



December 13, 2009

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1418-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: CMS-1418-P: End-Stage Renal Disease Prospective Payment System Proposed Rule

Dear Acting Administrator Frizzera:

Thank you for the opportunity to submit comments on the "End Stage Renal Disease (ESRD) Prospective Payment System" Proposed Rule. The Northwest Kidney Centers is the world's first out-of-hospital dialysis program, based in Seattle Washington, founded in 1962. Over 48 years we've weathered many challenges including severe scarcity of any funding for dialysis in the 1960s and operating a dialysis admissions committee (labeled at that time by Life magazine as the "*Life or Death Committee.*") As well, we have actively participated in federal policy advocacy for forty years. We have long term perspective and are eager to provide comment on the bundling rule.

OVERVIEW

Last year in our 14 facilities and in 210 homes, the Northwest Kidney Centers provided 145,000 Medicare-funded dialysis treatments to 1360 dialysis outpatients. Over 15% of our patients are on home therapy: 65 home hemodialysis patients and 145 peritoneal dialysis (PD) patients. We work closely with 40 nephrologists who practice in small and large group practices and academic settings. Because we provide care to ½ of 1% (0.5%) of US dialysis patients, we consider ourselves a Small Dialysis Organization (SDO) provider.

As you are aware, there are 550 dialysis providers in the USA, operating 5000 facilities and caring for 400,000 dialysis patients. Our national dialysis industry is unique: we have 2 for-profit large dialysis organization (LDO) providers, and about 548 small dialysis organization (SDO) providers who operate for-profit, not-for-profit, small chains, independent and hospital based facilities. (Like the USRDS, we do not use the term Medium Dialysis Organization (MDO) because all dialysis providers in the US are actually quite small in relation to the two LDOs.) Together the two LDO providers operate thousands of facilities and care for 70% of dialysis patients in the USA. The next largest provider, the largest SDO provider, operates 209 facilities and cares for less than 4% of the Medicare patients on dialysis. With the support of the Federal Trade Commission, in the last decade our ESRD field has evolved into an oligopoly dominated by two LDOs. The for-

profit LDO companies are also vertically integrated; they contract with nephrologists to establish practices, provide vascular access and disease management, and sell laboratory testing, dialysis equipment, dialysis supplies, dialysis drugs and numerous other services that SDOs often purchase due to limited alternatives.

NKC serves nearly 80% of individuals requiring dialysis in King County Washington, a geographically large region in western Washington State. The other 20% of dialysis patients in King County are cared for by one large for-profit dialysis organization (LDO) which is 100 times bigger than NKC. Today, after a rapid decade of LDO growth, 55% of the Washington State dialysis patients are treated by for profit dialysis companies and 45% by non profit, independent SDO providers.

Our comments to you on the Proposed Rule are heavily influenced by our history as the world's oldest outpatient dialysis program, by our position as a SDO within an oligopoly environment, and by our mission as a community based, not-for-profit provider of care dedicated to improving our community's kidney health. We intend to serve our community for future generations, in a respectful and trusting partnership with nephrologists, patients, staff and payers, especially CMS. Our comments to you are submitted with the assumption that CMS shares our mission to promote the optimal health, quality of life and independence of beneficiaries on dialysis. We are optimistic that if CMS adopts select revisions in the proposed Rule, together we'll be able to achieve this goal.

GUIDING PRINCIPLES FOR OUR SUGGESTIONS

The shift to the bundle is a huge change for dialysis providers. We will collaborate in new and different ways with our nephrologists, patients, laboratories, drug sources, medical record and billing vendors, etc. Our suggestions to CMS are guided by the following principles:

- **Do no harm.** Avoid deterioration in patient outcomes, quality, the patient experience and especially safety.
- **Avoid complexity.** Given the enormous change, complexity in rules carry risk to patient care. We suggest that over time, the bundle can be improved once we learn from experience, a classic performance improvement model. We urge straightforward, relatively simple approaches to initial implementation of the bundle.
- **Do not disadvantage small businesses.** The LDO oligopoly is extreme right now. Competition, which allows patient choice and access to care, is vitally important. The federal rules should support small businesses and work to level the playing ground for providers of all sizes.
- **Consider the impact on home dialysis patients.** A "in center hemo-centric paradigm" dominates our field. To meet Congress' and CMS's intent to support home therapy, we urge CMS to consider each rule in light of the impact on home peritoneal and hemodialysis patients.
- **Balance the rationale for change against potential of negative impact from revised incentives.** The proposed rule contains persuasive rationale for many changes. However, a reason to change needs to be balanced against potential adverse incentives. Sometimes the change imperative outweighs the risk of adverse

incentives. Other times troublesome incentives outweigh the rationale to change. We will comment on this delicate balancing act throughout this letter.

POSITIVE ELEMENTS OF PROPOSED BUNDLE RULE

The Northwest Kidney Centers (NKC) is pleased with many aspects of the proposed bundling rule. We applaud CMS for:

1. **Selecting the treatment (not per week or per month) as the basis for payment.** This approach maintains the model we know well. A per treatment model accommodates the ebb and flow of dialysis patients between facilities, changing modalities, to transplant, in and out of the hospital and patient travel. It allows for a more smooth transition to the complex new bundle than would have been possible under other alternatives and minimizes administrative burdens.
2. **Maintaining nephrology and hospital services outside the bundle.** CMS is wise to avoid changing too many parameters in the care paradigm. Shifting incentives and administrative burdens are avoided by maintaining separate payment for nephrology, vascular access services and hospital services.
3. **Maintaining the same base payment for home treatments as in center.** This approach supports home hemodialysis and peritoneal dialysis therapy. Cost report data for these therapies is not well validated but historical information would imply that home therapy is less expensive per treatment once a patient is stabilized at home. However, when compared to in center cost report data, PD and home hemodialysis cost reporting is probably not as accurate, given more complex allocations. Recently the GAO acknowledged that there is insufficient home hemodialysis data, and it is extremely variable as well, to accurately report nationwide home hemodialysis training costs.

