



The Renal Network, Inc.
ESRD Network 9/10

December 7, 2009

Centers for Medicare & Medicaid Services
Department of Health & Human Services
ATTN: CMS 1418-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

I am writing on behalf of the Board of Trustees for The Renal Network, Inc. Our organization holds the contract for ESRD Network 9/10 and is comprised of the states of Indiana, Ohio, Kentucky and Illinois. Our collective volunteer force of renal professionals and consumers represents more than 700 dialysis facilities treating 42,448 dialysis patients in the Midwest. Thank you for the opportunity to comment on the proposed rule for the Prospective Payment System (PPS) as mandated through the Medicare Improvements for Patients and Providers Act (MIPPA).

As an ESRD Network, we are charged with meeting specific goals on behalf of End-Stage Renal Disease patients:

- 1. Improve the quality and safety of dialysis-related services provided for individuals with ESRD.*
- 2. Improve the independence, quality of life, and rehabilitation (to the extent possible) of individuals with ESRD through support for transplantation, use of self-care modalities (e.g., peritoneal dialysis, home hemodialysis), and in-center self-care, as medically appropriate, through the end of life.*
- 3. Improve patient perception of care and experience of care, and resolve patients' complaints and grievances.*
- 4. Improve collaboration with providers and facilities to ensure achievement of goals 1 through 3 through the most efficient and effective means possible, with recognition of the differences among providers (independent, hospital-based, member of a group, affiliate of an organization, etc.) and the associated possibilities/capabilities.*

5. Improve the collection, reliability, timeliness, and use of data to measure processes of care and outcomes; to maintain a patient registry; and to support the goals of the ESRD Network Program.

After a review of the proposed rule, our organization is concerned that implementation of the PPS, as currently outlined, will have a detrimental effect on the delivery of high quality patient care. In many areas, the PPS goes directly against ESRD Network quality goals established to ensure patient safety, independence/availability of home therapies, and improved experience of care. Additionally, the proposed PPS runs counter to the recommendations made by the Institute of Medicine (IOM) in the report, *Crossing the Quality Chasm: A New Health System for the 21st Century*. The report states that health care should strive to be safe, effective, patient-centered, timely, efficient and equitable. As we will outline in the following paragraphs, the PPS fulfills none of these six health care objectives. In reality, if implemented the PPS will cause a shift away from patient centered care defined by evidenced based decision-making, toward care fragmented among different health care providers and settings based upon economic incentives.

1. Dialysis facilities will be required to supply their patients with Medicare Part D prescription medications which must be dispensed through a licensed pharmacy. The Method II reimbursement option will be eliminated. These two changes will cause an increased administrative burden which, in turn, may cause smaller and/or independent dialysis units to close. Small Dialysis Organizations (SDOs) and independent providers may lack corporate infrastructure needed to fulfill requirements, such as establishing secondary reimbursement relationships to allow billing for pharmacy requirements and DME goods and equipment. This will result in decreased access to care for ESRD patients as fewer dialysis providers are able to adopt and maintain the PPS. It may have a profound effect on the ability of pediatric dialysis centers to provide peritoneal dialysis, as most now use the Method II arrangement to support their home PD programs.

Additionally, dialysis facilities may choose to make arrangements with only a few pharmacies which will limit the patient's access to obtaining medications. It may also cause patients to seek ESRD medications from the selected pharmacy, and go elsewhere for other meds due to insurance mandates. In addition to fragmenting care, medication reconciliation will be more difficult when multiple providers are involved, raising safety issues as drug interactions may go undetected. It may also cause hardship to the patients who must travel to different pharmacies to obtain all their needed medications. This model is not safe, timely or efficient.

