



**DIALYSIS CLINIC, INC.**  
A Non-Profit Corporation

H. Keith Johnson, M.D., Chairman of the Board  
James Perry, President  
Ed Attrill, Secretary and Treasurer

1633 Church Street Suite 500  
Nashville, TN 37203  
Phone: (615) 327-3061  
Fax: (615) 329-2513

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Centers for Medicare & 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

Ladies and Gentlemen:

Thank you for allowing Dialysis Clinic, Inc. (DCI) to comment on the End Stage Renal Disease Prospective Payment System (PPS) Proposed Rule released on September 15, 2009. DCI is a nonprofit dialysis provider treating approximately 13,000 patients in the 209 dialysis facilities that it owns and operates in 26 states. Eighty-seven percent of these patients are insured by Medicare, Medicaid, HMO Medicare or the Department of Veteran Affairs. Although DCI is the third largest provider of outpatient dialysis in the country, we by no means possess the characteristics of the Large Dialysis Organizations (LDOs). We believe that it is more appropriate to describe DCI as a medium size dialysis organization.

A primary goal of the PPS is to promote operational efficiencies. This is certainly a worthy objective, but because the current proposal relies on several serious miscalculations and inaccurate assumptions, it inadvertently threatens our most important common objective: high quality patient care. DCI has provided excellent care efficiently for many years. For several years, the United States Renal Data System (USRDS) has found DCI to have the lowest patient mortality, lowest hospitalization rates and the lowest utilization of drugs and laboratory services among the national dialysis providers. The 2009 USRDS Annual Data Report (ADR) also ranks DCI as the national provider with the lowest monthly cost to CMS, at \$1,366 per patient per month, compared to a national average of \$1,425 per patient per month. Inspection of the USRDS data shows that DCI's low costs reflect the most conservative laboratory testing and drug administration practices in the field.

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DCI also does an excellent job of anemia management. According to the 2009 USRDS ADR, DCI had the highest proportion of patients in the target hemoglobin range of 10-12 g/dl, consistent with FDA labeling for erythropoietin, with an average ESA cost per patient per month \$38 below the national average. Although one might expect that such an organization would fare well under a bundled reimbursement system, the PPS as presently drafted would have dire financial consequences for DCI, and would jeopardize the quality of our patients' care.

In the following pages we show how we analyzed the impact of the proposed regulations using up-to-date DCI patient data. We show how several aspects of the proposed rule will threaten the financial viability of many dialysis facilities, and put at risk our ability to maintain the current quality of our services to ESRD patients. We also discuss alternative approaches that would minimize the unintended consequences of the PPS.

Our conclusions are drawn from an extensive analysis of patient records from DCI's medical information system. This system was developed beginning in 1982 as part of DCI's non-profit mission to foster research and to improve the quality of care for ESRD patients. It has been continually enhanced over the years to become an extensive database of patient care statistics including demographics, co-morbidities, extensive clinical data, pharmaceutical, laboratory and cost information. This system is well-suited to analyze the potential impact of the PPS, and DCI data have proven to be of high quality in activities such as the batch submission process for Crown Web, Fistula First and E-lab.

The purpose of this synopsis of DCI's achievements, capabilities and practices is twofold. First, we want to remind you that under the existing reimbursement system, DCI has provided care that is both clinically excellent and socially responsible; we have successfully limited our cost to the taxpayer. Second, our analysis is based not on conjecture, but on complete and reliable patient data. Careful examination of these data leads us to the conclusion that the PPS as presently drafted will distract dialysis providers' attention from improving patient outcomes to containing cost. Some providers will shift their focus in order to survive, others to maximize financial return. Whatever the motivation, the consequences will not be good for patients.

Our data analysis included about 10,000 Medicare patients. We extracted DCI facilities from the CY2011 Proposed ESRD PPS Facility Level Impact File provided on the CMS website, and compared the projections to actual calendar year 2007 data for our patients. In a second analysis, we used our 2009 patient data to understand how the PPS would affect DCI today.

