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**Re: CMS-1418-P: Medicare Programs; End-Stage Renal Disease
Prospective Payment System; Proposed Rule**

We who have chronic kidney disease (CKD) are appreciative of the care provided by the Medicare ESRD program, which allows us access to the life-saving therapies of dialysis and kidney transplant. We appreciate that the reason for the introduction of the Prospective Payment System (PPS) regarding the bundling of dialysis treatment and related care is to achieve improved outcomes while continuing to allow access to quality care while controlling expenditures.

RSN created a discussion board (www.KidneyPublicPolicy101.com) where individuals who will be most affected by the proposed PPS (i.e., patients, their family members, and care providers) could ask questions and express their thoughts about the bundle. RSN also hosted more than 20 conference calls with a patient workgroup to discuss various aspects of the Proposed Rule, and also held a three day patient summit on bundling. RSN's goal is to provide the patient's perspective to CMS on the proposed rule and how it may impact our lives.

RSN strongly encourages CMS to consider the following suggestions for the sake of all people with CKD:

Unit of payment

Patient support for per-treatment reimbursement for dialysis services

- Ø Patients who reviewed the pros and cons of reimbursing by week or month came to the conclusion that monthly payment may negatively impact our ability to travel (due to administrative issues) could decrease provider focus on patient compliance with treatment

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

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schedules. In other words, a monthly payment system could lead to more missed treatments, which is known to be associated with increased hospitalization costs.

- Ø *Recommendation: RSN supports the PPS proposal that includes a per-treatment reimbursement system.*

Medically Justifiable Treatments

Patient observations regarding the proposal to allow additional dialysis sessions when medically justified

- Ø Patients support the proposal to allow additional medically justified dialysis sessions.
- Ø More dialysis has consistently been shown to improve patient outcomes, and this provision is necessary for patients who require additional dialysis therapy.
- Ø *Recommendation: RSN supports the PPS proposal to cover additional dialysis sessions that are medically justified.*

Lab Tests

Patient issues with the proposal to include laboratory tests in the bundle and allow only \$9.00 per treatment for reimbursement.

- Ø Patients are concerned that rationing laboratory testing by decreasing reimbursement may place patients at risk for adverse outcomes.
- Ø Patients are concerned that dialysis facilities will decrease the frequency of monitoring parameters such as potassium, calcium, phosphorus, and hemoglobin. There is a high potential for unmonitored peaks and valleys in these laboratory values that could adversely affect the standard of care.
- Ø Patients who are medically complicated, or starting or changing therapies may be particularly vulnerable.
- Ø Laboratory tests that are often clinically valuable but infrequently used (e.g., C-reactive protein) may not be ordered if extra expense is incurred.
- Ø Patients are concerned that the proposed rule does not include guidance on how often or when to evaluate laboratory parameters. For example, blood drawn at the beginning of dialysis may give different results from blood drawn at the end of dialysis.
- Ø Patients who require non-ESRD Labs services may be required to have the blood draw at another draw center to avoid administrative burden on the dialysis facility. This is counter productive to the Fistula First Initiative and an undue burden on the patients' time and travel expense.
- Ø If laboratory tests related to the evaluation for kidney transplantation are included in the bundle it may decrease their use and potentially jeopardize a patient's ability to receive a transplant.
- Ø *Recommendation: RSN suggests that CMS: (a) provide a specific listing of labs that are included in the bundle, (b) provide minimal standards of care for how often and when tests should be performed, and (c) exclude laboratory tests used to evaluate patients for transplantation.*

Medications

Patient issues with the proposal to include oral ESRD-related medications in the bundle:

