵ Section 1881(c)(6) of the Social Security Act.

⁶ 77 Fed. Reg. 40,952, 40,959 (Jul. 11, 2012).

⁷ 75 Fed. Reg. at 49,063.

⁸ *Id.*

resource requirements to provide the training service.⁹ For instance, an analysis of the 2009 Medicare Cost Reports showed that providers with HHD training claims reported training and treatment delivery costs that averaged \$430.29 per session, which is twice as expensive as maintenance HHD treatments per session.¹⁰

In order to ensure patient access to home dialysis modalities, CMS should consider using the best available information to update the home 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.

2. CMS should allow for home/self care hemodialysis training treatments to be paid at the frequency prescribed for each patient up to the number of days currently allowed within CMS regulations.

The Alliance requests that CMS update the Medicare Claims Processing Manual to remove the three training session per week limitation for the small percent of HHD claims that include self training treatments. This request should not be considered a cost item, as we are not asking for an adjustment to the cap on the number of days permitted for initial home dialysis training.

Today, a discrepancy in home dialysis training reimbursement exists between PD and HHD. For PD, every training session (up to the cumulative allowable limit) is reimbursed. For hemodialysis generally, training reimbursement is technically limited to three sessions per week.¹¹

This limitation to payment of three HD training sessions per week is inconsistent with the allowable number of training treatments for HHD patients and with the way HHD training is practically administered. For example, a patient may receive more than three training sessions a week if they have a medical justification for more frequent treatments. Though the number of training sessions may be below the maximum number of initial training days permitted in CMS regulation,¹² the current claims processing direction would limit the number of paid training treatments, resulting in the number of training days delivered exceeding the number being reimbursed.

The Alliance believes that CMS should allow for home/self care hemodialysis training treatment to be paid at the frequency prescribed for each patient up to the number of days currently allowed within CMS regulation.

⁹ The training add-on payment was established at \$33.38 per training treatment, adjusted based on the geographic wage index for nursing salaries, in the ESRD PPS final rule for calendar year 2011. 75 Fed. Reg. at 49,063.

¹⁰ The Moran Company. Estimation of Costs for Home Hemodialysis: 2008 Analysis of Medicare Cost Reports

¹¹ According to the Medicare Claims Processing Manual, “[a] facility is not reimbursed for more than three ... hemodialysis training treatments in a single week.” Medicare Claims Processing Manual (Pub. 100-04), Chap. 8, §50.8.

¹² The current cap on training treatments under the ESRD PPS is 15 for PD and 25 for hemodialysis. 75 Fed. Reg. at 49,063.

3. CMS should update the revenue codes and cost reporting for ESRD to create a methodology that allows for better data for alternate dialysis modalities.

The lack of modality-specific data limits the ability of CMS and other stakeholders to analyze and assess key information regarding dialysis services. For instance, the use of a single revenue code 821 to describe both in-center and HHD makes it difficult to assess trends and evaluate the impact of payment measures on HHD. There are revenue codes available in the family of ESRD-related codes that could be utilized to reflect alternative modalities, including: revenue code 820-hemodialysis outpatient or home; or revenue code 829-outpatient hemodialysis, other. Assignment of a designated code for all alternate modalities would better capture the true treatment options that patients are choosing. As indicated previously by the Agency, these coding changes can be established through administrative issuance, and the Alliance encourages CMS to do so.¹³

4. CMS should establish a new technology adjustment.

The Alliance is concerned that there is no mechanism within the ESRD PPS to incentivize the development of new technology to improve the delivery of dialysis care. A recurring theme from Delegates that participated in the National Summit on Home Dialysis Policy was the need for continued investment and development of more user-friendly devices and tools to support individuals and family-caregivers in their home.

Innovation requires certainty that providers and patients have the resources and necessary incentives to adopt new items that demonstrate improvements in quality and efficiency. We believe that CMS should establish a new technology adjustor for FY 2013 and beyond that would allow for new technologies to be introduced in an appropriate manner, which in some cases may require review and establishment of reimbursement codes and funding.

