



*Service to those affected by chronic kidney disease*

August 16, 2022

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

From: Lori Hartwell  
Founder/President of Renal Support Network

**Re: CMS–1768–P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model**

Renal Support Network (RSN) empowers people who have kidney disease to become proactive in their care, and to work with healthcare professionals and all stakeholders to get the best care and health outcomes possible. I have been dealing with kidney disease since age two (1968), and spent 13 years on dialysis, with ten years on successful home dialysis, both hemodialysis and peritoneal dialysis. I'm currently doing well with my fourth kidney transplant. I founded RSN in 1993 to provide hope to my peers and advocate for the best care. RSN reaches hundreds of thousands of people who have kidney disease and their families through our many patient programs.

We appreciate the CMS's work to refine its Quality Incentive Program (QIP) with changes to the Prospective Payment System (PPS) and End-Stage Renal Disease Treatment Choices (ETC) Model Proposed Rule, and the chance to comment on these from the patient's perspective.

**Healthcare Professional Shortage**

We know there is a critical healthcare shortage and that it has been greatly exacerbated by the demands of the pandemic. We can't expect the overall treatment landscape to change without an adequate kidney health professional workforce. Sadly, the number of medical graduates entering the nephrology specialty has declined by nearly 50 percent. Similarly, the number of nurses trained in nephrology care is falling. Since quality kidney care largely depends on quality staff, it's imperative we look for solution short and long term. People who require dialysis are experiencing interruptions in the routine of dialysis care. Dialysis treatment schedules are constantly being changed, shifts being eliminated and facilities closing all due to lack of staff to operate. The stress of the job is causing people to retire early at a time when we desperately need all hands-on deck.

People on dialysis struggle to adjust their schedules, especially those who work or depend on a childcare schedule. Typically, people who work schedule dialysis after or before work hours.

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

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We request that CMS use its existing authority to establish a temporary upward adjustment to the dialysis PPS payment rate so dialysis facilities can compete against the other healthcare fields that don't have the financial limitations of a dialysis bundle. We all know that labor costs, inflation, and the extra precautions needed to keep patients safe during COVID is exasperating the problem. The administration needs to provide support for funding needed to solve this problem. If patients don't get the care they need in an outpatient facility, they end up in the hospital which we all know is not cost effective and patients suffer as a result.

### **Innovation**

Innovation has been the cornerstone of my survival and well-being. I, along with our members, have greatly benefited from the Medicare End-Stage Renal Disease Program. We are elated that innovation is a priority of this administration, with the Center for Medicare and Medicaid Innovation to the NIH funding that has stimulated new products to come to market to help people who have kidney disease. We need a reimbursement pathway that fosters patients having access to the treatment they need and ensures access to the therapy long after TDAPA.

The Medicare ESRD transitional drug add-on payment adjustment (TDAPA) was created to help patients have access to new therapies. Our members were thrilled when the CMS recognized the need to address this serious gap, as payment drives practice. There are a few issues that need to be addressed with CMS to ensure the payment policy is transparent and allows people to have access to new therapies. CMS needs to commit when it awards TDAPA to assessing the value of a drug for the treatment of ESRD patients, and if appropriate, adjust the base rate once the TDAPA period ends.

Innovative devices and technology are not reimbursed at as high a rate or percentage for kidney disease as they are for other chronic illnesses, so there is a lack of incentive to spend time researching new technology for the kidney world. We have seen firsthand how changes in care, like dialysis machine upgrades and CKD/ESRD drug improvements, have dramatically improved treatment outcomes for people who have kidney failure. Advances in biological sciences, coupled with the increasing availability of clinical data from electronic medical records, as well as improved medical imaging, offer many options for medical advances. The ESRD payment system must provide long-term payment mechanisms that adjust the bundle when new products come in. If there is never an option for increasing the bundled rate, lack of seed money for research and only a two-year promise of reimbursement will lead to less innovation and send the signal that people on dialysis patients are not as important as those with other chronic diseases.

### **Functional Categories and Innovation**

The current functional categories are not aligned with innovation. A case in point: a new anti-pruritic medication for itching. In the past, patients have been prescribed Benadryl to treat itching. Benadryl is not effective for this type of itch. It dries your skin out and makes you tired. An allergy itch is much different than the pruritis sensation of internal deep-rooted itch.

A law that mandates that Medicare spending must remain budget neutral is scary to people who live with the illness. Cutting payment to meet the demand of more people entering the Medicare system is a recipe for failure and isn't consistent with the goals of innovation. The kidney community is already at a disadvantage with most patients on Medicare. Unlike the other fields of care, patients are reliant on CMS getting this right.