As well, the assumption that home therapy is less expensive is not necessarily current. In our large NKC home program treatment, costs are rising rapidly. This is due to advances in medical therapy (e.g. NxStage services for home hemodialysis patients and icodextrin solution for PD patients). The new Conditions for Coverage impose new requirements (e.g. new care plans for patients shifting modality, monthly clinics, etc). The proposed rule is correct to pay the same base bundle rate for home treatments as in-center treatments.

4. **Allowing payment for more than three hemodialysis treatments per week with medical justification.** More dialysis is better for all patients. The literature is clear that more deaths occur after the two day “weekend” for patients on the traditional thrice weekly hemodialysis schedule. In our home hemodialysis program, patients demonstrate greatly improved outcomes through nocturnal and 5-6 treatments week. We applaud this proposed rule.
5. **Penalty triggers for poor quality – the QIP measures- are reasonable and don’t require laborious web entry via CROWNWeb.** The three measures are few in number, collected and reported today, and not unreasonable. We can work to improve our outcomes in these areas. We have specific comments about home adequacy

measures in this letter, but strongly support CMS' initial approach of selecting a few measures with solid historical analysis through KECC and national reporting on Dialysis Facility Reports (DFR). It will be important to advance quality measurement in the future to ensure beneficiary safety and outcomes, with valid and reliable measures that cannot be easily "gamed" and are reported nationally so that performance can be improved before implementation.

We are delighted that QIP will initiate without CROWNWeb data, which, as launched in February 2009, is a huge burden for SDOs under the single user interface model. Our organization participated in Phase 1 of CROWNWeb, so we have direct experience. We assigned clinical staff to keyboard enter clinical data each month. To date, CMS has made available the option of batch transmission of data to only three providers: the two LDOs and the largest SDO.

We believe that our sophisticated information technology department has the ability to submit data in the batch format that CROWNWeb requires. As well, we believe that the vast majority of 248 SDO providers have electronic records and the capability to batch submit. Batching data is more efficient and accurate than data that is manually input. Manually inputting the data costs a provider much more than batch transfer of the data.

It is not rational to require NKC to manually input data that is less accurate, detracts from patient care, and costs more money. Acting irrationally is, by definition, arbitrary and capricious.

We urge CMS to accept batch data from NKC and other SDO providers, perhaps through a clearinghouse model, that demonstrates our ability to format and submit valid data. After that process is well tested, validated, and meets security requirements, then CROWNWeb will be ready to support more QIP measure reporting.

SUMMARY RECOMMENDATIONS FOR CHANGES IN PROPOSED RULE

- 1. We propose that CMS maintain home training (self-dialysis) treatments outside of the base bundle, or create a separate payment adjustor to the base rate, recognizing the incremental costs of home dialysis training services.**
- 2. We propose that CMS adopt a specified list of laboratory tests that truly are "used for the treatment of ESRD" and include these tests, as drawn by the facility, in the bundle. All other labs would remain outside the bundle, whether ordered by nephrologist and drawn at the facility or elsewhere. These other labs would be independently billable to Medicare by the lab.**
- 3. We propose that the CMS dialysis lab list be deemed the "bundle labs."**
- 4. We propose that the "bundle labs" be implemented after the three year transition to avoid line item lab billing on the claim form during transition. We propose that labs be excluded from outlier computation.**

5. We propose that labs drawn for patient travel e.g. hepatitis B, be excluded from the bundle.
6. We propose the oral drugs in the bundle be limited in class. Given that the MIPPA law requires transition, we propose that a minimal number of oral drugs-specified oral drugs with an IV equivalent- should be initially included in the bundle.
7. We propose that CMS make clear that oral Vitamin D and oral iron are the only currently available “oral drugs with IV equivalent” that will be included in the bundle.
8. We propose that the payment for oral drugs in the bundle be based on the price at which the SDO would need to buy the drug from a pharmacy under arrangement.
9. We propose that oral drugs without an IV equivalent be excluded from the bundle, until the 2014 or later.
10. We propose that the bundle uses the current four well tested adjustors (age, BMI, BSA and pediatric) the first 120-day new patient adjustor and hepatitis B adjustor. We propose eliminating all other patient-specific co morbidity adjustors.
11. We propose the bundle uses a single pediatric category of <18 years.
12. We strongly endorse CMS's decision to not include a race or ethnicity adjustor.
13. We propose that a low volume adjustment should be applied to currently identified isolated essential facilities (IEFs), for example those on Indian reservations, regardless of the number of treatments performed each year.
14. We propose that Secretary takes MIPPA-approved action and provides an adjustor to the base bundle for all treatments in facilities majority owned by SDO providers. SDOs would be defined a company (for-profit or not-for-profit) that in total served less than 5% of US Medicare dialysis beneficiaries in 2009. This definition would be updated annually.
15. We propose that CMS release the final rule with time for SDOs to make a well informed decision re transition.
16. We proposed that the ESA monitoring policy be discontinued in 2011.
17. We endorse the use of the three quality measures proposed by the rule: hemoglobin <10 (negative measure), hemoglobin >12 (negative measure) and URR >65% (positive measure.)
18. We propose that hemoglobin measures together receive 50% weighting and URR measure receive 50% weighting.

19. We propose that hemoglobin < 10 receive 75% of weighting within its category and hemoglobin > 12 receive 25% weighting within its category.

20. We propose that home hemodialysis patient results for urea reduction ratios (URR) be excluded from a facility's results under QIP.