Access to care may be further impacted if facilities choose to screen patients prior to admittance depending upon the patient's level of need for medications and lab testing; the greater the need the more costly the patient will be to treat. Additionally, patients with amputations, hemiparesis or similar locomotion issues add economic and care burden to facilities. Patients who are treated twice weekly and those patients with a history of noncompliance to treatment (i.e., skipping treatments) will become financially undesirable. Dialysis facilities may opt to exclude these patients from their programs to avoid negative

economic impact, or attempt involuntary discharges of current patients.

These provisions may also limit a patient's ability to arrange transient dialysis as facilities will be cautious of arranging transient treatment if there is no established means of reimbursement between the patient's home facility and the transient facility. Transient facilities will have no incentive to obtain labs, or administer IV meds or higher dosages of ESA if medically indicated for the traveling patient.

2. Extra payment for home training sessions and/or self training sessions will cease. With no provision for extra payment in home training, fewer facilities will offer these therapies. The loss of the Method II option also may impact the availability of home therapy. Many providers rely on Method II to provide supplies and equipment needed for home dialysis. Facilities may elect for more stringent screening of their home therapy candidates; the elderly, disabled, and under-educated patients, all of whom may require more in-depth training, may be excluded. The ESRD Network program strives to make the patient more involved in his or her treatment, taking on as much responsibility as is appropriate to each individual patient. Home therapy and self dialysis empower dialysis patients to take charge of their treatment. Additionally, outcomes for home hemodialysis are consistently higher than outcomes for traditional in-center hemodialysis, indicating it may be a better choice for patients who are able to use it. These options will be lost if dialysis providers eliminate or downsize their home therapy programs.

3. The per treatment unit of payment will remain, with three treatments per week allowed (more based on medical necessity). Maintaining the traditional form of reimbursement doesn't address the delivery of treatment for innovative therapies such as shortened daily dialysis or nocturnal dialysis. Facilities which seek to provide these innovative treatment options for their patients must continue to bill under a per unit treatment which does not compensate for the way in which the treatment is actually delivered. Maintaining the status quo in this area also leaves no room for modalities which may be introduced in the future.

4. All lab tests ordered by the nephrologist will be included in the bundled payment. Currently, patients often have blood drawn during dialysis for non-ESRD tests such as lipid panels and HgbA1C. Patients often receive intravenous medications for non-ESRD indications while on dialysis, such as antibiotics for foot ulcer, or anti-seizure medications which require monitoring during therapy. It is convenient to do this testing and IV therapy during the dialysis treatment as the patient has been cannulated for dialysis, providing easy IV access for other needs. Performing these blood draws and IV procedures during dialysis decreases the number of needle sticks the patients must endure and fosters vein preservation. It also decreases the number of outpatient settings the patient must visit, and makes the patient more compliant with his/her physician orders as it decreased the appointments the patients must make. Under the new PPS, these labs will be reimbursed outside the bundle only if ordered by a non-MCP nephrologist. To do this, the dialysis provider will need to establish privileges for primary care physicians for each patient; this has the potential to sprawl out of administrative control. It also introduces safety concerns as the dialysis provider will be dealing with primary care physicians who are unfamiliar to them and extra steps will be added to the process of fulfilling physician

orders. The more economical and expedient solution for the dialysis provider may be to refuse to order non-ESRD related lab work. This will result in fragmentation of care, patient noncompliance, and additional stress on the AV access.

Often, the nephrologist serves as the primary care physician for the dialysis patient. This is helpful to the patient by simplifying his/her care under one physician; however, it will become more complicated if the nephrologist orders non-ESRD tests for his/her patient. In this scenario, the non-ESRD tests will be included in the bundle because they were ordered by an MCP nephrologist. Consequently, the nephrologist will need to refer the patient to a non-nephrologist to order these tests. The nephrologist may decide to withdraw as the primary caregiver to simplify the non-ESRD needs but this will complicate care for the ESRD patient by adding more providers and care settings into the treatment mix. Timeliness of delivery decreases, and patient safety is compromised, with each step added to the process. None of these options is in the best interest of the patient, again causing fragmentation of care.

