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**Forum Coordinator**

Bonnie Freshly, MEd, CMP  
Richmond, VA

December 15, 2009

Submitted via the regulations.gov website

(<http://www.regulations.gov/search/Regs/home.html#submitComment?R=0900006480a30c15>)

Ladies and Gentlemen:

The Forum of ESRD Networks appreciates the opportunity to comment on the Medicare Program Proposed Rule: End-Stage Renal Disease Prospective Payment System.

In the attached document, we respond in detail to a number of points raised by the Proposed Rule.

Sincerely,

*Cynthia Kristensen*

Cynthia Kristensen, MD  
President, Forum of ESRD Networks

cc: Barry M. Straube, MD, Chief Clinical Officer and Director, Office of Clinical Standards & Quality (OCSQ)  
Jean Moody-Williams, Director, Quality Improvement Group, OCSQ  
Samantha Richardson, Director, Division of Quality Improvement Policy for Chronic & Ambulatory Care, Quality Improvement Group, OCSQ  
Cheryl Bodden, MSA, Division of Quality Improvement Program Policy and Evaluation, Quality Improvement Group, OCSQ  
Kathleen Egan, RN, MSN, Project Officer, Boston Regional Office I  
Edwin Huff, Project Officer, Boston Regional Office I  
LT Crystal Russell, CHES, MPH, Project Officer, Dallas Regional Office VI  
Glenda Payne, MS, RN, CNN, Project Officer, Dallas Regional Office VI  
Sharon Last, Project Officer, Kansas City Regional Office VII  
Steven Preston, PhD, MPH, Project Officer, Seattle Regional Office X  
Forum of ESRD Networks' Board of Directors  
Forum of ESRD Networks' Executive Director Advisory Council  
Forum of ESRD Networks' Medical Advisory Council

# Medicare Program Proposed Rule: End—Stage Renal Disease Prospective Payment System

Comments submitted by: the Forum of ESRD Networks  
December 15, 2009

## Comments on the Medicare Program Proposed Rule: End—Stage Renal Disease Prospective Payment System

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The Forum of ESRD Networks (The Forum) supports many of the Centers for Medicare & Medicaid Services' (CMS) goals in the Prospective Payment System (PPS) to provide more cost-effective care, eliminate waste, and create a culture of value-based purchasing. However, the Forum is concerned that the provisions of the PPS do not support some of the goals of the ESRD Network Program nor some of the goals set out in by the IOM to cross the quality chasm. We appeal to CMS to reassess the proposed rule for PPS to focus on the establishment of a dialysis care system that is patient-centered, unfragmented and comprehensive.

We believe that implementation of the PPS in its current form will have unintended adverse consequences. Economic incentives in the proposed PPS will fragment care, making it less safe, effective, patient-centered, timely, efficient and equitable. In the absence of a demonstration project, the potential for harm to patients has been untested.

### **OVERVIEW of KEY POINTS:**

- The bundling of oral medication and all nephrologist-ordered laboratory tests will decrease patient access to care.
- Home dialysis training will be discouraged. Additional payment for home training sessions and/or self training sessions will cease and Method II will be eliminated.
- The inclusion of ESRD-specific oral drugs in the bundle will discourage the use of oral medications that may be more effective and safer than less expensive alternatives and may increase fragmentation of care.
- The inclusion of all laboratory tests ordered by MCP nephrologists will contribute to fragmentation of care, vascular damage and facility administrative burden.
- The inclusion of all intravenous medications administered in the dialysis facility will increase the use of alternate intravenous access, particularly PICC lines.
- The PPS does not take into account specific pediatric issues and costs that confront pediatric dialysis programs, and there is inadequate consideration of pediatric-specific comorbidities.
- The limitation on payment for three treatments per week discourages the delivery of newer innovative therapies that allow better quality of life, return to the workforce and encourage rehabilitation.
- Proposed case-mix payment adjusters do not align incentives for high-quality care.
- The implementation of reimbursement based on the QIP in the dialysis provider setting may affect quality of care in unanticipated ways.
- Unintended adverse outcomes will be difficult to evaluate since initial outcomes analysis will be based on limited claims data.

## **EXPLANATION OF KEY POINTS:**

- 1) **The bundling of oral medication and all nephrologist-ordered laboratory tests will decrease patient access to care.**
  - a) Hemodialysis patients treated twice weekly and patients who miss treatments will become financially undesirable because dialysis facilities will be responsible for laboratory and medication costs for the entire month, but will be reimbursed only for treatments delivered. This has the potential to increase involuntary discharges.
  - b) Facilities treating transient patients will have an incentive not to perform laboratory tests or to administer medications. Patient travel and emergent treatments away from the patient's permanent facility may be severely curtailed unless facilities have financial agreements with each other; patients not treated by large dialysis organizations will be particularly disadvantaged.
  - c) We recommend removing oral medications that are not the equivalents of currently employed intravenous ESRD-related medications from the PPS bundle.
  
