



August 28, 2014

Marilyn Tavenner, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, DC 20201

**Re: CMS-1614-P Medicare Program; End Stage Renal Disease Prospective Payment System and Quality Incentive Program**

Dear Administrator Tavenner:

On behalf of Home Dialyzors United (HDU), we are pleased to offer comments on the proposed rules calendar year 2015 End Stage Renal Disease (ESRD) prospective payment system and the payment years 2017 and 2018 ESRD Quality Incentive Program (QIP) which was published in the Federal Register, vol. 79, no. 133, pages 40208-40315.

Home Dialyzors United, a 501(c)(3) non-profit organization, is the only dialysis patient group dedicated solely to home dialysis. Our mission is to educate, support, and advocate for home dialysis. We believe that patients and care partners can live a normal life including employment, education, volunteerism, family life and leisure pursuits and that every patient should have access to the treatment modality they and their physician feel is best.

We further believe that CMS can help patients with chronic kidney failure (ESRD) reach those goals by implementing an equitable payment system for home dialysis and by establishing quality measures that are truly patient centered.

HDU's comments are addressed at payment issues and QIP measures that disproportionately affect the lives, wellbeing and clinical outcomes of home dialysis patients and their families

**Calendar Year 2015 End Stage Renal Disease Program Prospective Payment System**

While the rule contains many technical modifications and apparently non-substantive and administrative clean-up of some definitions, we are dismayed that, again this year, CMS continues to turn its collective back on the problem facing patients who would like to choose home dialysis.

That problem, as we have discussed at length over the years, is Medicare's inadequate reimbursement for home hemodialysis patient training; it simply doesn't come close to covering the total incremental cost of providing this essential service. This means there continues to be a disincentive to provide

training, making it difficult for patients to learn about and gain access to the potentially life-changing clinical and psychosocial benefits of home hemodialysis.

**Dialysis patients have a right to choose the appropriate dialysis modality for themselves, including home dialysis** and CMS is not following Congress' directive to ensure that as many patients as can be treated at home should be so treated. <sup>1</sup>Medicare's own ESRD Conditions for Coverage require that patients be made aware of all modalities, including home modalities – and, that centers must make patients aware of modalities that the facility does not offer<sup>2</sup>. The inadequate payment for upfront training, a service necessary for patients to be able to safely transition home, means that only about ¼ of centers offer home hemodialysis training and even fewer actively train patients on a regular basis. This problem won't be fixed until Medicare fully reimburses providers for the realistic costs associated with patient training.

To that end, HDU is urging CMS to update its payment policy to include full reimbursement for HHD training as part of the final rule for 2015. Today, Medicare pays only about \$50 per training session toward the costs of having an experienced nurse, social worker and dietitian provide one on one training to new patients, while Medicare's own data shows the real cost of providing training is about 5 times that or more. Last year, you acknowledged an awareness that 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. This takes more than the 90 minutes per training day that you have allowed for in your payment.

We hear regularly and consistently from HHD patients, care partners and others who have trouble accessing HHD treatment for themselves (or know someone who has), as well as for those who have experienced the benefits and want to make sure everyone has access. Many HDU members have experienced firsthand the clinical and life benefits of home dialysis and we often say that it has given us back our lives.

We challenge you to be thoughtful but persistent to get this right this year. CMS might accomplish the increase in payment in various ways. Examples include: pay the 120 day adjustor when a patient is in initial training or use funds that are reserved for outlier payments to cover the differential cost of training. Another example would be to use the dollars that would be spent if peritoneal dialysis (PD) patients actually trained 15 days instead of about 8. PD is paid the training add-on plus the difference between the PD daily rate and the full bundle so there is potentially 7 extra days of full bundle plus \$50 that is going untapped within current regulation. This equates to about \$2100 per new trained patient. New money could also be brought into the system.

### **End Stage Renal Disease Quality Incentive Program**

The Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) amended the Social Security Act to require CMS to create an ESRD QIP that establishes performance standards, assesses the total performance of each facility and applies payment reductions to each facility that does not meet a minimum performance score<sup>3</sup>. The QIP reduces payment by up to 2%.

