



Service to those affected by chronic kidney disease

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August 30, 2021

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Re: CMS-1749-P – CY 2022 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Initiative Program (QIP)

Renal Support Network exists to empower people who have kidney disease to become proactive in their care and to work with healthcare professionals, regulatory agencies, and legislative leaders to get the best care and health outcomes possible. We thank CMS for this opportunity to comment on proposed rules for CY 2022 Payment Policies: Physician Fee Schedule, Quality Incentive Program, End-Stage Renal Disease Treatment Choices (ETC), and Acute Kidney Injury.

*End Stage Renal Disease Prospective Payment System – Physician Fee Schedule*

**RSN believes that the Medicare program payment policies should support innovation to improve patient care and identifying therapies that will offer choice and better care to people who have an illness.** Innovation in dialysis care can result in more convenient and more effective care for patients on dialysis. New medications, diagnostic approaches, and medical options offer the hope of better treatment that can potentially result in more efficient and cost-effective care, increased life expectancy, and improvement in a patient's quality of care and life.

**RSN asks that CMS incentivize the adoption of innovative products using a pass-through payment (TDAPA and TPNIES) for the products to gather at least two full years of clinical data at ASP+6 percent.** That means payment for drugs at the average sales price plus six percent to cover overhead costs, adjusting the base rate incrementally to provide sustainable funding for the long-term adoption of such products. We also ask that once a product is added to the bundle, CMS should collect real-time utilization data to ensure patients are getting the benefit of that option, instead of being placed on a cheaper therapy that saves dollars for the provider. It concerns us that medications can be withheld or skimmed on, and patients are unaware this is happening. In all sectors of healthcare, we know payment drives practice. RSN appreciates that CMS is trying to balance resources and ensure people receive the best quality care.

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An illness is too demanding when you don't have hope!

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### End-Stage Renal Disease Quality Incentive Program (QIP)

**RSN believes the QIP should focus on a small number of measures that report outcomes in areas where there are real gaps in care and that have clear performance-, process-, and patient-based results.**

Measuring care in the ESRD QIP is a new frontier in healthcare. While necessary, too many measures disincentivize treatment. The allowable margin for improvement may be too small, or it may be too cumbersome for a facility to try and drive care in an area when the incentive is not worth the time, resources and energy.

If more and more measures are added, the withhold may need to be increased to have a meaningful impact. The ESRD QIP has a 2 percent withhold of dialysis payment based on the measures in the QIP. It would be beneficial to provide a QIP bonus payment (a “carrot”) to those who are exceeding performance standards. For any year in which the outlier pool funds are not used, or money withheld due to lack of performance, CMS should allow these funds to be used to address health disparities, innovation, access to care or other payment policy priorities.

The measures that stand out as high priority are:

- Risk-standardized hospitalization rate measure
- Risk-standardized readmissions rate measure
- blood stream infection measure that is valid and reliable
- Hemoglobin < 10 g/dL measure
- Serum phosphorus measure

**RSN proposes that the Catheter > 90 days clinical measure be changed to a vascular access *catheter last* measure.** RSN believes a catheter is the worst choice for a patient’s well-being and has the greatest mortality risk. This will correct a misalignment with payment incentives and allow doctors to make the best choice for patients.

**RSN asks that you consider developing a transplant referral measure with a best practice guide to assist the dialysis team in helping the patient make an appointment to get listed, track where success is happening, and learn how barriers can be addressed.** A kidney transplant is a “gift of life” and a scarce resource. Once transplanted, the patient is responsible for their care and has to take initiative as well as take daily medication to help their organ thrive, but we need help to get there. Which helps both patients and taxpayers.

CMS is requiring dialysis facilities to report their Percentage of Prevalent Patients Waitlisted on the kidney or kidney-pancreas transplant waitlists. This is a well-intentioned effort to encourage more people to be listed. However, there are many barriers to getting on the list outside the control of a facility, including travel distance to the transplant center, financial means, caregiver availability to drive to and from appointments, etc. Once transplanted, patients are required to visit their clinic 2-3 time per week, and many centers will not even consider a patient unless a proven caregiver, sometimes two, are listed to support transplant success with the necessary follow up. Some other areas that prevent patients from getting waitlisted are: other surgical procedures, active recurring infections, high BMI, malignancy, active

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substance abuse, chronic non-compliance, psychosocial issues, other medical complications, and patient choice/beliefs.