- 2) **Home dialysis training will be discouraged. Additional payment for home training sessions and/or self training sessions will cease and Method II will be eliminated.**
  - a) The increased payment in the first 120 days will defray some of the increased expense associated with incident patients. However, most patients who elect home dialysis do so after the first 120 days, such that there will be little incentive to initiate training particularly for home hemodialysis.
  - b) Without additional payment for training, facilities will offer home treatment to fewer patients, and in particular will not offer it to elderly, less able and less educated patients anticipated to require more prolonged training, thus increasing disparities in care.
  - c) Facilities that specialize in home dialysis and accept patients from other facilities specifically for home treatment will be disadvantaged. Larger home dialysis programs tend to have better outcomes than smaller programs; discouraging these sizable programs for reimbursement reasons in favor of small potentially more isolated home programs may result in poorer outcomes.
  - d) The loss of the Method II option will particularly affect small dialysis organizations and independent providers which lack corporate infrastructure needed to establish secondary reimbursement relationships to allow billing for DME goods. It may profoundly impair pediatric dialysis facilities' ability to provide peritoneal dialysis, as most now use Method II to support their home PD programs.
  
- 3) **The inclusion of ESRD-specific oral drugs in the bundle will discourage the use of oral medications that may be more effective and safer than less expensive alternatives and may increase fragmentation of care.**
  - a) Dialysis providers will turn to the most economical alternatives when deciding upon oral medications. For example, it is likely that dialysis providers will abandon the use of cinacalcet hydrochloride to control hyperparathyroidism, increasing the parathyroidectomy rate. While the argument may be made that parathyroidectomy may be more cost effective over time, patients should have a choice and some patients are poor surgical candidates. Parathyroidectomy is not universally effective and there are surgical comorbidities in addition to residual hyperparathyroidism or unintended

hypoparathyroidism. The provision of outlier payments for patients with higher drug costs than initially estimated by the PPA may not adequately mitigate the likelihood that facilities will not provide certain medications, particularly non-calcium phosphate binders and cinacalcet.

- b) Disparities in care will increase. Nephrologists may be placed in the untenable position of determining not which medications are most appropriate for a patient, but which patients within the facility are most deserving or have the greatest need for certain medications. Facilities, which have the financial responsibility, will be placed in an adversarial position with the physicians, and the patients will be placed at risk.
  - c) The necessity for contractual arrangements between facilities and pharmacies to provide ESRD related oral medications may affect patient safety as well as medication access. While the larger dialysis providers have internal pharmacy options, smaller providers generally do not. In areas with multiple pharmacy options, the facility may not be able to contract with all pharmacies, and patients may resort to obtaining ESRD medications from one pharmacy and non-ESRD medications from another due to insurance or geographic reasons, resulting in concerns regarding medication interactions, reconciliation and tracking
- 4) **The inclusion of all laboratory tests ordered by MCP nephrologists will contribute to fragmentation of care, vascular damage and facility administrative burden.**
- a) ESRD patients routinely require measurement of non-ESRD related laboratory tests, including lipid concentrations, glycosylated hemoglobin, prothrombin time and anticonvulsant levels, as well as tests required in preparation for transplantation.
  - b) Sampling for these tests at hemodialysis improves adherence to testing orders, and allows tests to be performed more quickly than if patients are required to visit outpatient phlebotomy facilities. However, under the new PPS, these tests will be reimbursed outside the bundle only if ordered by physicians who do not bill the MCP for outpatient dialysis. If the patient is sent to an outside laboratory, the nephrologist may be unaware of results and the ordering physician may make non-dialysis treatment changes without regard to the implications of kidney failure and dialysis therapy.
  - c) Preserving veins is essential to our national effort to promote native vein fistulas. Venipuncture for laboratories outside of the dialysis unit causes damage to vessels.
  - d) To protect patients' veins and assure that the nephrology team receives the test results, many facilities will be required to credential each patient's primary and specialty care physicians so that the tests may be drawn at hemodialysis. The administrative burden may be insurmountable, and non-dialysis physicians will need to order such tests at outpatient laboratories.
  - e) The Forum recommends that there be a defined list of ESRD-related tests with specified frequencies that are included in the bundled ESRD payment. Non-ESRD related testing should be excluded from the bundle
- 5) **The inclusion of all intravenous medications administered in the dialysis facility will increase the use of alternate intravenous access, particularly PICC lines.**
- a) Dialysis providers will decline to administer intravenous medications not directly related to kidney failure, such as antibiotics for infected diabetic foot ulcers. The non-dialysis personnel who administer these drugs outside the dialysis unit will employ alternate

intravenous access, often a PICC line, which damages sites for future hemodialysis vascular access.

- b) Many antibiotics should be administered during or at the conclusion of dialysis in order to optimize blood levels and thus effectiveness of the antibiotic. If the patient must receive the antibiotic at other times, such as on non-dialysis days, therapy may be inadequate, increasing the risk of recurrent infection and hospitalization.
- c) The use of other novel medications that must or should be administered during the dialysis treatment, such as desferoximine or sodium thiosulfate (a potentially promising therapeutic adjunct for the treatment of calciphylaxis), will be discouraged if not eliminated.