- Ø The proposal theoretically could improve access to medications for uninsured patients who currently cannot receive these medications and for patients who have difficulty getting to a pharmacy. However, it is fraught with potential challenges for patients who are currently receiving medications covered by Medicare Part D.
 - Ø Limits access to needed medications—especially to more costly or innovative drugs.
 - Ø Providers may make clinical decisions for medications based on cost rather than clinical necessity and efficacy if it is not adequately funded.
 - Ø Access to appropriate care may be delayed or we may return to past clinical practices (i.e., providers will attempt to use less expensive medications first before reluctantly using more expensive medication treatments).
 - Ø The lack of quality measures for bone and mineral metabolism puts the patient at great risk if the effects of these medications are not monitored.
 - Ø Cost shifting may occur if patients are required to undergo risky procedures (e.g., parathyroidectomy) rather than have facilities pay for medications.
 - Ø Patients who already may have difficulty obtaining transportation may be required to visit the pharmacy more often (i.e., dialysis facilities may be reluctant to approve a 30 day supply of medications).
 - Ø Patients may not be allowed to use the pharmacy of their choice for ESRD-related drugs. This may also create a safety issue if patients go to multiple pharmacies (one for ESRD and another for other medications and the pharmacies will not be able to monitor and coordinate possible drug interactions).
 - Ø The \$14 per treatment medication allotment (approximately \$6 per day) is inadequate to pay for the medications required by patients (most take an average of 10 different medications and lipids, PTH, and hepatitis serologies and many of them are costly).
 - Ø Co-insurance for patients are anticipated to increase significantly (little or no co-insurance is currently required under Medicare Part D for many patients).
- Ø *Recommendation: CMS should not include oral medications in the bundle until quality measures are in place and an accurate evaluation of the costs of medications (including patient co-insurance payments) has been completed.*

Quality Measures

Patient observations regarding the quality measures proposed in the CMS PPS:

- Ø Patients are concerned that the proposed quality measures are inadequate to ensure a high quality of patient care and outcomes.
- Ø While monitoring hemoglobin and dialysis adequacy are important, use of annual averages does not adequately reflect the day-to-day quality of care provided to patients.
- Ø Additional and vital factors that reflect the quality of care are not included. Examples include hospitalization, employment, patient satisfaction, bone and mineral disorders, infection, iron parameters, albumin, vascular access choice, and many others need to be continually monitored.

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- Ø The dialysis adequacy quality measure does not reflect differences in treatment recommendations across different dialysis modalities.
- Ø *Recommendations: RSN recommends the inclusion of additional quality measures, including the patient's satisfaction with treatment. We stress the needs for safeguards to be in place to ensure that Nephrologists will be able to continue to order the necessary services to provide appropriate care for people on dialysis. If the current quality measures are retained, we suggest evaluation of monthly or every three month averages rather than annual averages to assess the quality of care.*

The ESRD Networks

Patient concerns regarding the responsibilities and funding of the ESRD Networks in monitoring quality care for Medicare beneficiaries:

- Ø The ESRD Networks were created to monitor and ensure a high quality of patient care, but the definition of quality of care often varies among the Networks.
- Ø It is vital that patients are aware of the ESRD Networks as we transition to the bundle, and that the Networks provide a mechanism for receiving and acting on patient observations regarding the quality of care that is provided. Networks need to represent both the providers and the patients, but should primarily protect the interest of the latter. (Note that after several decades, most patients are not aware of the responsibilities of the Networks, or how they impact the care that patients receive.)
- Ø *Recommendations: RSN suggests the implementation of an ESRD Network Program that will effectively protect and support patients. Components of this program should include: (a) nationally mandated best practice Network quality standards to ensure that the quality of care is being judged consistently throughout the country, (b) coordination of services (e.g., central website for services and educational materials), (c) a national standard to eliminate the difference between complaints and grievances (all patient "complaints" should be classified as grievances and follow an official grievance resolution procedure).*

Co-Insurance

Patient concerns about the potential for increased co-insurance under the ESRD PPS:

- Ø The new provision that patients need to cover the 20% co-insurance for lab tests and medications will be extremely burdensome for many patients.
- Ø Lab tests currently have NO co-insurance payments, and oral medications under Medicare Part D are covered by a number of different insurance and supplemental plans that require little or no co-insurance payments.
- Ø Under the proposed ESRD PPS, a relatively healthy patient with no co-morbidities and no outlier payments could now have a co-insurance of \$46.30 per treatment. That's approximately \$7,223.00 per year!
- Ø While patients in 29 states have access to Medigap coverage to help with these additional costs, patients under the age of 65 in the remaining 21 states do not and would suffer a huge increase in out-of-pocket expenses.
- Ø Many already financially-strapped patients will not be able to afford these payments.