21. We propose that peritoneal dialysis adequacy results be excluded from QIP.

22. We propose that CMS require additional quality indicators to be affixed to the claim form, to monitor the effect of the bundle on patient care and to allow time to implement batch submission of quality data via CROWNWeb.

SPECIFIC RECOMMENDATIONS

HOME DIALYSIS

We believe the proposal to eliminate the historical payment for home training offers the greatest risk to beneficiary safety in the entire proposed bundle rule. Inadequate or rushed home training, due to significant funding constraints, poses a severe safety risk to patient life. A patient and helper who are not ready to conduct hemodialysis self treatment at home can inadvertently put the beneficiary at risk of harm and death. A peritoneal patient who does not practice scrupulous infection control practices that should have been learned and demonstrated in training risks peritonitis, sepsis and death.

NKC opened our home hemodialysis program in 1966 and it has operated continuously ever since. We've tried many forms of equipment and therapy regimens and have served thousands of people in their homes for 43 years. We operate one of the nation's largest single home programs, serving 210 patients today, which is nearly 16% of our dialysis census.

SDOs are often leading champions for home dialysis. A number of SDO providers have achieved a 20% or better home utilization rate versus a national average of approximately 8%. Our motivation to operate a large home program is because we passionately support the therapy as optimal for patients, not because it is particularly cost effective.

At NKC, our home training costs are very significant, at least \$300 more in incremental cost per treatment than a routine composite rate treatment. For several decades we have operated with an exception rate, which today provides about \$80 toward this incremental cost. Exception rates are eliminated in the bundle.

Almost all of our home hemodialysis patients are on frequent treatment and so initial training, one on one with a nurse, covers five days a week for 4-6 weeks. PD patients train for 4-8 treatments. Both types of home patients return for retraining when there are new protocols, changes in equipment, innovations in care, or if they have safety problems relating to technique.

At NKC it takes between 9 to 18 months of home treatment cost savings, compared to in center treatments, to fund the initial investment of home training. Some of our patients never complete training, try home and do not like it, or use this therapy as a means to become healthy enough to obtain a kidney transplant, often within 18 months. Our up front “return on investment” of home training is never realized for a number of both home hemodialysis and PD patients. Giving rising costs for home therapy, our experience is that the payback period for both PD and home hemodialysis is growing.

Even though the home treatment payment is the same today as in center, home therapy is not viewed as a cost effective model for providers to save money. If providers viewed home hemodialysis and PD as cost effective today, why is home therapy so small and shrinking year by year (less than 7% of patients are on PD and less than 1% on home hemodialysis)?

The proposed case mix adjustor for the first four months would not address the incremental costs of home training for the majority of NKC patients seeking the home treatment. At our organization, each year only one or two patients start home hemodialysis within their first year on dialysis. Instead, about 95% of all of our new home hemodialysis patients change modality from in center hemodialysis, after at least a year on dialysis. As well, at NKC 55% of our 129 new PD patients between April 2008 and June 2009 transferred to PD from in center hemodialysis after at least a year on dialysis.

1. We propose that CMS maintain home training (self-dialysis) treatments outside of the base bundle, or create a separate payment adjustor to the base rate, recognizing the incremental costs of home dialysis training services. The payment should be applied to each training treatment session, initial and retraining, since each session is medically necessary. CMS may choose to continue the practice of imposing caps on the number of initial training treatments.

It is highly unlikely that a training rate will encourage inappropriate trainings without subsequent home dialysis i.e. “gaming” of the system. Here is why:

- Home training can only occur in facilities certified by Medicare to conduct such training. Currently only 15% of facilities are certified for home hemodialysis training and 50% for PD training.
- Home training requires a doctor’s order.
- The new Conditions for Coverage outline extensive requirements for home training including specialized staff, policies, facility requirements, etc.
- PD training requires a surgical procedure before training begins (insertion of a PD catheter.) Such a significant event would not occur without physician order and patient consent and thoughtful concurrence.
- Hemodialysis home training now predominately utilizes new equipment and a 5 times/week regimen. The patient must move from the in center, thrice weekly environment and equipment to train with specialized equipment and a 5/week treatment schedule. These are major changes not easily adopted without serious intent on behalf of the patient, doctor and provider.
- A home visit is an important step to qualify a patient for home therapy.
- CMS current applies caps on initial home training sessions which have allowed adequate training.

In summary, the conversion to home is too big of a change for patients for this system to be easily or often “gamed.”

Inadequate funding for home training in the bundle has the potential of leading to safety catastrophe, enormous liability risk and will certainly lead some SDO programs to close home dialysis programs, not increase use of home therapy. In the 12/10/09 MedPAC meeting, the presenter postulated that because the bundle will pay the same for all modalities, home therapy may grow. The evidence of the past decades refutes this supposition. PD volume has dropped since the early 1990’s despite the same composite payment as in center. Home hemodialysis volume is miniscule, despite the same composite payment as in center.

The proposed Rule includes the current costs of home training in the base bundle that applies to treatments throughout the nation; in fact, the proposed rule rewards those who are not offering home training with a small amount of funding in the base bundle and penalizes those who are doing it by asking them to absorb very high costs. An adjustor for home training will lower the bundle base rate for all 37,000,000 US treatments by a negligible amount. Because historical payment for home training has been identified as inadequate, we urge CMS to create a payment for home patient training using best available information on actual resource requirements.

The enthusiastic support of this provision by Kidney Care Partner members, representing patient groups, professional organizations, and providers, and by NRAA members, representing SDOs, is evidence that the renal community is overwhelmingly supportive of a specific payment for home training. Comments to CMS from patients throughout the US confirm their strong desire to support home training funding.

