



Several nationally recognized experts with ties to Northwest Kidney Centers were invited to be among the 23 people presenting commentary when Medicare held a Town Hall Forum in Baltimore on the bundling proposal Oct. 23, 2009. Here is what they had to say:

Bill Peckham, NKC trustee emeritus, on dialysis for 19 years

I have been a Medicare beneficiary due to ESRD since July 1988 when at age 24, I received a kidney from my oldest brother.

My underlying condition - FSGS - recurred in the transplant; I started dialysis in September 1990. After first dialyzing in-center I switched to home dialysis in September 2001. At home I enjoy a healthier, more frequent dose of dialysis. I currently dialyze five nights a week, overnight, while I sleep.

I appreciate the opportunity to comment on the ESRD Prospective Payment System Proposed Rule. My comments are grounded in my belief that all Medicare beneficiaries with severe kidney disease should be able to live the lives they were meant to live but for their bum kidneys.

I know dialysis works. As I read through and thought about the proposed rule I asked myself:

Will this proposed rule increase or decrease the burden of dialysis on those who are ill?

After many hours of thought and deliberation, numerous conference calls and meetings ... I don't know the answer. I don't know what all this rule will do but I have concerns. It is a big change! Including Part D medications?!? Really? As the kids say, OMG.

I am a payment policy hobbyist. This is my avocation, not my occupation. And this was a lot to evaluate. I am not entirely confident in my understanding of each of the many elements in this proposed rule. Some things I'm sure of; other things not so much.

First, the thing I am most sure of is the need for a separate home dialysis training payment modifier. Home dialysis training is not a routine service. It is expensive and right now access to home training is limited by insufficient training capacity.

Including training in the base rate will further constrict access to home dialysis. Each training session should be paid at a level commensurate with the amount of one-on-one nursing time training requires.

Second I am confident that this rule would be improved if covered labs were defined on a list rather than defined as those ordered by the MCP.

My nephrologist (who receives the Medicare Capitated Payment each month) should also be able to act as my primary care doctor. This came up this summer when I had a cancer diagnosis. I would not have wanted to endure the added appointments this proposed rule would have required. Non ESRD labs, drawn in the unit, should be paid outside of the ESRD bundle.

Having routine labs defined by a list would also better accommodate travel. Labs related to travel should be specifically excluded from the bundle – travel is important, please don't make it harder.

In general I think the complexity of the new rule will drive further dialysis provider consolidation, in an already consolidated industry. I think ownership diversity is healthy. I don't understand CMS's choice to define small volume facilities in terms of patient census rather than in terms of the size, and therefore the purchasing power, of the provider.

CMS should define "small volume" as units owned by providers who serve less than 1% of the total dialysis census. This would help slow the rush to oligopoly by giving truly small providers additional resources to operate under the new payment rule.

I doubt anyone can fully predict the impact of having dialysis units administer oral medications. It's too big a change. In the face of this uncertainty I urge Medicare to be constrained by prudence. Simplifying the rule would be prudent and also would help small providers cope with this far reaching change. Do not expand the bundle beyond what is required by MIPPA. Scale back the complexity.

This is an historic change that will guide and constrain the provision of dialysis for a generation. It's critical to get this right. I urge caution. Thank you.

Connie Anderson, RN, NKC vice president of clinical operations

Northwest Kidney Centers is a not-for-profit, community based, small dialysis organization that provides in-center as well as home dialysis treatments. We currently serve about 1365 patients. Of those patients 63 are on home hemodialysis and 138 on peritoneal. We are one of the largest single providers of home therapies.

NKC fully supports the efforts of CMS to revise the payment systems for the ESRD program. It is imperative that CMS should provide policies so that the ESRD beneficiaries receive the best quality of care and that care is not compromised in any manner. I would like to offer the following comments on behalf of NKC:

I wish to acknowledge CMS for many positive features in the bundle.

1. Payment is on a per treatment basis
2. Nephrologists services are not included in the bundle.
3. Recognition of payment for more frequent hemodialysis with medical justification.

I would like to offer comment on two issues in the bundle that could have a negative impact on the care provided to our patients.

