



Home Dialyzors United

Seema Verma, MPH
Administrator Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington DC, 20201

RE: CMS-1674-P

Dear Ms. Verma:

Home Dialyzors United (HDU) is pleased to have the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) notice of proposed rulemaking entitled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program” published in the Federal Register, vol. 82, no. 127, pages 31190 to 31233. This proposed rule includes provisions that update the end-stage renal disease (ESRD) prospective payment system (PPS) for 2018, updates the payment rate for individuals with acute kidney injury (AKI) when furnished in dialysis facilities, and addresses the ESRD quality incentive program (QIP). HDU appreciates the CMS effort to improve the both the payment for service and the QIP measures.

We find nothing in the proposed rule that removes known barriers to home dialysis but your proposed regulations still do not fully meet the original intent of Congress: “The maximum number of patients who are medically and psychologically appropriate candidates for home dialysis and transplantation should be so treated.” With only about 2% of patients receiving home hemodialysis, and about 10% on peritoneal dialysis, home therapy is clearly underutilized and falls short of meeting the Congressional mandate.

The low utilization of home hemodialysis in incident dialysis patients is of grave concern to HDU. A recent study by Eric Weinhandl (attached) showed that there were <2000 incident dialysis patients on HHD during a 7-year period. This reflects not only lack of education to patients in Stage 5 CKD, but also the effect of requiring medical justification for more frequent hemodialysis. In other words, providers may feel that home HD is only for those patients requiring more than 3 treatments per week, and payment for more than 3 treatments per week requires medical justification, which itself may be perceived as unavailable to an incident patient who has not “failed” in-center hemodialysis and/or presented with multiple clinical problems.

We recognize that there is no one-size-fits-all mode of dialysis, and are strongly committed to ensuring that patients are fully informed as to their



Home Dialyzors United

treatment options and how each option fits their treatment and life goals. However, we believe that a significant number of the nearly 90% of dialysis patients still receiving traditional in-center treatments three to four hours a day, three times a week, could benefit from switching to home dialysis modalities. Traditional in-center treatment itself can be disabling, stressing the heart and other vital organs and may contribute to premature death. In too many cases, patients who would like to continue working, must undergo their in-center treatments during working hours. Even if they are able to find work that accommodates their treatment schedule, many are too exhausted from their dialysis session to work. In short, too many patients are still living to dialyze, rather than dialyzing to live.

Because there is nothing in your proposal to remove barriers to home dialysis such as described above, our members, who usually submit hundreds of letters to you during each annual rulemaking cycle have little to comment on this year. HDU appreciates the ongoing dialog that we have had with the Agency to improve patients outcomes and the overall patient experience. We are disappointed that you have chosen not to address the persistent barriers to home dialysis in this rule-making cycle. Choosing not to act is not benign. Beneficiaries are harmed by that inaction.

Exclusion of home dialysis therapies notwithstanding, HDU would like to offer comments on several areas of the proposed rule:

- Prospective Payment System (PPS) as it pertains to home dialysis modalities, including patients who may reside temporarily or permanently in a LTC environment
- AKI patient inclusion in the QIP
- Patient focused QIP measures
- Inclusion of social risk factors in the ESRD QIP

PPS and Home Dialysis

HDU greatly appreciates last year's payment increase for home training. However, we would encourage CMS to be diligent in seeking and removing remaining barriers to patient access. Among these barriers, HDU believes extending the pre-dialysis education to Stage 5 CKD patients is imperative to ensure that patients are fully cognizant of their dialysis choices and are therefore able to make the modality choice that best fits their lifestyle. Currently, the kidney disease education benefit requires that the claim includes diagnosis 585.4 (CKD-4). That is, Stage 4 is an eligibility criterion for reimbursement. However, the majority of incident patients "crash" into dialysis during Stage 5 CKD, unaware that they even had kidney disease, further compounded with lack of education regarding the RRT options available to them. CMS could and should do



Home Dialyzors United

more to advertise the existence of this education benefit since many providers are unaware that it even exists.

In order to preserve quality care for all patients, CMS should consider the implications in states where the bundled payment rate is low because of lower than average labor costs. Many centers in those states are unable to find local qualified staff. The result is that those states with the lower bundled rate may actually incur much higher costs due to the expense of attracting and retaining staff. Centers may need to resort to filling positions with individuals from further away or leaving some positions unfilled thus impacting the quality of patient care. When difficult choices like these need to be made, home dialysis training suffers.

Thank you for including statements last year that dialysis in a nursing home is considered home dialysis. For the approximately 10% of dialysis patients who call a SNF or other LTC home, either short term, long term or permanent, having the ability to receive their dialysis in their home can offer significant clinical and psychosocial advantages. We appreciate CMS's recognition of this in last year's final rule. Your statement that dialysis delivered in the LTC setting is home dialysis is appropriate and is important in helping assure that these patients retain the rights that all patients have to choose the care and setting that they and their physician feel is best to meet the clinical and personal needs of the individual patient.