Although some LDO providers suggested to CMS a “pilot” for this provision, this is not the position of KCP, NRAA or others in the renal community and should be vigorously rejected. A pilot tests new options for efficacy; there is no need for a pilot to study a service that has been in place since 1964. Existing programs might not be able to sustain themselves while the pilot generates data (on what subject?); potential new programs would be put on hold while the funding is sorted out. The home modality will be harmed by the pilot model. Only by fairly reimbursing home training at units able to meet the stringent Conditions for Coverage requirements will the use of this healthier modality grow.

Home training is not a routine treatment service, incurs significant costs, and applies to a small number of US patients. Financial stability is a core component of an effective, high quality home dialysis facility program. CMS should create a unique payment to compensate for the significant incremental costs of this vital prerequisite service to encourage providers to enthusiastically promote home therapy and allow patients to go home on dialysis. The additional costs associated with home training are appropriate and necessary, and should be fairly reimbursed.

LABORATORY TESTS USED IN THE TREATMENT OF ESRD

Under the proposed rule, the bundle base rate includes all laboratory tests associated with a dialysis patient as ordered by a nephrologist who receives monthly capitation payments (MCPs). This may appear to be an elegantly straightforward approach, but actually it is

quite complex and has the potential to severely disrupt the patient's relationship with a multitude of physicians and result in significant burden to beneficiaries

Our organization contracts with a local full service laboratory for all lab services required by our patients. We pay the lab directly for ESRD composite labs. We are removed from laboratory billing, revenue, expense, or profit with respect to non-ESRD composite lab tests.

Our nephrologists report that for many dialysis patients they serve as the principle physician, coordinating all medical care. They order lab tests for a variety of reasons, many not related to ESRD.

Our holistic focus on patient care results in our willingness to draw blood and other specimen samples for non-ESRD lab tests, and send the samples to the lab at no charge. It is of great benefit to patients – in terms of saving their vital access and their time- to draw non-ESRD labs at their dialysis center. It is our policy that these labs orders must come from the nephrologist whether they are the primary or principle care physician or are not. In this way, the nephrologist, who oversees ESRD care, is knowledgeable about laboratory results and transmits them to the nursing home, transplant program, primary care doctor, coumadin clinic or other service needing lab information on our patients.

Our home hemodialysis patients draw their own non-ESRD labs when the doctor orders them and the patients mail them to the contract lab. As well, for home hemodialysis and PD patients, non-ESRD labs are drawn during their monthly clinic visit with a NKC nurse.

The current laboratory system enhances coordination of care and bridges gaps in the continuum of care, to the satisfaction of patients and physicians, and also supports efforts to provide cost effective and high quality patient care.

There are major ESRD contract labs in the USA. The two LDOs operate their own labs and sell services to SDOs. As well there are several independent ESRD laboratories who serve SDOs. The LDOs have the great advantage of lower lab costs for their own facilities and have the benefit of incurring margin on their Medicare book of business. Today, SDOs are limited to paying negotiated rates for only composite labs.

We assume:

- Under the proposed rule, SDOs would be responsible to pay a contract lab for all tests ordered by MCP physicians for our patients regardless of setting or the need
- Due to administrative complexity, we would not be able to contract with multiple labs in our region. Therefore, when the nephrologist orders a lab test, the dialysis patient would need to have it drawn by NKC and processed by our single contract lab. This approach may be a particular burden to peritoneal dialysis patients who only come to the unit once a month who may be forced to come to the facility mid month or more often to get blood drawn for labs.
- All SDOs without labs- the vast majority- will have to negotiate with a contract lab to pay for labs included in the bundle. Contract labs will expect to earn a profit on this business. This contracting step will be avoided by LDOs who presumably will incur only the costs of labs, another example of a cost differential affecting SDO providers.

- Effective January 2011, all laboratory tests must be listed on the claim form. If the facility is in the transition, facilities will be paid 75% of the total MAP for these tests on the claim.
- As well, facilities will be responsible for collecting 20% co insurance on the bundle which includes labs, a new beneficiary cost. The contract labs have never had to collect co insurance as currently labs are paid at 100% MAP.
- Labs drawn for a patient to travel and be treated in another unit will be included in the bundle.
- The proposed rule will encourage facilities to remove the nephrologist from the non-ESRD lab communication route and replace it with the non-nephrologist's name so the lab cost will be separately billable by the lab, outside the bundle.

2. We propose that CMS adopt a specified list of laboratory tests that truly are “used for the treatment of ESRD” and include these tests, as drawn by the facility, in the bundle. All other labs would remain outside the bundle, whether ordered by nephrologist and drawn at the facility or elsewhere. These other labs would be independently billable to Medicare by the lab.

We ask that CMS adopt the tested model of “composite” labs, but for the purposes of the bundled approach, employ an expanded list of labs. We strongly propose that CMS fund labs in the bundle based on accurate and current lab MAP costs and utilization. We are extraordinarily concerned because the funding for labs in the proposed rule is vastly lower than our estimated actual costs.

The current proposed rule may result in nephrologists sending their dialysis patients to other physicians to get lab orders because the nephrologist is precluded from ordering non-ESRD and primary care labs for their dialysis patients. This disruption in care could be dangerous to patient health. For example, wound cultures of a diabetic toe are vitally important but costly. The proposed rule would provide no incentive for the nephrologist to order the culture and the dialysis unit to draw it. Instead the patient would need to go to a non nephrologist or emergency department to get the order for this lab simply to keep the costs outside of the bundle.

Instead, with our proposal, SDOs will probably contract with a lab for a defined set of bundle labs, which will enhance our ability to manage costs.

Finally, we urge that CMS include 100% of the Medicare Allowable Payment for the defined set of labs in the bundle, recognizing that even so, providers will be responsible for collecting the 20% co pay of the bundle allowable amount.