1. Laboratory services

As a SDO we contract for lab services with an outside vendor. Proposed in the bundle are all diagnostic laboratory services for the treatment of ESRD as ordered by the MCP physician. We felt this will impact the care provided to the ESRD patient for the following reasons. Annualized NKC performs about 131,000 separable billable lab tests at a cost of about \$32.57/treatment. All NKC labs are done through a contracted lab service and many of the separable billable labs are for treatment of other disease states. The \$32.57/treatment does not include the labs that are currently in the composite rate. The proposal to include all labs in the bundle for the \$9.18/treatment will no way meet the costs of all of the labs ordered by the MCP. This is because the MCP nephrologists in many cases are also the primary care physician. To add all labs would add a significant layer of complexity to the coordination of care that could result in poor outcomes for patients and less access to physicians.

Effective 2011 NKC would be responsible to bill all labs under the bundle. NKC does not operate a lab and therefore the administrative burden to set up billing systems would be significant.

We would therefore like to propose that CMS consider a defined set of labs for the treatment of ESRD only. This would help alleviate some of the administrative burden for the SDOs that buy their lab services. The most significant burden is the ability to set up systems for billing. It also would allow time for CMS to gather more data on ESRD labs and the MCP as the primary care physician.

NKC believes that version 1.0 provided by CMS in "Dialysis Labs at a Glance" used as a tool for the surveyors more accurately reflects the appropriate tests for ESRD patients.

We propose that CMS fully bundle those tests that are defined as ESRD related only. Delay the inclusion of separately billable labs. All other lab tests, regardless of who orders the labs, MCP or others, should be outside the bundle. Eliminate the transition period and during that time collect data on lab costs so that the bundle does include enough money to cover costs of ESRD labs in order for small dialysis organizations to survive. Without this, patient care will fall into a morass of confusing duplication of effort, and inadequate transmission of critical clinical information.

2. Peritoneal Dialysis Training

ESRD beneficiaries should have access to all modalities of treatment. NKC agrees with CMS that home dialysis is an important option. One such home modality option is peritoneal dialysis. PD offers a unique class of patients and does not necessarily cost less. In the current system there are add-on reimbursements for training costs. Training is not a routine dialysis service and requires a unique set of skills provided by a Registered Nurse.

NKC opposes CMS's proposal that there is no adjustor for home training in the bundle. CMS based this on the premise that most patients will have a payment adjustor in the first 120 days and therefore would cover the additional costs for training. NKC's experience does not prove this to be true. In 2008 only 44% of patients new to dialysis started directly on PD whereas 56% patients transferred from in-center hemo to PD after the first 4 months. Adequate funding for training is important in order for centers to be able to offer home as a therapy.

We propose that a PD adjustor outside of the bundle is warranted for training sessions and that the current system of capping the number of training sessions seems to be working well.

Quality measures are important to patient outcomes. NKC supports measures for quality but let's do it right. KECC does not track PD quality parameters such as adequacy. We would like to propose that CMS hold on adding peritoneal quality parameters until there is sufficient time to gather data to establish what we be the most effective adequacy quality measure for PD. We do however support the anemia measures.

We also feel that the proposed lab system within the bundle will be a disincentive for facilities to offer home as a therapy and patients to choose home as an option. CMS must provide a clear and bright line for lab tests which are included for home patients in the bundle. We propose a limited list defined for ESRD treatment only. Otherwise CMS will be removing coverage for tests that are done in arrangement with the ESRD facilities or through various physician offices in the patient's local communities. This would be an administrative burden to coordinate lab testing for home PD patients, as well as coordinate the primary care physicians and MCP physicians following the patients, and have all of these various laboratories bill the ESRD facility.

In conclusion: Thank you for this opportunity to present testimony regarding the proposed bundle. Most important points are:

1. Provide a limited list of lab tests for ESRD treatment only
2. Delay the lab transition until more and better data is available
3. Training dialysis should be an add-on adjustor.
4. PD quality measures should be delayed

**Christopher R. Blagg, MD, FRCP, former director of Northwest Kidney Centers
and Robert S Lockridge, MD**

Merging reimbursement for home hemodialysis training into the proposed bundle is a serious mistake. Several government agencies - MedPac, GAO, CMS and the Congress - have all expressed interest in seeing more individuals with end-stage renal disease dialyzing at home in the future. Why does CMS believe that their proposed inclusion of home hemodialysis training costs in the proposed bundle will encourage more use of home hemodialysis?

As of 2007, the USRDS reported only 2,999 (0.8%) of 368,544 prevalent U.S. dialysis patients were on home HD. At the same time, 11 countries had a higher percentage of their dialysis patients on home HD than the U.S. We have known for more than 40 years that home HD is the best dialysis treatment for patients willing and able to do it, and who are fortunate enough to have access to a training program. Now, with the even more striking patient benefits found with daily and nightly HD - including patient survival that appears similar to that with a deceased donor transplant - and with the development of more patient-friendly equipment, there has been a recent small but steady increase in the use of home HD. Current estimates are the prevalence is now slightly over 1%.