Section III. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for Payment Year (PY) 2015

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 home patients, including the pediatric population, of which about 50 percent dialyze at home,¹⁴ be appropriately assessed and included in the QIP. The inclusion of this population in the QIP ensures that quality improvements extend to all modalities, not just in-center care.

One of the key policy consensus actions that emerged at the National Summit on Home Dialysis Policy was the need for stakeholders to work with CMS to develop appropriate quality measures for home dialysis modalities. Delegates particularly emphasized the need for patient involvement in the development of these measures, to ensure they address issues that will lead to improved quality of life. The Alliance looks forward to working with CMS on this issue and

¹³ 75 Fed. Reg. at 49,058.

¹⁴ U.S. Renal Data System, *USRDS 2010 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 Kidney Diseases, Bethesda, MD, 2010.

specifically submits the following comments on the proposed ESRD QIP for payment year 2015 and beyond:

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

The Alliance believes that patient experience is an important indicator of quality of care. Home dialysis patients have historically demonstrated improved satisfaction with their care. 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.”¹⁵ 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 current In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) was designed for use only with in-center hemodialysis patients. Therefore, the Alliance urges CMS to establish a process to facilitate the development and adoption of a patient experience instrument validated for assessing the home dialysis population. In developing this process, the Alliance encourages collaboration with stakeholders, particularly home dialysis patients, to ensure that the survey instrument is appropriate for the home setting. Finally, the new instrument should include pediatric patients and their families/care providers – this last point is especially important, as pediatric patients themselves may not be able to complete a survey, so any survey instrument would need to include parents and other care providers.

2. CMS should extend the NHSN Dialysis Event Reporting Measure to PD.

The Alliance agrees that an important method of monitoring and improving patient safety is through the reporting and tracking of healthcare associated infections (HAIs). The Alliance supports CMS’ proposal to retain the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure, as detailed in the ESRD PPS proposed rule for calendar year 2013,¹⁶ but recommends that standards and monitoring should be considered for PD patients and should include episodes of peritonitis.

Peritonitis is a leading cause of morbidity for PD patients and has been “associated with mortality, hospitalizations, and termination of PD therapy.”¹⁷ As further detailed in the National Kidney Foundation’s clinical practice guidelines for Peritoneal Dialysis Adequacy:

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.

¹⁶ 77 Fed. Reg. at 40,971.

¹⁷ Krishnan M, Thodis E, Ikononopoulos D, et al., Predictors of outcome following bacterial peritonitis in peritoneal dialysis, *Perit Dial Int* 22:573-581, 2002, available at <http://www.ncbi.nlm.nih.gov/pubmed/12455568?dopt=AbstractPlus>

*Although peritonitis rates have improved significantly during the past several years, peritonitis remains a major issue for PD units. It is important for facilities to develop strategies for tracking peritonitis rates, assessing the organisms responsible for peritonitis, and developing strategies to better understand the reasons for peritonitis.*¹⁸

Currently, there is no national level data available regarding PD peritonitis rates in adult patients, which limits the development of performance standards to guide quality improvement efforts. One of the consensus items that emerged from the National Summit on Home Dialysis Policy was the need for improved data sharing amongst home dialysis stakeholders to enable the development of appropriate benchmarks. We recommend that CMS work with the dialysis community to establish an infection surveillance process for PD.

3. The Alliance supports the Kt/V Measures; CMS should clarify the PD Kt/V Dialysis Adequacy Measure and establish a reporting threshold; and CMS should establish a Kt/V measure for PD in pediatric patients.