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- Ø Dialysis facilities can currently refuse to treat patients for failure to pay, and patients who cannot afford co-insurance payments may be forced to forego necessary treatments or possibly stop dialysis therapy.
- Ø While we applaud additional reimbursement for low volume facilities, we recognize that this will unjustifiably increase the co-insurance for the patients in these facilities.

- Ø *Recommendation: RSN recommends that patients' rights be protected by ensuring that the new system does not increase co-insurance and potentially deny patients access to care. A clear definition of how the ESRD PPS affects patient co-insurances is needed. All patients need access to Medigap insurance (either by a federal mandate or a state by state statute change).*

Home Dialysis

Patient concerns on the home dialysis provisions in the ESRD PPS:

- Ø The inclusion of training costs in the bundle will not incentivize home dialysis.
- Ø Training for home dialysis can occur at different times after starting dialysis (and normally does not occur in the early months after starting dialysis).
- Ø The extra payment for training should be linked to the training (not an arbitrary time that is not linked to training). There should also be a re-training provision to allow as many patients as possible to access home therapy modalities. There are two different types of dialysis that require different training—equipment and expertise.

- Ø *Recommendation: RSN recommends that reimbursement for home dialysis training be a separately reimbursable item. The extra payment for training should be enough to adequately compensate the professional staff while ensuring that patients receive an appropriate, high-quality training.*

Case-Mix Adjustors

Patient concerns regarding administration burden and components of the case mix adjustors:

- Ø Many patients find the treatment case-mix adjustors confusing, are concerned how this will be implemented, and fear that some patients will be labeled as high-cost patients without qualifying for a case-mix adjustor.
- Ø We anticipate a massive administrative burden to keep track of multiple case mix adjustors that frequently change which will require the facility to hire additional staff. This will be especially true for smaller facilities that do not have information automatically downloaded into CROWNWeb. Face time with professionals is one of our most valuable resources and this policy seems to take that away from us.
- Ø We are concerned that if CMS mandates multiple case-mix adjustors it will decrease the overall base payment rate, taking away funding needed to care for the great majority of patients.
- Ø The case-mix adjustors system seems to open the door for many errors where patients are over or under classified with qualifying case-mix adjustors.
- Ø Many of the currently proposed case-mix adjustors will be difficult to document. For example, it does not seem reasonable to provide a case-mix adjustor for a recovered

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alcoholic with years of sobriety but not provide an adjustment for patients returning from the hospital when it is well documented that additional resources are typically needed.

- Ø The literature and the CMS analysis support the fact that African-Americans require more resources than other racial/ethnic groups. We believe that race may be a viable case-mix adjustor using a Black versus non-Black definition, as was recently recommended at the American Society of Nephrology Annual Meeting. Although, several case mix adjustors can lead to potential discrimination and need to be reviewed before making the final selection.
- Ø Similarly, data has shown that females on dialysis require more resources than males.
- Ø *Recommendation: RSN suggests simplifying the case-mix adjustors' policy to include only those factors that do not need to be continually documented (e.g., gender and race). The additional money that was budgeted for the other case-mix adjustors should be added to the base rate to provide more consistent reimbursement for all patients.*

Case-Mix Adjustor for the First 120 Days

Patient concerns with the description of the first 120 day case-mix adjustor:

- Ø The 120 day period should cover all patients during the resource-intensive start of dialysis. As written, the policy would provide only 30 days of increased reimbursement for patients who under the age of 65 (since these patients do not become eligible for Medicare until the 90 day coordination period expires). Over 50% of all new patients on dialysis would be negatively affected by this provision (since the median age of patients starting dialysis is 64.4 years).
- Ø There is significant data that intensive care at the initiation of dialysis is extremely important and potentially life-saving.
- Ø There is potential for patient manipulation by inappropriately being placed in home training programs to become Medicare eligible to garner reimbursement. .
- Ø *Recommendation: RSN opposes the high case-mix adjustor for the first 120 days when many patients will be unable to qualify. We recommend rolling the allotted funds into the base rate. If the 120 day period is retained, we recommend ensuring that all patients receive 120 days of additional reimbursement, regardless of when Medicare becomes primary.*

Access to Care

Patient concerns about decreased access to care:

- Ø Patients are concerned that the ESRD PPS may inadvertently severely limit or deny many patients access to care.
- Ø The increase in co-insurance may deny many patients access to necessary treatments due to insufficient personal funds.
- Ø The anticipated requirement that patients use pharmacies that are approved by the dialysis facilities may deny patients access if transportation to these pharmacies is an issue (which it may be for many patients). This is especially applicable to patients being treated by small dialysis organizations.
- Ø Patients are concerned that there will be cherry-picking of the best (i.e., most profitable) patients, placing many others at risk for being denied services.

