



Service to those affected by chronic kidney disease

August 8, 2023

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

Re: CMS-1782-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 and currently have a successful 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 engagement programs.

Creating access to Medicare for people with ESRD was indeed a compassionate decision for individuals with chronic kidney failure. It was a significant step towards providing healthcare for those who were previously unable to afford or obtain lifesaving treatment. We have come a long way from the 1960s and I have personally benefitted from numerous innovations in the kidney community since first being diagnosed.

However, after 50 years, the system is under great pressure. We are well on our way back to the days of "Who Shall Live?" if something isn't done to correct this. Facilities will continue to close, reduce shifts or have long wait times to start home therapies due to lack of nurses. The reality is that ESRD disproportionately affects racial and ethnic minorities, and they will be hit the hardest.

The kidney health care system is becoming more challenging for patients to get the care they need. The latest CMS proposed payment rule for 2024 will continue to exacerbate access to care and puts people who require dialysis at risk.

The lack of nurses is causing people with kidney failure to have limited access to treatment. Access to care will continue to dwindle if not addressed and people who need dialysis won't have access to it. The CMS proposed 1.7% increase will result in a payment of \$4.42 totaling \$269.99 per treatment. This is not sufficient to provide the quality staff we need to survive and thrive. It's having an impact and we report the following comments from people who rely on dialysis to live.

"I was discharged from the hospital, and they are having trouble finding me a dialysis shift in my area."

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

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"I can't travel as dialysis facilities are full."

"My unit closed, and I must drive further to get care."

"The dialysis shift I was assigned doesn't work with my lifestyle."

"Only shift open is at 5am. I'm often late and the staff are upset with me. I want to start home dialysis but there is long waiting list due to lack of training nurses."

"Our nurse had an emergency, and it delayed the treatment as the facility worked to find another replacement for the day."

"I'm afraid my unit will close it is privately owned and they struggle to stay afloat."

"A unit in San Antonio just closed last Friday with 100 patients needing to find other units to take them."

"My favorite nurse left during covid so have many others."

"I haven't had a home dialysis nurse for a year."

ASK: Increase the payment based on inflation to dialysis facilities so they may recruit and retain the best nurses for our care.

We should be giving people with kidney failure hope that new and innovative treatments are being developed, just as for other major conditions like cancer and HIV/Aids, but sadly innovation is not being supported by the payment rules.

The Transitional Drug Add-on Payment Adjustment (TDAPA) attempts to support patient access to new therapies introduced to the ESRD Prospective Payment System (PPS) and not yet accounted for in bundled payment. But the amounts are not sufficient to encourage development of new therapies. Instead, it's a race that is fixed to lose from the start.

When a new product comes to market the company has to sell as much as they can in a three-year period, as their future payment will be dependent on that. After three years of sales of Korusva, CMS reviewed the usage (limited to a subset of patients experiencing severe itching/pruritus) and allocated an additional nine cents to every patient treatment payment that has Medicare. This is not by any means enough for providers to provide the drug to the patients who need it. A long-time nephrology nurse said, "that doesn't pay for the syringe." A nephrologist said, "I am cautious of prescribing new innovative therapies to my patients as I may have to take them away after the TDAPA period due to lack of payment."

Also, currently 40 percent of people living with ESRD are on Medicare Managed Care Plans (Medicare Advantage) and that number continues to increase. If the Managed care numbers continue to grow it will deplete any funding for Medicare Fee for service. Sadly, Managed care has no pathway to add innovation. The term "value based" means it must save money first instead of recognizing treating a symptom of an illness. Not sure how Korusva can fit this criterion unless patients scratched so much, they were hospitalized for an infection. Of course, studies would have to be performed and it would take years for managed care patients to have access to this drug.

Further, there is no way for CMS to know if the patients who need it get the drug due to lack of a robust quality reporting measure. Without an adequate payment mechanism, if a small facility has a cluster of patients needing the drug, they lose money. This one-size-fits-all approach does not work for innovation, and the two-year deadline to get utilization up is haphazard and not scientific. A small startup company may not have the resources to get a treatment to market and provide the proper education to all involved in that window of time. This payment model is deterring investors

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to develop and research new products for us. Their investments are instead flowing to other disease areas. Adequate payment for innovation that follows the patient who requires the treatment is necessary to encourage the development and adoption of new treatments.

RSN wants new treatment options to have a fair opportunity to enter the marketplace, have stability and ultimately improve our quality of life and well-being. Having payment options that make this possible is critical. When payment rates are static, nonexistent, or not adjusted to incentivize innovation, it creates a less competitive environment resulting in limited competition and limits progress in the field. Choice is important.

RSN is hopeful that there are several therapies that will offer choice and better care to people who have kidney failure. Innovation in kidney care can result in more convenient and more effective care for people. 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 our quality of care and life.

ASK: Payment for innovation should follow the patients who needs it and not be given to everyone on Medicare Fee for Service. The 9 cents should be reevaluated to ensure patients have access to innovate products and not deter future innovation.

Payment drives practice, and the needle must be threaded very carefully to stitch a plan that does not hinder our quality and access to care. By addressing the challenges of the payment system inadequacies and the healthcare professional staffing pipeline, we can aim to provide better care, ensure access for those in need, and avoid situations where patients cannot even get through the door for treatment. We are worth saving.

We thank you for the opportunity to comment on the proposed ESRD payment policies. We remain very concerned that financial rather than quality and innovation incentives are driving healthcare practice decisions. We need more trained staff, more support for measuring and funding innovative treatments, higher bundled payments for dialysis care centers, and policymakers who can come together to solve the health care staffing shortage!

We thank you the opportunity to comment. Please let me know if you have any questions or need additional information.

Warmest Regards,



Lori Hartwell
President & Founder