The Alliance supports CMS' proposal to remove the URR Hemodialysis Adequacy measure and replace that measure with three measures of dialysis adequacy "for adult hemodialysis (HD) patients (in-center and home hemodialysis (HHD)) receiving three treatments weekly, adult peritoneal dialysis (PD) patients, and pediatric HD patients receiving three to four treatments weekly" based on Kt/V for the performance year 2015 ESRD QIP and in future payment years.¹⁹ We strongly agree with CMS that the proposed measure to calculate adequacy for HHD should only apply to patients receiving three treatments weekly, as there are presently no standardized methods to calculate Kt/V for patients that receive more frequent treatments.

The Alliance requests that CMS clarify key components of the proposed PD Kt/V measure. First, the method for calculating the denominator of the PD Kt/V measure as described in the proposed rule for payment year 2015 is inconsistent with the method detailed in the National Quality Forum's approved PD Kt/V adequacy measure (#0318), which requires that a patient be on PD for at least 90 days to be included in the denominator.²⁰ Under the ESRD QIP proposed rule, a patient on dialysis for less than 90 days is excluded from the denominator.²¹ The Alliance is concerned that without clarification of the modality for which this exclusion applies, the technical specifications for the PD Kt/V measure could be interpreted to mean that a patient who has been on hemodialysis for 90 days or more and then transfers to PD would be immediately eligible for inclusion in the measure denominator on the first day that the patient receives PD treatment. The Alliance requests that CMS clarify the modality language so that it

¹⁸ Clinical Practice Guidelines and Clinical Practice Recommendations, Clinical Practice Guidelines for Peritoneal Dialysis Adequacy, Guideline 5: Quality Improvement Programs (2006 Update), available at http://www.kidney.org/professionals/kdoqi/guideline_upHD_PD_VA/pd_guide5.htm.

¹⁹ 77 Fed. Reg. at 40,973.

²⁰ See National Quality Forum, NQF #0318 Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum, Measure Submission and Evaluation Worksheet 5.0, available at http://www.qualityforum.org/Projects/n-r/Renal_Endorsement_Maintenance_Project/measure_0318.aspx.

²¹ 77 Fed. Reg. at 40,973 (referring to technical specifications for the measure available at <http://www.dialysisreports.org/pdf/esrd/public-measures/PeritonealDialysisAdequacy-ktv-2015-NPRM.pdf>).

is consistent with the NQF measure and ensures that only patients that have been on PD for at least 90 days are included in the denominator of the measure.

Second, the Alliance urges CMS to align the proposed PD Kt/V measure with the reporting requirements under the ESRD Conditions for Coverage Interpretative Guidelines Measures Assessment Tool.²² The Interpretive Guidelines state that PD adequacy should be measured at least every four months,²³ and the Measures Assessment Tool states that each patient should be tested for PD adequacy at intervals less than or equal to every four months.²⁴ Under the proposed PD Kt/V measure, a patient becomes eligible for reporting under the QIP on day 91 of initiating PD. Should a patient not have an adequacy measure during that month when the patient first becomes eligible for reporting under the QIP, the proposed measure requires facilities to apply “the most recent Kt/V value in the prior 4 months to the calculation for that month.”²⁵ Based on our understanding of the proposed rule, if a patient does not have a Kt/V value in the period of 91-120 days, the facility would fail to satisfy the QIP PD adequacy measure if the facility does not have a Kt/V value from the prior four months to report, but the facility would still be within the acceptable four-month interval for adequacy measurement under the Measures Assessment Tool. This could result in a facility being penalized during this time interval (between 91-120 days). Therefore, to align the proposed Kt/V measure with the Measures Assessment Tool, patients should not be counted in the denominator if they have not been on PD for 90 days, and the facility should not be penalized for not including these patients in the first month that they are eligible to be included in the denominator if no Kt/V measurement is taken until the fourth month.