3. We propose that the CMS dialysis lab list be deemed the “bundle labs.”

CMS has already identified a list of 32 laboratory tests associated with ESRD treatments which is included in the surveyor guidance documents for the Conditions for Coverage (“Dialysis Labs at a Glance”.) This is an acceptable list for the bundle. However, if CMS wishes to broaden this list, we concur with the Kidney Care Council lab list of 49 tests to be included in the bundle.

4. We propose that the “bundle labs” be implemented after the three year transition to avoid line item lab billing on the claim form during transition. We propose that labs be excluded from outlier computation.

It will be a huge burden for SDOs to conduct lab billing on the claim form during the transition. This will require development of new interfaces with contract labs and timely downloads. If the rules do not require lab detail for transition billing or outlier payment, then there is no reason to list labs on the claim at all, before or after 2014. Thus we avoid a huge administrative burden to SDOs to produce lab billing interfaces with contract labs.

As well, if CMS adopts a “bundled labs” list, then labs could be excluded from outlier computation and not required on the claim form for outlier computation.

5. We propose that labs drawn for patient travel e.g. hepatitis B, be excluded from the bundle.

We have concern that facilities will deny lab tests to patients who wish the freedom to travel. Just as vaccines are excluded from the bundle, we urge that travel labs also be excluded and remain separately billable by the independent lab.

ORAL DRUGS

Under the proposed rule, all ESRD-related drugs are included in the bundle including those with IV equivalents and specified oral drugs without IV equivalent. Our organization is unique as we operate an onsite outpatient pharmacy for our “own use”, i.e. our patients; this may be the nation’s only fully owned and operated on site renal specialty pharmacy. We employ three expert renal pharmacists. Thus, we have a unique perspective on the costs and utilization of oral drugs by dialysis patients.

Since NKC operates an outpatient pharmacy we are well aware of the complexity of state rules, the limited availability of skilled pharmacy staff, and contracting, purchasing, compliance and billing issues. We postulate that it is highly unlikely that SDOs will open a pharmacy in the 12 months remaining before the bundle rule goes into effect.

We assume:

- SDOs who do not operate a pharmacy will be paying for oral drugs in the bundle “under arrangement”, with a national mail order or local pharmacy.
- Oral drugs with an IV equivalent provision will affect all peritoneal dialysis programs. Many facilities support fewer than 10 PD patients. The administrative complexity of arranging for drugs under arrangement will especially affect home programs.
- The volume of oral drugs required by a SDO will be small from the perspective of a contract pharmacy. Thus we assume limited discounts off retail prices will be offered under arrangement with SDOs.
- The oral drugs will be included in the outlier calculation
- The monthly claim will require line itemization of oral drugs dispensed or purchased under arrangement each month, requiring very timely information transfer, for outlier computation.

- As stated in the proposed rule, the payment for oral drugs will be fixed at \$14 per treatment, regardless of the provider's election to transition to the bundled payment rate. Thus, this element of the proposed rule will not allow providers to go through a transition to minimize negative impact.

6. We propose the oral drugs in the bundle be limited in class. Given that the MIPPA law requires transition, we propose that a minimal number of oral drugs-specified oral drugs with an IV equivalent- should be initially included in the bundle. By starting small, the administrative burden to SDOs will be minimized. In 2011, the SDOs will need to learn the process of how to purchase the oral drugs with IV equivalent and dispense them, or to send patients to a pharmacy to obtain them directly, with payment to that pharmacy provided by the SDO. Those providers with PD programs will learn how to set up this system.

The law requires transition to reduce impact on providers, which is especially important for SDOs. Given the complexity of transition with Part D, which CMS believes is not possible, the minimum number of oral drugs- those with an IV equivalent- should be in the bundle until the transition is complete in 2014.

7. We propose that CMS make clear that oral Vitamin D and oral iron are the only currently available “oral drugs with IV equivalent” that will be included in the bundle. Oral Vitamin D is a drug that is generally taken by home peritoneal dialysis patients. CMS should use current information about oral Vitamin D utilization and Part D plan payment levels to ensure the base rate appropriately includes these costs. For example, from our pharmacy data we know that our median IV dose of Zemplar is 4.6 mcg. An equivalent dose of oral Zemplar is 6.4 mcg. Also, oral Zemplar is twice as expensive as IV Zemplar per mcg. Thus a dose of IV Zemplar costs \$14.50 vs. a dose of similarly effective oral Zemplar which costs \$45.00. Providers with home programs will be responsible for these oral drug costs.

We ask that CMS clarify that oral antibiotics, oral pain medications, oral antianxiety medications and oral anticoagulants (which have IV equivalents used in dialysis facilities) are not included in the bundle. These oral drugs are commonly prescribed for non ESRD use.

8. We propose that the payment for oral drugs in the bundle be based on the price at which the SDO would need to buy the drug from a pharmacy under arrangement. Presumably this would be the Part D equivalent of the Medicare Allowable Payment, if such a price is available despite varied Part D plans. Even so, we expect contract pharmacies will penalize SDO providers relative to bundle payment by expecting profit on these contract arrangements.

9. We propose that oral drugs without an IV equivalent be excluded from the bundle, until the 2014 or later. We have current data from the subset of our patients who use our pharmacy. We know how many of our dialysis patients take calcimimetics and oral phosphate binders. We purchase these drugs through large wholesalers. At NKC, given today's utilization and dose levels, our cost to provide these classes of drugs would much higher per treatment than the \$14/treatment in the proposed rule. The annualized cost for us to purchase Sensipar and oral phosphate binders is at least \$5000/year/patient.

Many patients take both classes of drugs, for an annualized cost of over \$10,000/year. This results in a minimum cost of \$64/treatment for these patients.