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<sup>1</sup> Section 1881(c)(6) of the Social Security Act.

<sup>2</sup> <http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Downloads/ESRDfinalrule0415.pdf>

<sup>3</sup> Section 153(c) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275)

Although HDU agrees philosophically with the QIP program, we have serious concerns as the program goes forward.

Most importantly, HDU feels that

- there is a complete lack of measures that are truly meaningful to patients and
- by implementing too many measures a diluting effect is created on the overall impact to facilities.

For example, the 8 clinical and 3 reporting measures proposed for 2017 would increase to 11 clinical and 5 reporting measures in 2018. Facilities could literally ignore 1 or 2 measures without significantly affecting their bottom line.

**The almost total emphasis on biochemical markers ignores the everyday quality of life issues that are ultimately more meaningful to patients than laboratory measurements.**

### **Payment Year 2017**

Bloodstream Infection Measure: HDU agrees that the bloodstream infection measure is an extremely important issue. Every episode of infection in ESRD not only threatens the patient's health, oftentimes resulting in hospitalization, but also directly impacts quality of life. In addition, by increasing the time in training for home patients may actually prevent infections, but centers lose money in training and are unlikely to invest the time under the current payment.

ICH-CAHPS: HDU strongly disagrees with the way the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) is structured. The very title, using the term "In-Center," ignores home dialysis patients who comprise approximately 10% of the ESRD population. The law mandates that all patients be administered a satisfaction survey, not just in-center patients<sup>4</sup>.

Adequacy: Kt/V has long been used as the accepted marker for dialysis adequacy. Studies have shown, however, that Kt/V is inherently flawed. We appreciate that CMS recognizes that the formula currently used for Kt/V is applicable only for patients who dialyze three times per week, and that the patients dialyzing at other frequencies are exempt from the measure. Given that the data on the adequacy measure shows that this measure is not in need of further improvement, or has topped out for driving a change in clinical behavior, HDU recommends that adequacy be moved to a monitoring measure rather than assigning it a monetary value. Doing so would also help to correct the "dilution" effect caused by implementing too many QIP measures as well as the lopsided focus on Kt/V as opposed to other more meaningful clinical markers that speak directly to the health and well being of the patient.

### **Payment Year 2018**

With the proposed 2018 QIP measures of 11 clinical measures and 5 reporting measures, the "dilution effect" will be even more significant.

Patient and Family Engagement: HDU applauds CMS for including a Patient and Family Engagement/Care Coordination sub domain in the clinical measures. However, HDU feels this may be

<sup>4</sup> Section 153(c) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275)

a secretarial simplification rather than a wholehearted effort to include measures that have real meaning to patients. Once again, the ICH-CAHPS completely ignores satisfaction among the home dialysis population. While the Standard Readmission Rate is a step in the right direction, it does little to truly assess a patient's actual progress in the business of living a normal life. The SRR is a statistic that statistic is not directly meaningful to patients.

Clinical Depression Assessment and Pain Assessment: The new reporting measures are well intentioned, but HDU feels that the Clinical Depression Assessment and Follow-Up and the Pain Assessment and Follow-up need to be developed further with clear guidelines and with inclusion of the total patient population, including home dialysis patients. Presently, facilities report depression to CROWNWeb once a year and pain assessment twice a year. Assessment frequency also needs to be addressed since the patient's status can fluctuate more rapidly due to such issues as comorbidities and sentinel life events. A more frequent assessment would be logical and more actionable.

All too often, a patient is assessed for depression and given medications to hopefully relieve the symptoms of depression but he or she is never assessed for other psychosocial and quality of life issues that are directly contributing to the depression (such as nutritional deficiencies, sleep disorders, medication side effects or interactions, or change in functional ability). Furthermore, without thoroughly treating and correcting the depression, patients have been denied kidney transplantation for mental health issues. Follow-up must not be synonymous with only prescribing anti-depressants. As demonstrated in multiple clinical articles, depression improves when patients are moved to home dialysis modalities<sup>5</sup>. It is essential that any depression metric include a means to assess whether patients are engaged in their own care and if the care plan includes goals to support the patient in meeting their life goals for wellness, employment, education and family.