**6) The PPS does not take into account specific pediatric issues and costs that confront pediatric dialysis programs, and there is inadequate consideration of pediatric-specific co-morbidities.**

- a) We are concerned that the case-mix adjustment does not take into account the higher cost of providing specialized pediatric care, which results from the wide range and limited choice of pediatric sized disposable equipment (needles, hemodialysis and peritoneal dialysis catheters, dialyzers etc) as well as personnel costs associated with higher nurse-patient ratios, increased clinic times to provide support for children and their parent/family caregivers as well as monitor growth and development and carry out procedures such as blood draws and fistula cannulation which are technically more difficult in children.
- b) The co-morbidities defined by the PPS (diabetes, alcohol/drug dependence etc) do not apply to children and ignore common co-morbidities associated with pediatric ESRD including pulmonary hypoplasia, developmental delay, failure to thrive, seizure disorders, deafness, stem cell transplantation, other solid organ transplantation, congenital heart disease etc. Thus, the PPS does not allow for increased facility effort of caring for pediatric ESRD patients and their associated other organ dysfunctions, which are commonly managed by the pediatric dialysis program in collaboration with other pediatric sub-specialists.
- c) Finally renal osteodystrophy is a common problem in the pediatric ESRD population and leads to poor growth and slipped capital femoral epiphyses. Renal osteodystrophy should not be excluded from the pediatric ESRD co-morbidity list as it requires extra effort to modify diet, monitor with more frequent labs, promote medication adherence, and frequently change medication dosages in the growing child.

**7) The limitation on payment for three treatments per week discourages the delivery of newer innovative therapies that allow better quality of life, return to the workforce and encourage rehabilitation.** Therapies such as shortened daily dialysis or nocturnal dialysis as well as other modalities which may be introduced in the future may not be considered medical necessity, but may have much better outcomes than traditional thrice weekly hemodialysis, including fewer hospitalizations and lower drug costs.

**8) Proposed case-mix payment adjusters do not align incentives for high-quality care.** Adjustment for recent bacteremia creates a perverse incentive to prolong catheter use, and

adjustment for recent bacterial pneumonia creates a perverse incentive not to administer pneumococcal vaccine.

**9) The implementation of reimbursement based on the QIP in the dialysis provider setting may affect quality of care in unanticipated ways.**

- a) For example, with the initial emphasis being placed on URR and anemia management, other aspects of treatment may be ignored as facilities intensify efforts to meet payment for performance (P4P goals). 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.
- b) CMS will use claims 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 between the 2010 and 2012.
- c) The QIP should be formulated not to stifle quality improvement. Basing incentives on the national mean performance on a limited number of laboratory variables of minimal or uncertain relationship to overall and hospital free survival means that the 50% of facilities statistically likely to be meeting these standards of quality assurance will have no incentive to develop and improve more sensitive and specific indicators. On the other hand, enforcing non-evidence based, hypothetical "optimal" indicators will unfairly jeopardize the reimbursement of the other 50% of facilities who are working to meet the QA standards. Any QIP process should encourage innovation across a broad spectrum of quality indicators. Quality improvement should not be de-incentivized by an overemphasis on quality assurance.
- d) Likewise, the QIP should not stifle innovation and should be based on evidence of benefit. The per treatment URR standard, for example, may be unobtainable for patients who receive frequent short dialysis treatments but the therapy may offer significant benefits to patients as well as advance the quality of dialysis care for the entire ESRD population.
- e) Consideration needs to be given to facilities with extraordinary challenges, e.g., nursing home facilities whose patients have serious chronic and acute comorbidities and cannot be treated in other outpatient facilities. In this example, anemia standards may be unobtainable, yet the facilities fill important needs in the community and their costs may be higher due to patient acuity.
- f) The full implementation of CROWNWeb will mean that data will potentially be available for analysis. However, providers that cannot batch submit data will experience a substantial drain on resources and time which will distract from patient care and impact quality.

**10) Unintended adverse outcomes will be difficult to evaluate since initial outcomes analysis will be based on limited claims data.**

- a) It will be critical for the Networks to detect and evaluate the consequences of the reimbursement changes, and unintended consequences may be difficult to measure even with a robust data system. The Networks need to appropriately assess quality of care, access to care, and disparity issues though the analysis of timely, accurate, validated and

complete patient-level data. For example, since ESA and vitamin D analog doses for African American patients have been shown to be higher than for Caucasian patients for the same outcomes, the lack of patient specific data, including race, will cause disparities in care to go unrecognized. Unfortunately, the information systems that are required to address these issues may not be available and, to date, the level of Network access to CROWNWeb data is unclear. Claims data are incomplete, not timely and will not provide an accurate assessment of the quality of care provided by a dialysis facility.

- b) There appear to be no provisions for the considerable additional Network resources that will be required to address potential adverse consequences of the changes in payment