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Its important for patients to have access to innovative treatments and to create a reimbursement pathway to ensure that. We have put forth a lot of effort to advocate for innovation. Our point is that CMS's payment policy should not create barriers to patients having access to treatments that can help us feel better and thrive. Innovation gives people hope that their health issues and side effects of an illness can be addressed with a solution. We need to stop using outdated functional categories and focus on making sure that the bundle rate is adjusted when appropriate to support innovation.

I support adopting an add-on after the TDAPA period ends for new products that CMS determines are in the existing functional categories. It is important to let nephrologists and patient know that appropriate funding will be available once the TDAPA period ends.

### **Phosphate Binders - Oral Drugs**

Although dialysis removes phosphorus, it usually does not remove enough, and many patients require phosphorus-binding drugs. Phosphate binders are supposed to be taken within 5 to 10 minutes before or immediately after meals and snacks. Patients are often advised to take additional binders if they eat something high in phosphorus. Phosphorus is found in high amounts in protein foods, so patients who are trying to increase their albumin may need to take an additional binder. Phosphorus content is not required on FDA food labels. We try to educate people that many foods are full of phosphorus as it is a preservative. Who knew that Lipton bottled iced tea is loaded with phosphorus!

It's important that the doctors be able to prescribe the most effective treatment for their patients. Some phosphate binders can cause GI issues in patients and thankfully there is choice. There is no mandate for their inclusion in 2025. These products cannot be managed in a facility the way other oral drugs have been. This critical distinction leads me to ask that the phosphate binder not be included in the bundle.

### **Quality Measures**

The program's intent is to promote patient health by providing a financial incentive for dialysis facilities to deliver high-quality patient care. CMS payment reductions of up to 2 percent if a facility does not meet or exceed the minimum requirement is problematic when there are so many measures. Continuing to add more measures are is going to crowd the withhold of 2 percent giving each measure have less of an impact on patient care.

We are pleased with the Kidney Care Quality Alliance (KCQA) measures that are in development for home dialysis and are under NQF review. Actionable, validated, and reliable measures are important to driving quality care. It is a quandary that as we develop more measures, we need to ensure that there is a reasonable gap for improvement and that the dialysis facility has control over that measure.

RSN's goal is always catheter last.

The Hypercalcemia measure is topped out and should be replaced with Serum Phosphorus. Additionally, we are concerned about the Standardized Transfusion Ratio (STrR) Measure. The STrR is based on transfusion information from hospitals to which dialysis facilities do not have access, and the facilities' role is critical. If not managed properly, anemia can lead to debilitating symptoms. The information of why the patient experienced blood loss is not available. A GI bleed can lead to patient requiring multiple units of blood. We prefer a hemoglobin less than 10 g/dL measure.

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Anemia occurs when there are not enough healthy red blood cells to carry oxygen to your body's organs. People who have kidney failure are often anemic as the kidneys make a hormone to stimulate red blood cells. When your kidneys no longer work, you don't produce this essential hormone. People who are anemic feel cold and have symptoms of tiredness or weakness. Many patients describe that as feeling like a washed-out rag.

We ask CMS to elevate the hemoglobin less than 10 g/dL measure that can help show how well facilities are managing anemia. Since treatments for Anemia are included in the bundle and financially benefits facilities that give less, a meaningful actionable measure is even more critical. I recently saw webinar by a Medicare Advantage proponent that was stating if you draw the hemoglobin at the right time, you can save \$1,300 month.

RSN also suggests that CMS consider the CAHPS survey be implemented 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.

Critically, a patient experience process measure of dialysis treatment should be developed. RSN is 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. These 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 patients' 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 they 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.

The ESRD QIP measures and the Facility Compare Five Star program have inconsistencies and don't always provide the full picture. It's confusing to patients and to industry. Facilities can have a high score, meet quality improvements, but have a low star rating. Our community has significant frustration with this.

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With respect to the Percentage of Prevalent Patients Waitlisted (PPPW), we fully support CMS efforts to get more people transplanted, but this measure should be replaced with an actual transplant measure. The reality is there are people who don't want to seek a transplant, and their wishes should be respected. Meanwhile, other people who want a transplant are waiting months for an appointment, the workforce is stretched, and existing incentives are pushing people to get a transplant consultation just to check a box. On top of that, while 100,000 people are on the transplant list, only about 60,000 are in active status. We need to work on ways to get patients who are inactive status back on the active list.