Likewise, Pain Assessment and Follow-up must not consist of simply administering the Numerical Pain Scale and providing the appropriate analgesic. Much of the pain, whether acute or chronic, experienced by patients may have its origin in psychosocial needs (such as lack of exercise, inactivity during treatment, treatment associated anxieties or other easily treatable co-morbidities). Again, here is where patients on home dialysis modalities have improved scores in this area. An assessment for interest in home dialysis must be part of this plan, or this metric may result simply in masked pain rather than actual resolution of the underlying problems.

Healthcare Personnel Influenza Vaccination: HDU does agree with the NHSN Healthcare Personnel Influenza Vaccination but since most health facilities already require influenza vaccination, this QIP measure simply contributes to the dilution effect.

## **Rule Suggestions**

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<sup>5</sup> Finkelstein F, et al. Daily hemodialysis improves depressive symptoms at 12 months of follow-up: Interim results from the FREEDOM study. Hemodialysis International. 2009;13(1):111.

Finkelstein F, et al. Depression and end-stage renal disease: a therapeutic challenge. (link is external) Kidney International. 2008;74:843-845.

Lopes AA, et al. Screening for depression in hemodialysis patients: associations with diagnosis, treatment, and outcomes in the DOPPS. (link is external) Kidney International. 2004;66: 2047-2053.

Kimmel PL, et al. Multiple measurements of depression predict mortality in a longitudinal study of chronic hemodialysis outpatients. (link is external) Kidney International. 2000;57:2093-2098.

Lopes AA, et al. Depression as a predictor of mortality and hospitalization among hemodialysis patients in the United States and Europe. (link is external) Kidney International. 2002;62:199-207.

HDU feels that any future QIP measures need to be more meaningful to patients. **The ultimate goal of any rule is to contribute to the patient's clinical outcomes, wellbeing and quality of life.**

Employment rate of ESRD patients (aged 18-54): To truly measure wellbeing and quality of life, which are indicative of positive clinical and psychosocial outcomes, HDU recommends that the employment rate of ESRD patients (aged 18-54) who are employed or actively seeking employment be included in future measures. The ESRD Networks already have the statistics and clinics are required in the Conditions for Coverage to refer patients for vocational rehabilitation, but that data is not currently included in the QIP. Employment statistics should begin as a monitoring measure and gradually move to a reporting measure. The almost immediate result would be more facility emphasis on broad based rehabilitation services which address the clinical and psychosocial needs of patients and patient life goals rather than a simple patient referral to Vocational Rehabilitation. In implementing such a measure, care must be taken to ensure that patients are not “pushed into a work setting” before all physical and psychosocial needs are met. In addition, patients must never be penalized for re-entering the workforce by suffering inappropriate loss of disability and Medicare coverage in the process.

### Summary

Home Dialyzors United appreciates the efforts that CMS makes in ensuring that ESRD patients receive optimal care. We believe, though, that there should be **“nothing for the patient, without the patient.”** Therefore, we are also asking that more active patients and care partners be included in the rule making process and in the ultimate decision making. For patients and their families, quality of life is not one of many goals. Oftentimes, it is the only goal, for to achieve quality of life, the clinical issues must be first managed to the optimal degree. Lab values are less important to them than having the overall good health and flexibility to be present at a child's school event, go out with friends, attend school full or part time, enjoy a meaningful job, volunteer in their community, travel, join in family events or participate in the innumerable other activities that make life worth living. For those reasons, HDU, is an ardent supporter of all measures that make these things possible.

HDU and its Board of Directors appreciate your consideration of our comments.

Sincerely,

Jim Smith, President (Dialyzer)  
Pat Colongione, Treasurer (& former HHDcare partner)  
Denise Eilers, BSN, RN (& former HHD care partner)  
Benjamin Ruback, Secretary (Dialyzer)  
Melissa Sondergaard (Home dialysis care partner)  
Robin Franzi, Public Policy Committee (Dialyzer)