The Alliance also urges CMS to work with the provider and patient communities to determine the right percentage of eligible patients to include in the PD Kt/V measure calculation. The provider community can provide historical information on the actual percentage of measurements that are collected in this period due to the logistical challenges of collecting the quality measure information for this patient population. PD patients are not seen at the facility on a regular daily schedule, which significantly limits the facility’s ability to act upon aberrant or out of target adequacy measurements. For instance, PD patients may miss their scheduled visit for their adequacy measurement for reasons outside of the facility’s control (hospitalization, other medical or non-medical issues, patient choice, travel, etc.), which may prevent the facility from obtaining the PD Kt/V measurement even though it was ordered appropriately. Furthermore, if the patient does not follow instructions for PD adequacy collection exactly, the measurement may be invalid and require repeating. For some patients, the PD Kt/V measurement may be challenging to obtain due to patient and facility scheduling conflicts. The Alliance believes it is reasonable to make an allowance for a specified percentage of patients who, despite the best intentions and efforts of the facility, are unable to obtain a PD Kt/V measurement or ordered repeat measurement within the four-month interval.

²² CMS, ESRD Basic Technical Surveyor Training, Interpretive Guidance, Interim Final Version 1.1 (Oct. 3, 2008), available at <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/esrdpgmguidance.pdf>.

²³ *Id.* at 198.

²⁴ CMS, Measure Assessment Tool (MAT), Version 2.1, available at <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/surveyorlaminates.zip>.

²⁵ 77 Fed. Reg. at 40,973 (referring to technical specifications for the measure available at <http://www.dialysisreports.org/pdf/esrd/public-measures/PeritonealDialysisAdequacy-ktv-2015-NPRM.pdf>).

Finally, the Alliance also recommends that CMS work with the American Society of Pediatric Nephrology and other pediatric home dialysis stakeholders to develop an appropriate adequacy measure for pediatric PD patients.

4. CMS should establish a lower reporting threshold for Anemia Management and Hypercalcemia.

As discussed above, because home patients are not seen at the facility on a regular basis there are unique challenges to collecting quality measure information from this patient population. Yet, under the proposed anemia management and hypercalcemia measures for performance year 2015, facilities would be required to report on all home patients at least once a month.²⁶ With regards to the proposed anemia management reporting measure, the agency indicates that “we do not intend for this proposed measure to encourage unnecessary testing or unduly burden a facility.”²⁷

As described above for the Kt/V measure, we also encourage CMS to work with the provider and patient communities to determine the right percentage of eligible patients to include in this measure. The provider community can provide historical information on the actual percentage of measurements that are collected in this period. A revised reporting threshold level for both proposed measures would ensure that facilities take necessary actions to collect this information from home patients, but would not be penalized for collection and testing issues that are outside of their control.

5. The Alliance supports the proposed adjustment methodology for clinical measures.

The Alliance supports CMS’ proposed adjustment methodology for clinical measures, which seeks to ensure that “any error in measure rates due to a small number of cases will not adversely affect payment.”²⁸ From the home perspective, this is very important as many facilities have fewer than 25 home patients, so measures such as Kt/V for PD patients would need to be appropriately adjusted. Additionally, this adjustment is important to ensure that smaller home-only facilities are not disadvantaged in the scoring calculations.

The Alliance would like to highlight that because most dialysis units have a small number of pediatric patients, often below the threshold for reporting (n=11), the care provided to a significant percentage, if not a majority, of pediatric patients is not captured. The Alliance encourages CMS to develop a method to monitor the care of these patients in a meaningful way, which may include the development of statistical analyses beyond simple percentages of patients meeting a given measure.

²⁶ 77 Fed. Reg. at 40,973-74.

²⁷ 77 Fed. Reg. at 40,974.

²⁸ 77 Fed. Reg. at 40,984.

Conclusion

The Alliance appreciates the opportunity to provide comments on the ESRD PPS for calendar year 2013 and the ESRD QIP for payment year 2015 and beyond. We look forward to working with CMS in the future to advance policies that support appropriate utilization of home dialysis.

For a list of organizations participating in the Alliance's working groups, please visit our website at www.homedialysisalliance.org. Please feel free to contact Lindsay Punzenberger at 202-466-4721 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 extending to the right.

Stephanie Silverman
Director