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- Ø A procedure is not in place to protect the rights of the patients (see earlier statement on complaints versus grievances). The Networks also do not appear to have the authority to protect the patient's rights. The Department of Health and Human Services investigates patient complaints, and they do not have enough funding to investigate the patient complaints they receive now, let alone the anticipated increase in complaints under the bundle. This creates an ongoing and growing backlog in basic facility surveys, further undermining the way quality of care is monitored.
- Ø *Recommendation: CMS should recognize the potential for decreased access to care and decreased quality of care under the bundle. Policies and procedures need to be in place before the ESRD PPS is implemented to ensure a clear method of monitoring the access to care while providing patients an easily accessible grievance process.*

Pediatrics

Patient observations about the provisions for pediatrics in the ESRD PPS:

- Ø Pediatric patients have special needs and many transition issues that are not addressed by the case mix adjusters outlined in the draft ESRD PPS.
- Ø *Recommendation: CMS should proceed with extreme caution when implementing a new system for pediatrics, and must carefully consider the unique circumstances of this unique and fragile population.*

Innovation

Patient concerns about the potential effects of the ESRD PPS on innovation:

- Ø Patients are concerned that the ESRD PPS will discourage innovations in technology, medications, and lab tests, leading to stagnation in the quality of care provided to people with ESRD.
- Ø There is a legitimate concern that research dollars may no longer be available to conduct research on conditions that affect people with kidney disease if investors perceive that the reimbursement system disallows profit. The reimbursement system needs to include provisions that will encourage ongoing investment and innovations that will improve the quality of care and outcomes for patients with kidney disease.
- Ø *Recommendation: The ESRD PPS should include incentives that will encourage investment and innovation to improve outcomes for patients with kidney disease.*

Patient Employment

Patient concerns about how the current and proposed systems discourage patient employment

- Ø One of the primary goals of the ESRD program was to help patients retain employment and/or return to work. This goal appears to have been almost forgotten over the past few decades. We need to identify the barriers to employment (including financial disincentives) and develop a plan to incentivize the renal community and patients to return to work or stay employed. We also need to utilize existing government services (e.g., Ticket to Work), and monitor and track outcomes of employment.

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- Ø Recommendation: CMS should develop a plan to encourage and track employment status for patients with kidney disease.

Kidney disease is a devastating illness and it requires knowledgeable, skilled staff, dedicated physicians, and the tools, resources, and reimbursement to ensure that our quality care, quality of life, and length of life are sustained and improved. The PPS needs to be funded appropriately to provide quality care.

The proposed rule is extremely complicated and represents a significant change in how dialysis care will be reimbursed. Patients are concerned that the untested nature of the proposed ESRD PPS and the potential that the new system may lead to global changes in how dialysis facilities operate could result in a significant and potential life threatening change in the quality of care that is provided. To ensure that patients are adequately protected, we respectfully request that CMS publish an Interim Final Rule to enable further review and comments.

RSN would like to remind everyone involved in this decision that if we do not get this right, patients will pay with their lives. These individuals are your neighbors, the people sitting next to you at the movies, and the individuals you greet on the street. Given the epidemic nature of kidney disease, it is likely that the disease will soon affect you, your family, your friends, and your colleagues (if it has not already)! We welcome the opportunity to continue this dialogue and invite you to call us at anytime if we can help you understand the patient's perspective on this potentially life-altering issue.

Thank you,



Lori Hartwell

About RSN

The Renal Support Network (RSN) is a patient-run, patient-centered advocacy and education organization that strives to help patients with chronic kidney disease (CKD) improve their employability and develop their personal coping skills and special talents.