**RSN suggests that CMS consider the CAHPS survey be executed once a year and be condensed or broken up into domains to help patients avoid survey fatigue, before developing this reporting measure into a clinical measure.** Patients may perceive the survey as onerous since it contains 52 questions and is administered by a third party they do not know. In our experience, longer surveys result in patient fatigue, lack of focus, and potential inaccuracy in terms of the answers being provided. A once-a-year survey will allow facilities to react to the feedback and to implement necessary changes. Different groups of patients could be asked different questions and an amalgam of the answers could comprise results submitted for that facility. And as goal is to significantly increase the number of patients doing dialysis at home over the next few years, RSN believes it makes sense to include home dialysis patients in the survey.

**RSN is of the opinion a patient experience process measure of dialysis treatment measure should be developed.** We are concerned that the CAHPS survey is not providing meaningful information to improve insight into and impact on patient care and outcomes. The survey falls far short in addressing the plethora of minute-to-minute patient experiences during dialysis treatment which can run the gamut of care.

CMS should consider adopting a reporting measure to ensure that the patient has a voice during every dialysis treatment. Example: after each treatment, patients could be asked whether they were: (a) not at all bothered, (b) somewhat bothered, (c) moderately bothered, (d) very much bothered, or (e) extremely bothered during a treatment. If the patient reports they were bothered, a series of additional questions could be asked to qualify their response based on common difficulties of patient experiences, such as access problems, low blood pressure, crashing, cramping, or other pertinent indicators.

Collecting this information would help providers understand why patients do not stay for the entire treatment, why they miss treatments, or feel so tired/depressed that they go home and go to bed for the remainder of the day. A brief, structured conversation with the patient can also provide the physician and the facility manager with insights on whether a patient is tolerating treatment or not, and on the potential need for adjustments before a major problem emerges. In addition, this approach could be used to assess quality of care for home dialysis patients, an area of focus that is greatly needed.

### End-Stage Renal Disease Treatment Choices (ETC) Model

The ETC Model was created to encourage greater use of home dialysis modalities. Home dialysis allows for greater flexibility for people who have kidney failure to do dialysis on their own time. The original goal is to have 80 percent of new ESRD beneficiaries dialyze at home or have a transplant by 2025. Currently, less than 15 percent of beneficiaries are on home dialysis and is unrealistic. RSN constantly promotes home dialysis through our many educational materials and support groups. The reality is that people have to overcome several barriers to be approved for home dialysis, and yet more to achieve success. Some of the most common barriers are: lack of space in the home, trepidation about self-administering, resistance to having medical supplies in the home and fear of the unknown, including feeling unwell and being low energy – which often happens. People should have the choice of the modality that works best for them.

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We don't want a patient to be placed on home dialysis to check off a box, or to be rushed into home dialysis if they just minimally meet the requirements but are not fully committed to their care. The patient then ends up failing on the treatment. This is not in the spirit of this initiative. Retaining people on home dialysis successfully should be the goal.

**RSN suggests regulations be changed to allow for a paid caregiver or for respite care when needed.** This will increase home dialysis numbers. Also, since the bundle payment includes funds for staff, RSN requests a pilot to see if incentivizing the patient with a monthly fee or some financial means (reduce or waive Medicare fee) can increase patient adoption of home dialysis. I have been on all treatment options (Home hemodialysis and Peritoneal dialysis [PD] for 10 years) and am very short in stature. I needed help moving supplies and hanging bags. Motivating a patient with payment will allow them some extra funds to get the help or space they need to be successful.

**RSN is in support of efforts to expand in-center nocturnal dialysis.** This is tricky, as nephrologists must do rounds in the evenings and sadly there is a shortage of them. Large dialysis organizations (LDO) may have an advantage here due to them having more resources. CMS should not set a policy that disadvantages patients in LDOs by creating differential scoring based on the number of facilities owned by a single entity. Nocturnal in-center dialysis is not widely available and we should not create any barriers to providing this option.

RSN also supports making ETC quality performance data available to patients and others annually.

### Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

**RSN asks that CMS reimburse providers for COVID-19 patients who are placed on home dialysis after being hospitalized during the Public Health Emergency. And that CMS provide an immediate waiver to allow AKI patients to select home dialysis with their physician.** Lastly, RSN has been tracking with concern the fact that one of the complications of COVID-19 is AKI. There are more AKI patients than ever before. To address this surge in patients, some hospitals have started them on home dialysis. Yet once they are discharged, Medicare program rules don't allow reimbursement for these patients because regulations limit such reimbursement to in-center dialysis. The overall treatment goal for people who need dialysis is to transition as many as possible to successful home dialysis.

Thank you for the opportunity to provide comments on the Proposed Rule. I am available to answer any questions.

Sincerely,



Lori Hartwell  
President/Founder