We believe that the proposal to include payment for home HD patient training in the general bundled rate is a serious mistake.

In the proposed rule, the bundled per dialysis rate for Medicare entitled patients during the first four months of dialysis will be 1.473 x the standard rate to account for the extra costs associated with stabilizing patients at home, administrative and labor costs associated with new patients, and the "initial costs incurred to train patients and their caregivers to perform home dialysis," This shows a lack of understanding of realities of home HD training.

According to the USRDS Report, 43% of new patients have not seen a nephrologist before starting dialysis, and so will almost certainly need vascular access surgery, time for the access to mature, and time to learn to needle their blood access before they can go into training for home HD. In fact, only 10 to 15% of home HD patients complete or even start training in the first four months of dialysis. Some will already be Medicare entitled because of age or disability or will have Medicare as secondary payer, but others will not become Medicare entitled until 60 to 90 days after starting dialysis and so will only be eligible for the proposed increased bundle for between 30 and 60 days.

In fact, most home HD patients start training after the first four months of dialysis, having decided to change to home HD months or years after starting dialysis. PD patients often begin having difficulties with their treatment after one to three years and have to change to HD (the dropout rate for PD is about 30% per year). At least some of these, having experienced the advantages of self-dialysis at home, will welcome the opportunity to be trained for home HD. In addition, there are also occasions when patients already on home HD require one or more retraining dialyses on new equipment or for other reasons. Thus, the great majority of home HD training dialyses occur after the first four months of dialysis.

CMS notes that training costs used in its calculations are based on cost reports, but details are not available. In general, cost report data for home HD training suffer from the fact that details of what should be included have never been clearly defined and so costs reported to CMS (and the GAO) almost certainly are not comparable between different programs. What is certain is that current reimbursement of an extra \$20 per training dialysis is grossly inadequate.

ESRD facility training costs are also proposed to be included in the base period bundled payment rate. Based on USRDS 2007 data, assuming 425 patients a year train for home HD (based on 1,253 patients trained between 2005-2007) and if (for example) cost report data show an average additional cost of \$250 per training hemodialysis above the proposed regular bundled rate, then for 20 training dialyses (most patients can be trained with this or fewer dialyses once able to use their blood access) this would result in a total cost of \$5,000 per patient trained and the total extra cost would be \$2.125 million.

However, if distributed across 46,622,520 dialyses (based on 333,018 prevalent hemodialysis patients at the end of 2007 and an average 140 treatments per year per patient) this is slightly less than five cents per dialysis. If CMS were to use estimates of home HD training costs based on the current extra \$20 per training dialysis 3 times weekly for 13 weeks, a total cost of \$780, and distribute these costs similarly, this would be less than one cent per dialysis.

These amounts would hardly be an incentive to train patients for home HD! For the majority of patients who are trained for home HD after the first 4 months of dialysis (currently about 80 to 90% of home HD patients), it will take a year or more depending on the frequency of dialysis before the training costs are recovered, even though the cost of a hemodialysis at home is significantly less than the cost of an in-center dialysis. It is also well recognized that when a new home HD program starts up it needs to train and send home 12 to 15 patients before it recovers its start-up costs.

CMS has elected to describe home HD training costs as "renal dialysis services" and include them in the regular bundle. With only about 1.0% of U.S. prevalent dialysis patients on home HD and only a small proportion of dialysis facilities actually providing training this is hardly a routine service as yet.

Proposal: The simplest and fairest way to reimburse home HD training and the retraining of patients in whom Medicare is primary, whenever it occurs, would be to remove the "initial costs incurred to train patients and their caregivers to perform home dialysis" from the bundled rate for the first four months of dialysis and to provide an adjustment to the basic rates for a home training HD at a level based on cost report data. This could be for an initial course of up to say 25 training dialyses and a similar rate for individual retraining dialyses. This would help incentivize providers to train more patients for home HD.

Summary: The decision by CMS to continue one single payment for an individual HD treatment, whether in center or at home, and the equivalent for PD, is praiseworthy. However, inclusion of home HD training costs in the general bundle will hinder, not help, in encouraging, use of the best forms of dialysis, including more frequent nightly nocturnal home HD. The latter was the choice of knowledgeable nephrologists in a recent survey when asked what treatment they would choose for themselves if they could not have a kidney transplant.