5. ESRD-specific oral drugs will be included in the bundle. Dialysis providers will turn to the most economical alternatives when deciding upon oral medications, creating medical management based on economic rather than patient need. For example, due to the associated high cost, it is likely that dialysis providers will abandon the use of cinacalcet hydrochloride to control hyperparathyroidism. This will ultimately increase the number of patients undergoing parathyroidectomy. Although it may be argued that surgical parathyroidectomy is less expensive than medical parathyroidectomy with cinacalcet hydrochloride, patients will be denied the opportunity to choose between the alternatives. Parathyroidectomy is not universally effective and there are surgical comorbidities, in addition to residual hyperparathyroidism or unintended hypoparathyroidism. Likewise, testing and replacement for 25-OH vitamin D will most likely be abandoned due to the cost. The overall effect will be to increase the number of patient surgeries and lower the quality of bone disease management through the uneven control of the condition.

6. The PPS will establish a Quality Improvement Project (QIP) by the year 2012.

The implementation of reimbursement based on the QIP in the dialysis provider setting may impact quality of care in unanticipated ways. For example, with the initial emphasis being placed on URR and anemia management, it is possible that other aspects of treatment will be ignored as facilities intensify efforts to meet P4P goals. Additionally, the outcomes from home dialysis patients will be excluded from the QIP, leaving these patients vulnerable to under-treatment. With the current momentum in increasing the percentages of prevalent AV fistulae, it would be more desirable to include this indicator in any first round of P4P.

The accurate assessment of anemia management may be compromised due to unachievable goal-setting. For example, the proposed Network Redesign states that facilities should achieve a goal of $\leq 5\%$ of patients with a mean hemoglobin of ≤ 10 gm/dL, and $\leq 35\%$ of patients with a mean hemoglobin of >12 gm/dL. In order to achieve the maximum percentage of patients within the target range of 10-12 gm/dL facilities need to achieve mean hemoglobin of 11.0 gm/dL. In order to maximize the percentage of patients within the target, facilities need to

avoid a situation where they will over correct for hemoglobin values outside the target range by too frequently altering the ESA dose in the mistaken belief that they can eliminate all patients either above 12.0 or below 10.0 gm/dL. Network 9/10 determined the 95% confidence interval (CI) around the percentage of patients within the target range so that facilities can judge how well they are performing in comparison to the Network adjusting for facility size. Based on an analysis of greater than 22,000 individual hemoglobin measurements in December 2003, the average dialysis facility can expect 55.9% of patients within the recommended target range in any one month period. This value is based on facilities achieving mean hemoglobin of 11.0 gm/dL. Therefore, a goal of $\leq 5\%$ patients at < 10 gm/dL and $\leq 35\%$ patients above 12 gm/dL is statistically unrealistic.

It is our understanding that CMS will use data from the year 2010 to assess quality when the QIP begins in 2012. To assess quality on two-year old data is counter to the fundamentals of quality improvement, which demands timely data analysis. Further, to withhold reimbursement based on two-year old data will have the effect of punishing facilities which have made advancements in quality in the interim between the 2010 and 2012.

The Networks will need to understand how to assess quality of care, access to care, and disparity issues. Unfortunately, the data systems that are required to evaluate these issues may not be available and, to date, the Network access to CROWNWeb data is unclear. Billing data are not timely and will not provide an accurate assessment of the quality of care provided by a dialysis facility to its patients.

In summary, The Renal Network, Inc., representing ESRD Network 9/10, is concerned that these aforementioned aspects of the PPS do not support goals of the ESRD Network Program nor the goals set out by the IOM toward a health delivery system that is patient centered. We request that the proposed rule for PPS be reassessed to focus on the delivery of dialysis care that is patient-centered, unregimented and comprehensive.

Sincerely,

A handwritten signature in black ink, appearing to read "George R. Aronoff".

George R. Aronoff, MD
President