This is a list of transplant barriers we received from people who are on dialysis:

- Lack of transplant center in geographic area
- Received a previous unsuccessful transplant
- Economic concerns of not being able to afford tests/medication, fear of losing existing insurance
- Medicare/State Program/Insurance issues
- Fear of losing kidney after 3 years post-transplant
- Fear of medication side-effects
- Fear of loss of wages of caregiver/family member unable to go to mandatory tests, etc.
- Physical barriers out of patient's control such as too old to be considered, too sick to be considered, reoccurring illness that will impact graph
- Lack of education about transplant process/eligibility and how to navigate the process and/or how to proceed
- Accessibility for testing process due to transportation for necessary tests, bloodwork, transplant center, etc.
- Fear/Guilt of accepting a living donor kidney
- List of requirements too long and do not feel they will live that long, not worth the hassle
- Non-compliance issues of patient or previous or current substance abuse
- Highly sensitized with antibodies leading to higher rate of rejection
- Lack of health insurance
- Fear of surgery, and risk of dying
- Lack of caregiver for support before, during or after transplant surgery
- Loss of visiting the dialysis center

### ETC Model

RSN advocates to support incentives for self-care and home treatment. More flexible modalities are what everyone should want. Dialysis treatments are a good paradigm for what "home" care can mean, by maintaining the best quality of life for a patient and by helping them stay actively employed. Economically, home modalities have the added benefit of freeing up medical staff time and resources. Creating incentives for home dialysis will not only address the ever-increasing health care staff shortage but will also help alleviate transportation obstacles.

Studies of those with access to these treatments have shown patients to be generally healthier, needing fewer medications and requiring much less frequent hospitalization. All promote a better quality of life for the dialysis patient, again making them more likely to be able to live the life they were meant to live. In addition, new payment models need to be considered, for example: whether a patient can be paid a stipend to do their own home treatment, allow a caretaker to be paid to

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assist them, or provide respite care for caregivers. I was on home dialysis for 10 years and was able to maintain employment and do dialysis myself. I was younger and had more energy. Today, I'm unsure if I could keep a full-time job outside of the home, care for my family/home and still do the amount of dialysis needed to be healthy with other conditions I have developed over the course of five decades of living with this illness.

The changes to the ETC Model, a mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants, are expected to preserve or enhance the quality of care furnished to people with Medicare while reducing Medicare expenditures. RSN is concerned about the goal of 80 percent of people on dialysis choosing home treatment by 2025. Barriers to this are real for patients, and they need to be addressed so the patient does not go home and feel overwhelmed and give up. Often people crash into dialysis and do not feel well. It can take a while to feel better and for the nephrologist to help you become stable and get your numbers back in acceptable range. Home dialysis retention is important, and we know that measures are being developed to address this.

This is a list of home dialysis barriers we received from people who are on dialysis or have received a transplant, and their family members:

- Home environment not sterile enough, big enough or appropriate for maintenance or storing items
- Anxiety and stress issues of dialysis process
- Fear of self-cannulation
- Will have to add wiring or plumbing for home use of machine
- Family not trustworthy and worried about damaging equipment or misplacing dialysis-related items
- Cost of missing work, for either themselves or caregiver, for training
- No one to help – fear of doing it alone
- Lack of family support or fear of family response of having the illness in the home
- Fear of serious medical incident
- Physical issues and unable to lift medical equipment
- Fear of robbery because needles and medical supplies in home
- Fear of burnout and patient often feels guilty about the time and energy their caregivers provide
- Unstable health or cognitive issues
- Homeless or unstable home situation
- Plan of care is to be transplanted and catheter placed in abdomen is not a medical recommendation by transplant team
- Don't trust themselves to be compliant or to sign off dialysis early
- It will be too difficult for them to learn and do properly
- Patient feels isolated at home and the socialization of a dialysis facility reduces anxiety

Self-care in-center dialysis could provide many of the advantages of home-based dialysis and remove many of the barriers that prevent patients from choosing to do dialysis at home. Self-care in-center dialysis is a real step toward helping people get more comfortable with caring for themselves and every avenue should be explored to incentivize this treatment option. Facilities who help teach the patient about their treatment and self-care in-center should be recognized and

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rewarded as this is a step in the right direction for patients' to be more informed and engaged about their care.

Also, people who have acute kidney injury should be able to adopt a home therapy if that is the treatment, they feel is best for them.

### **Avoid Enforcing QIP Penalties for PY 2023**

The kidney care community along with other healthcare industry had and continue to have unique challenges during the pandemic and should not be penalized. Dialysis provision was very stressed due to the increase of people who experienced kidney failure because of COVID, and to the healthcare teams and administration doing everything possible to isolate and move treatments in different facilities around for people who had contracted COVID. This is the only illness that requires such serious maintenance where you must receive treatment a minimum of three times a week in a crowded treatment room. In addition, the reality is some patients who get a catheter are reluctant to schedule another vascular access procedure due to concerns about being in any healthcare setting. It's not fair to penalize providers when patients are making choices based on fear of contracting COVID-19.

We thank you for your work on improving the care people on dialysis receive. Please let me know if you have any questions or need additional information.

Warmest Regards,



Lori Hartwell, President & Founder