We believe that our current costs are understated because many patients are not prescribed these oral drugs because of the significant cost to the patient, even with Part D coverage. As well, many patients do not purchase these very expensive drugs when they meet the Part D “donut hole”. We estimate utilization of these drugs could easily rise when the current unfortunate Part D financial barriers are removed. In that case, we estimate our overall cost per treatment is \$50/treatment (in today’s dollars.)

It is possible that patient care might greatly improve via coordinated services if these classes of drugs are included in the bundle. We urge, then, that this action should be taken after Congress acts on proposed health reform legislation to close the donut hole; if passed, we’d expect utilization patterns to shift, current cost data to be gathered and thereafter the bundle could include these drugs. This will require several years, which will allow the bundle implementation to occur without violating MIPPA law requiring bundle transition. In the meantime, providers can set up systems to obtain, dispense and bill oral drugs with IV equivalents.

PATIENT LEVEL ADJUSTMENTS

The rule proposes to continue to use age, body surface area, body mass index and pediatric status as payment adjusters. New adjusters are patient sex, 12 co-morbidities and a “new patient” adjustment to account for the higher costs during the first four months of treatment.

The case-mix adjusters proposed by CMS significantly lower the base payment rate, by over 21%. This base rate “tax” is required to keep the program budget neutral.

The adjusters do not take into account the proposed oral drug use in the calculation. Thus they may be incomplete.

The adjusters poorly predict the variation in resource utilization, less than 40% of variability.

We are concerned that patient level adjusters provide a false sense of security that SDO providers are protected given their inability to spread risk across thousands of patients. However we believe this is a flawed assumption.

We assume:

- Our internal systems will need to be changed to collect the necessary information for the new co morbidity adjusters (with the exception of sex, new patient, and hepatitis B status.) Sometimes we have this information today; oftentimes we do not and it will be difficult to collect it in the future. We cannot verify CMS calculations nor replicate them internally because most of the adjusters are not available to us. This puts us at a distinct disadvantage in determine whether to transition into the bundle, an option required by MIPPA and of particular importance for SDOs who have limited ability to spread risk.

- The adjustors will need to be collected rapidly before claims are submitted in the following month. Since some require hospital data e.g. septicemia or bacterial pneumonia, facilities are at high risk of not capturing data in a timely manner across the gaps in the continuum of care.
- Given the anticipated difficulty in collecting many adjustors each month, the adjustor “tax” will remove funding from the ESRD program with little chance to fully recover it.

10. We propose that the bundle uses the current four well tested adjustors (age, BMI, BSA and pediatric), the first 120-day new patient adjustor and hepatitis B adjustor. We propose eliminating all other patient-specific co morbidity adjustors. In the spirit of limiting complexity and risk, we propose that the bundle starts with the current adjustors plus the new patient and Hepatitis B adjustor, and that future adjustors be included after the transition.

There are well documented staff and drug costs associated with new patients and the new Conditions for Coverage clearly outline the intense responsibilities during this period. Many nephrologists and patients chose a “trial of dialysis” despite many co morbidities. This new patient adjustor would recognize the cost of this option. If CMS concludes this adjustor is required to protect small providers who cannot easily spread risk, we suggest that the adjustor weighting be recalculated to ensure accuracy. The proposed weighting of 1.47 appears quite high. There is limited administrative complexity or burden to using this adjustor.

As well, there are clearly evident facility costs to the care of patients with hepatitis B. The new Conditions for Coverage added to these costs via new rules. There is no administrative complexity or burden to using this adjustor as it does not change each month.

We do not support including sex (female) as it is unclear to us why a person’s sex causes higher use of resources, and despite presumed correlation of sex and costs, nearly half of the nation’s patients are female. An adjustor for nearly half of the nation’s treatments adds complexity and does not warrant lowering the base rate for all. There is no limited access to dialysis by sex. (Also, we note that when case mix adjustors were first introduced five years ago, the male sex was a proposed adjustor. The shift from one sex to another, in just a few years does not give us assurance that sex should be an adjustor.)

Hospitalization data is very hard to obtain. In addition, by paying for infections and hospitalizations, the proposal actually serves as a disincentive for reducing catheter use. It is extremely difficult to obtain accurate data re alcohol/drug dependency and HIV status. We do not recommend using cardiac arrest, pericarditis, septicemia, bacterial pneumonia, GI tract bleeding, sickle cell anemia, cancer, myelodysplastic syndrome, monoclonal gammopathy. If CMS decides to use infections as an adjustor, we recommend the addition of adjustor peritonitis in PD patients.

We urge CMS to consider the compounded effect of multiple adjustors that may have singular associations but do not warrant compounding when used for a single patient and treatment.

CMS may choose to add adjustors in future years. In the spirit of limiting complexity and administrative burdens, the current adjustors plus first 120 days and Hepatitis B status is adequate.

11. We propose the bundle uses a single pediatric category of <18 years. We partner closely with Seattle Children's Hospital and occasionally care for their pediatric patients who require more frequent home hemodialysis. The proposed several pediatric age and modality categories are unnecessarily complex. None of the proposed co morbidities in the bundle apply to children. Today's composite rate multiplier more appropriately values the complexity and actual costs of pediatric dialysis treatments. We urge that pediatric treatments be removed from the bundle or a new adjustor be calculated so that facilities that care for pediatric patients are not penalized and access to dialysis for children becomes limited.

RACE AS AN ADJUSTOR

12. We strongly endorse CMS's decision to not include a race or ethnicity adjustor.

We oppose use of a payment adjustor based on race or ethnicity. As CMS rightly observes in the rule, data collection regarding race and ethnicity is fraught with problems concerning accuracy, especially in the identification of race or ethnicity. The several published papers reporting higher ESA use among "African Americans" depended on the definition of race as affixed on the 2728 form by the nephrologist, without patient input nor a clear definition of the term.