However, HDU strongly encourages CMS to develop a policy that "dialysis follows the patient," across all inpatient and residential settings receiving Medicare or Medicaid payments. While we recognize that such a policy is beyond the scope of the proposed rule, HDU believes this policy is critical to fulfilling all four goals in the Quality Strategy, and that the patient receives appropriate care no matter where "home" may be.

Last October, CMS issued a final rule regarding "[Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities](#)." In late July, CMS released updated [Interpretive Guidance](#) to help long term care facilities and long term care (LTC) facility surveyors implement the rule, including specific language regarding dialysis in this setting. Highlights from the guidance include:

- clearly supports a patient's right to choose dialysis therapy, including a requirement that where home dialysis is desired by the patient in a skilled nursing facility (SNF) that does not offer the service, the SNF must work to identify SNFs where the patient may consider transferring for their care.
- defines topics where the ESRD facility must educate the LTC staff on the needs and care of dialysis patients.
- permits dialysis or LTC staff, or others as desired by the patient, to



Home Dialyzors United

provide home dialysis treatments when they have been trained by the ESRD facility as home dialysis care partners and where their involvement is clinically appropriate.

Under current practice, when a patient on dialysis is admitted to a hospital, skilled nursing facility, or other inpatient or residential setting, the facility determines what kind of dialysis the patient will receive and on what schedule.

It is also unconscionable that Medicare itself is currently spending more than \$300 million year to transport patients between SNFs and dialysis facilities. That is to say nothing of what Medicaid spends. These resources could be diverted to pay for a higher reimbursement in the SNF/LTC setting, should a payment adjuster be pursued. The benefit to the patient would be immeasurable, in both quantifiable health benefits, and immeasurable quality of life benefits.(See Attached)

To that end, Medicare has talked at length in prior rule-making about the age-adjustor. Recently, CMS shifted the age bands and the impact of the adjustor for specific segments of patients. We think this effort misses the point. While it is true that some patients have higher costs because of their age, the Agency should also reflect an adjustor based on whether a patient resides in a LTC/SNF environment. Patients in rehabilitation or LTC are often higher acuity and require greater resources to deliver their dialysis care. This may include increased resources to transfer or monitor these patients. We recommend that an additional adjustor be considered for any patient temporarily or incident to the LTC setting.

The use of telehealth and its benefits, coupled with the undervalued home dialysis code are another issue that needs to be addressed, in order to reduce the barriers to home dialysis. Currently Congress is reviewing legislation that will allow the home and dialysis facility as originating sites for patients' monthly clinical assessment via telehealth. While we do not advocate for the use of telehealth as a means to intrude on the patient's privacy, it has been shown to have documented success in promoting patient accessibility and treatment compliance, especially in rural settings.

AKI patient inclusion in the QIP

In the proposed rule, CMS states that it intends to require facilities to report data on AKI patients under the ESRD QIP, and is seeking comments on whether and how to adapt any of the current measures to include this population, as well as the type of measures that might be appropriate to develop for future inclusion in the program that would address the unique needs of AKI beneficiaries.



Home Dialyzors United

HDU applauds the agency for its concern for the quality of care for patients with AKI in the outpatient setting. However, we are concerned about including patients with AKI in the existing QIP. Patients with AKI are, by definition of the term, different from those with chronic renal failure and the quality metrics are different. Therefore, we urge CMS not to include AKI and chronic patients in a single QIP.

HDU believes that current projections about AKI utilization in 2016 were far too low, so utilization could spiral quickly. HDU believes that CMS should consult with nephrologists who manage AKI, convene a TEP, and develop a system. Poorly designed systems may also inadvertently encourage adverse selection or “cherry picking”. For example, facilities that perceive too much financial risk associated with AKI patient volume may choose to restrict their access.

Additionally, AKI treatment is short term compared to the overall chronic population. Therefore, accurate collection and interpretation of data could negatively impact the overall QIP scores. In that situation, facilities may again resort to denying access for these patients.

Patient focused QIP measures

When Congress mandated the creation of the ESRD PPS and QIP, it intended to achieve the twin goals of lowering costs and improving quality of treatment. HDU continues to urge CMS to include more measures that are important to patients in the QIP – that is, to raise the standard for ESRD care from adequate dialysis to optimal dialysis, based on the patient’s treatment and life goals.

Although HDU cautions that as the number of measures in the QIP increases, the impact of any one measure is diluted, HDU supports the pain assessment and depression screening reporting measures as steps toward patient-centered measures. However, we strongly emphasize that these measures need to be further developed to ensure that the facility assesses the psychosocial and quality of life issues that may contribute to the patient’s depression or pain.

Additionally, HDU feels strongly that an additional measure be considered to reflect fatigue and recovery time. Patients report that their number one issue with quality of life on dialysis is fatigue, with fear of death at the opposite end of the spectrum. Part of addressing the fatigue issue is proper anemia management. HDU again strongly urges CMS to restore a measure establishing a minimal standard for anemia management. In the first QIP, centers were measured on how well they kept a patient’s hemoglobin within specified ranges. In subsequent years, the QIP looked only at whether a patient was being over-treated, but not whether he or she is being under-treated. We are particularly concerned that in the



Home Dialyzors United

month between visits to the center, a patient's anemia can progress from an acceptable level under the QIP, to a level that is disabling. The QIP should ensure that patients dialyzing at home are given appropriate anemia treatment. Avoiding the "epo yoyo" with proper anemia management will serve to address some of the fatigue issues, while recovery time after dialysis needs further assessment.

In addition, we believe the measure should ensure that appropriate follow-up steps are taken to help relieve pain and depression. Because HHD has been shown to improve patient scores in these areas, it is critical that follow-up include assessing the patient's interest in HHD and assisting the patient with the transition to HHD if that is the patient's wish.

In PY 2021, CMS is proposing that the ESRD Quality Incentive Program (QIP) include 16 measures, 9 of which are outcome measures, the rest being reporting/process measures. CMS is proposing to replace the two vascular access measures used in PY 2020 with two new vascular access measures that have been endorsed by the National Quality Forum.

HDU is also concerned that the increasing number of QIP measures may be burdensome to facilities. New QIP measures should be simple as well as easily implemented and reported. Clerical duties should not take professionals away from patient care. We also believe that continued reliance on process measures is not in the patient's best interest. For example, patients report that they are assessed each month for pain and depression, but that the conversation is no more than a check box on a form. Many patients have reported abandoning any discussion regarding pain and depression, when they are asked to quantify these feelings as a number only.

HDU continues to be concerned that using the CAHPS® In-Center Hemodialysis Survey as the basis for a measure for patient satisfaction ignores the experiences of home dialysis patients. Patients who are dialyzing at home still see a nephrologist and still interact with the center at least once a month. Therefore, most of the questions in the In-Center Hemodialysis Survey – such as those about the patient's experience with the nephrologist and with dialysis center staff -- are equally applicable to home dialyzors.

While surveys like the CAHPS® In-Center Hemodialysis Survey are designed to measure the patient's satisfaction with the quality of treatment, we continue to believe that CMS should adopt a measure that addresses the larger question of the patient's goals for treatment, and assesses how well the dialysis care supports the achievement of those goals. There have been numerous articles discussing the types of



Home Dialyzors United

measures that would foster better, patient-centered care. These measures would give greater weight to the patient experience and engagement, to clinical care coordination, to the assessment and alleviation of symptoms of ESRD, and to helping patients with poor prognoses choose the care that best meets their needs. For a more thorough discussion, see Moss and Davison, *How the ESRD Quality Incentive Program Could Potentially Improve Quality of Life for Patients on Dialysis*, www.cjasn.org, Vol. 10, pp. 888-893, May 2015.

The overarching goal of the QIP program should be to initiate measures which truly reflect patient centric outcomes as defined by the patient. Home dialysis, coupled with multifaceted holistic rehabilitation allows patients to live a normal life and be productive citizens. Foremost is the ability to stay employed, attend school, participate in family events and pursue their self-defined life goals. Unemployment in the 18-54 year-old dialysis population is close to 80%. That statistic would be intolerable for any other situation or condition. Maintaining employment helps fulfill the original intent of the Medicare ESRD legislation. As a corollary, employed patients not only enjoy a better financial quality of life but also have decreased depression. Therefore, we encourage CMS to look toward incorporating continued employment as a QIP measure.

Many of the current QIP metrics exclude patients who dialyze at home. Because of this, centers who are small or who offer only home dialysis are disadvantaged. This in turn may lead to centers being less willing to focus on home dialysis therapies, which harms Medicare beneficiaries who would choose and be ideally clinically treated at home. Efforts should be made to create metrics which drive change in provider behavior and which improve the care and options patient's experience

Inclusion of Social Risk Factors in the QIP

In December 2016, a report entitled "Social Risk Factors and Performance Under Medicare's Value-based Purchasing Programs" was released. This report study was mandated by Congress as part of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act. Included in the report were six social risk factors: dual eligibility, residence in low-income areas, Black race, Hispanic ethnicity, rural residence and disability.

HDU did not find the results surprising. Beneficiaries with social risk factors had worse outcomes on quality measures irrespective of their providers. Dual eligibility status was the most powerful predictor of poor outcomes among the social risk factors and providers who served larger numbers of patients with social risk factors tended to have worse QIP measures. Since dual eligibility is disproportionately associated with lower income, focusing on QIP measures that address these inequities is vitally important.