Race and ethnicity are often defined from a cultural context. Our Western Washington State region is multi-ethnic; in our case, we would be perplexed to define "African American." This adjustor is not verifiable for compliance reasons and easily gamed. It has the potential to shift payment for a large portion of the population if an adjustor is made for treatments to those defined as African Americans. Over 37% of dialysis treatments in 2007 were provided to patients reported as "black." For those who gain with an adjustor, others lose. CMS states that Asian Americans and Hispanics treatments would be paid less. It would be wrong to reimburse less for a patient's dialysis based on the patient's self identification with a particular ethnic or racial community.

CMS states that self reported African American status correlates with higher ESA and other drug use. There is correlation, but what is the causation? All other adjustors have a theory of cause (infections = higher ESA requirements). We've done some research: we consulted a principal investigator in the world's first Epogen clinical trials, which occurred at our organization. We reviewed the 1994 article in *Medicare Care* entitled "*The Relationship of Provider Organizational Status and Erythropoietin Dosing in End State Renal Disease Patients*" by Lissovoy et al and the 2007 *JAMA* article entitled "*Dialysis Facility Ownership and Epoetin Dosing in Patients Receiving Hemodialysis*" by Thamer et al.

We believe there is no genetic basis for differential ESA use based on race. We postulate that ESA dose levels relate to payment incentives, the provider's for profit status, and

patient factors influenced by socio-economic status and culture such as lack of primary and predialysis health care, diabetes status, catheter use, infections and hospitalizations.

In Washington State, our organization has successfully advocated for the Governor's Council to select chronic kidney disease as State priority health care disparity issue. Minorities are disproportionately affected by CKD. Let's get to the root cause of this terrible problem and fix it through CKD Stage 4 education, predialysis anemia and access care, and other means, not through a bundle adjustor.

We are not aware of any racially biased CMS payment policy which pays better (or worse) based on a definition of race. By using this adjustor, CMS opens itself to enormous risk of claims of racial bias and potential legal challenge.

As well, a race adjustor would provide more payment to dialysis providers in the South and urban areas, dominated by LDOs. But it would negatively affect minority patients directly because an adjustor would increase the bundle rate. For example, those who are defined as African American may personally incur higher co insurance, even if they are not higher users of ESAs because this adjustor is applied to their bill just because they are African American.

Those advocating for the race adjustor imply that facilities will discriminate against African Americans by withholding adequate amount of ESAs if the bundle does not have a race adjustor. We find this to be an odious position, insulting to our industry.

We believe all dialysis patients, without having to disclose their racial history, deserve the best care, provided equally to all. Despite repeated messages to CMS from providers in the field seeking to adjust the base rate, CMS's position in the proposed rule was correct. CMS should not impose a race or ethnicity adjustor in the bundle.

LOW VOLUME FACILITY ADJUSTMENT

The MIPPA law required at least a 10% adjustment in the base rate for low volume facilities. This is the current language of Sec. 1881 as revised by MIPPA: *(iii) shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent;*

In the proposed Rule, CMS defines a low-volume facility as one that over a three year period had not opened, closed or received a new provider number due to change in ownership and had not provided more than 3,000 treatments per year in each year prior to payment year. CMS proposes to pay low-volume facilities a 20.2 percent increase to the base rate.

In Washington State, SDOs strive to achieve economies of scale by building facilities big enough to spread costs. The two LDOs have built the majority of their new Washington State facilities with 6 or less stations. This makes these small units more likely to meet the CMS threshold of 3000 treatments. We believe it was not Congress' intent for CMS to

provide better payment, through an adjustor, for a branch of a huge LDO which has chosen to build a small facility.

There is no evidence that access to care has been limited in rural or other regions of the United States in the past decade. NKC provides care in rural Northwest Washington, and other SDOs operate outside of urban areas in our state as well.

All exception rates are removed with the implementation of the bundle. Unfortunately this change will affect isolated essential facilities who obtained exception status when that option was available.

We believe Congress' intent through the MIPPA low volume provision was to support choice and access for beneficiaries who need dialysis. This outcome can only happen if SDOs remain viable through the bundle transition, which may be very difficult for some. Congress recognizes our field is an oligopoly industry mostly funded by Medicare, a rather unprecedented situation in US healthcare. Small business should be supported to allow beneficiary choice, encourage competition, support home treatment, and improve quality.

13. We propose that a low volume adjustment should be applied to currently identified isolated essential facilities (IEFs), for example those on Indian reservations, regardless of the number of treatments performed each year. The adjustment should be made on current and accurate costs, but at least 10%. There are 37 facilities with current IEF Medicare exception rates, and 12 exceed the 3000 patient threshold, mostly in rural areas of Montana and Utah. The bundle base rate for all will be slightly lowered by providing this adjustment for IEFs, a negligible impact.

14. We propose that Secretary takes MIPPA-approved action and provides an adjustor to the base bundle for all treatments in facilities majority owned by SDO providers. SDOs would be defined a company (for-profit or not-for-profit) that in total served less than 5% of US Medicare dialysis beneficiaries in 2009. This definition would be updated annually. Truly, all SDOs in the United States are low volume facilities in a setting of oligopoly. The Medicare Payment Advisory Commission (MedPAC) has repeatedly reported that SDOs have higher costs of treatments and pay higher prices per unit of IV drugs. At its 12/10/09 meeting the MedPAC presenter noted that the Medicare margin for ESRD composite rate services and dialysis drugs is projected to decrease in 2010 by 0.7 %, from 3.1% to 2.4%. Since MedPAC has reported that the spread in Medicare margin for LDOs compared to all other providers (SDOs) is about 6%, one might postulate that SDOs are now incurring even further losses from Medicare, maybe over 3% per treatment. This situation of SDO loss on Medicare treatments is not sustainable in the long run; Medicare volume represents at least 75% of most providers' patients. Without CMS action, the nation faces even further consolidation of facilities into LDOs and loss of beneficiary choice and access to care, including home therapy.