Home Dialyzors United

Conclusion

HDU, a 501(c)(3) non-profit organization, is the only dialysis patient group dedicated to home dialysis. Our mission is to inspire, inform, and advocate for an extraordinary quality of life for the home dialyzer community. We know from personal experience that, with the right dialysis treatment, patients with ESRD (and their families and care partners) can lead a normal life, enjoying family and friends, and pursuing employment, education, volunteer and leisure activities. We also know that studies have repeatedly shown that patients who dialyze at home have better treatment outcomes.

HDU is pleased to note the continuing CMS shift toward incorporating the patient voice as it establishes new rules and regulations. We look forward to working with CMS going forward and would be happy to provide further input to help improve quality of life for the growing ESRD population.

Respectfully,

Home Dialyzors United

Denise Eilers, RN, BSN

President, et al



Home Dialyzors United

Attachments:

SA-PO1115

Cumulative Incidence of Kidney Transplant and Death in Incident ESRD Patients on Intensive Home Hemodialysis

Eric D. Weinhandl^{1,2*} and Allan J. Collins². ¹NxStage Medical, Inc., Lawrence, MA and ²Univ of Minnesota, Minneapolis, MN.

Background

Intensive home hemodialysis (HHD) has been primarily prescribed as a reactive therapy for patients who have accumulated years on dialysis. Clinical outcomes in incident ESRD patients on intensive HHD have not been described. We analyzed incidence of kidney transplant and death in incident ESRD patients on intensive HHD with the NxStage System One cyclor (NxStage Medical, Inc., Lawrence, Massachusetts).

Methods

HHD patients were ascertained from NxStage records. We identified patients who initiated HHD between January 1, 2006, and December 31, 2012, and within 3 months after the date of ESRD onset. Comparator cohorts of incident ESRD patients on conventional hemodialysis (CHD) or peritoneal dialysis (PD) were ascertained from United States Renal Data System (USRDS) records. We followed patients from dialytic modality initiation to the earliest of transplant, death, or December 31, 2013, but for a maximum of 5 years. For HHD, we estimated cumulative incidence of transplant and death. For each modality, we estimated transplant and death rates, standardized by age, race, and sex with HHD.

Results

The HHD cohort comprised 1898 patients. Mean age was 56.6 years, 70.4% were male, and 81.6% were white. At 5 years, cumulative incidence of transplant and death were 34.5% and 35.6%, respectively.



Home Dialyzors United

Medicare Payments for Transportation between Nursing Institutions and Dialysis Facilities

Eric Weinhandl^{1,2}

Linda Upchurch¹

Allan Collins³

¹NxStage Medical, Inc., Lawrence, MA USA

²University of Minnesota College of Pharmacy, Minneapolis, MN USA

³University of Minnesota Medical School, Minneapolis, MN USA

Background: Utilization of skilled nursing and other long-term care by dialysis patients has not been well-described. Most patients receiving such care undergo hemodialysis in off-site facilities and thus necessitate transportation before and after each session. Both Medicare and Medicaid provide payment for such transportation, although the former provides payment only during the 100-day interval after hospital discharge. We aimed to quantify Medicare expenditures on ambulance services between nursing institutions and dialysis facilities.

Methods: We analyzed data from the United States Renal Data System (USRDS). We searched Medicare Part B claims during payment year 2012 for ambulance services and retained such claims with an origin/destination code pair that indicated transport between nursing institution and dialysis facility. We tallied the number of patients with at least 1 ambulance service between nursing institution and dialysis facility, the cumulative number of patient-days with ambulance service, and cumulative Medicare payments for ambulance service.

Results: We identified 23,586 patients with at least 1 ambulance service between nursing institution and dialysis facility, 754,338 patient-days with ambulance service (32.0 days per patient), and \$310.1 million in Medicare payments for ambulance service (\$13,148 per patient; \$411 per patient-day). Medicare payments were highest in California (\$58.1 million); other states with high Medicare payments were New Jersey (\$30.9 million), Georgia (\$18.3), South Carolina (\$17.7), and Texas (\$16.1). For frame of reference, analysis of evaluation and management visits in nursing institutions indicated that dialysis patients accumulated roughly 30,000 patient-years in such facilities.

Conclusions: Medicare payments for ambulance service between nursing institutions and dialysis facilities constituted 1.1% of all Parts A and B expenditures on beneficiaries with end stage renal disease in 2012. Expenditures were highest in the Sun Belt and Middle Atlantic. Notably, the per diem cost of ambulance service was 75% higher than the cost of hemodialysis (\$235 in 2012). Increased adoption of dialysis delivery inside nursing institutions could directly reduce transportation-related Medicare expenditures (as well as Medicaid expenditures, which are likely greater). Further research about potential benefits of dialysis delivery inside nursing institutions is warranted.