The Avelere Company has documented the differences in cost of care between LDOs and SDOs (see NRAA bundling comment letter and attachment.) There is ample justification for a low volume adjustment for SDOs in light of documented higher cost and Congressional support for small American businesses. Under our proposal, all US facilities would receive this adjustment except for the two LDOs who have enormous advantage in buying power for IV drugs, oral drugs and laboratories and can together spread overhead costs over 70% of the nation's Medicare treatments.

TRANSITION DECISION/ESA MONITORING POLICY

CMS assumes that providers will decide whether to elect for their facilities to be paid fully under the bundle in 2011 or transition to this payment system. The proposed rule assesses that the administrative burden to make this decision is estimated to take one hour. We have already spent hundreds of hours trying to understand the complex bundle's impact on our fourteen facilities.

15. We propose that CMS release the final rule with time for SDOs to make a well informed decision re transition. We urge CMS to allow SDOs the time to consider the final rule and make a well informed decision re transition plans. We owe this to our patients. We understand that CMS has received comments asking for an Interim Final Rule. If this approach is adopted, we urge that the rule is released soon, to allow adequate assessment time for the transition decision.

16. We proposed that the ESA monitoring policy be discontinued in 2011. There is no incentive to overuse ESAs. This policy will be hard to implement during transition and it should be discontinued.

QUALITY MEASURES AND QIP PROGRAM

The rule proposes equally weighting two anemia management measures and one hemodialysis adequacy measure for calculating total QIP performance score. The rule acknowledges that home hemodialysis and peritoneal dialysis adequacy is not measured by the URR >65% and asks whether and how adequacy could be measured for home patients.

17. We endorse the use of the three quality measures proposed by the rule: hemoglobin <10 (negative measure), hemoglobin >12 (negative measure) and URR >65% (positive measure.) These quality measures address important clinical areas, are few in number, well defined by KECC, and collected and reported today on DFR reports. We are delighted that these measures are not collected via CROWNWeb, a program that requires SDOs to employ the single user interface to enter numeric data each month via keyboard for each patient. This is a laborious, time intensive and costly process which has been revealed in Phase 1 (which we participated in) and Phase 2 to have many problems.

18. We propose that hemoglobin measures together receive 50% weighting and URR measure receive 50% weighting. There are two categories of measures- anemia management and adequacy. Each should receive equal weight. The proposed rule weights anemia measures 66% which is disproportionate.

19. We propose that hemoglobin < 10 receive 75% of weighting within its category and hemoglobin > 12 receive 25% weighting within its category. The scientific evidence is clear; there is patient harm associated with low hemoglobin levels. The data are less clear for high hemoglobin levels. Under bundling, there is no incentive to overuse ESAs. We propose that within the anemia category, more weight be placed on addressing low hemoglobin.

20. We propose that home hemodialysis patient results for urea reduction ratios (URR) be excluded from a facility's results under QIP. URR does not take into account hemodialysis patients dialyzing more frequently than three times per week for which the reduction in urea is less for each treatment. The vast majority of home hemodialysis patients are on more frequent treatments than 3 times a week. Thus, as policy, all home hemodialysis patients should be excluded from the adequacy QIP measure. Currently this represents less than 1% of dialysis patients but for certain facilities that have regionalized home dialysis patient care, the proportion of home hemodialysis patients for the facility may be high. Thus inaccurate URR results due to home hemodialysis patients may determine QIP penalties for the entire facility's treatments for a year. If CMS does not censor out home hemodialysis patients' URR for QIP, facilities may decide the financial penalty associated with home patients dragging down QIP URR results are too severe, and home hemodialysis programs may be forced to close.

Weekly Kt/V is a more accurate measure of the adequacy of dialysis as it takes residual renal function and frequency of dialysis into account. A standardized measure of Kt/V should be included in the QIP when CMS has an accurate and efficient means to collect this data from all facilities (i.e. CROWNWeb batch submission), there is consensus on the proper formula used to calculate Kt/V, and submitted data is validated for accuracy.

21. We propose that peritoneal dialysis adequacy results be excluded from QIP. Once KECC collects and reports a peritoneal dialysis adequacy measure on the DFR, then this measure should be included in QIP. For the same reasons noted above, the financial penalties in QIP associated with inaccurate and thus poor adequacy results may be so severe that facilities close home PD programs.

22. We propose that CMS require additional quality indicators to be affixed to the claim form, to monitor the effect of the bundle on patient care and to allow time to implement batch submission of quality data via CROWNWeb. CMS has received many comments about the importance of monitoring quality during the transition to the bundle, and beyond. Ultimately MIPPA requires quality monitoring in multiple arenas. We do not recommend affixing hospitalization data to the claim form. Hospitalizations may be required for good quality care. It will be impossible to collect hospital admission information in the time required for claim submission early in the following month.

Instead, we propose these measures could be required to be submitted on the monthly claim:

- Access type in use on the last outpatient treatment- AVF, AVG, catheter
- Albumin level at last draw of the month – numeric
- Phosphorous (PO4=)- numeric

With the addition of these measures, CMS will be collecting adequacy, anemia, nutrition, access and bone measures, which covers a wide spectrum of quality. Oversight of patient safety will be enhanced.

CONCLUSION

We appreciate the opportunity to comment on the proposed bundle rules and look forward to working with CMS to ensure a safe transition to bundling for our patients. I welcome your contact to discuss any aspects of this letter.

Sincerely,

A handwritten signature in black ink that reads "Joyce F. Jackson". The signature is written in a cursive style with a large, flowing "J" and "A".

Joyce F. Jackson
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cc: NKC Board of Trustees; NKC nephrologists, staff and patients; Washington State Congressional delegation