**I. Other Drugs and Biologicals and their Oral Equivalents**

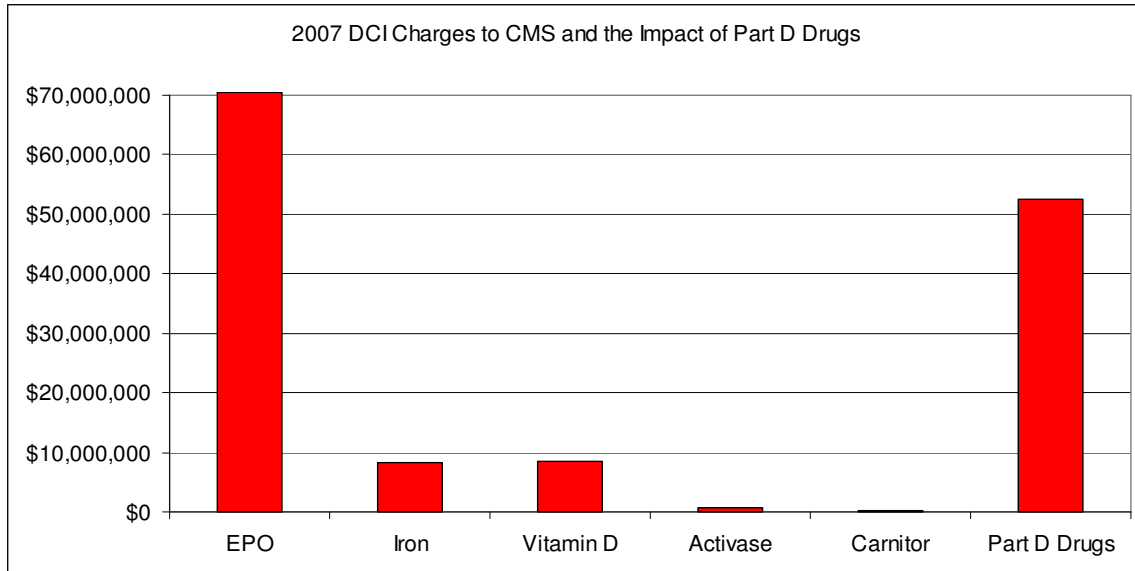
The proposed adjustment of \$14 per treatment will not cover the true cost of medications. We used the following methodology to evaluate the inclusion of drugs currently covered by Medicare Part D (henceforth, “Part D drugs”) and biologicals in the ESRD PPS. To estimate the total cost of Part D drugs, we reviewed complete medication prescription data for 2007. DCI’s electronic medical information system maintains a history of all medications prescribed to each DCI patient. To check for allergies and drug-to-drug interactions, medication data entry is structured using a national pharmacy database, which is updated quarterly, and medications must be entered in accordance with pharmacy standards. This system allows our physicians to write prescriptions from the medical information system and generates complete patient medication lists on care plans, physician encounter forms and transfer summaries when patients are hospitalized or receive other outpatient care. Each month, patients bring in their medication bottles and our nurses verify, reconcile, and record the patient’s medications to update the electronic medical record

Using this database, we identified all medications used in 2007 by DCI Medicare patients that are listed in Table 6 “List of National Drug Codes Used to Identify Former Part D Drugs for the ESRD PPS” of the Proposed Rule. We are unable to confirm the CMS finding that \$14 per treatment is an appropriate adjustment to account for ESRD related Part D drugs in the proposed bundled rate. ATTACHMENT 1 shows that DCI patients received the equivalent of \$36.77 per treatment of the drugs that CMS has proposed to include in the bundle, not \$14.00.

We performed a second analysis using annualized 2009 data to define changes in practice patterns and costs. ATTACHMENT 2 shows that current ESRD related Part D drugs are even costlier, at \$38.17 per treatment. ATTACHMENT 2 also shows the change multiple in drug utilization from 2007 to 2009. This clearly illustrates that a new drug, Renvela (sevelamer carbonate), is now highly utilized, but was not accounted for in the CMS analysis of 2007 data. Renvela replaces Renagel (sevelamer hydrochloride), which will no longer be manufactured. Other drugs such as Sensipar (cinacalcet) are also being prescribed more widely in 2009; the 2007 data used by CMS significantly underestimates their true cost in current practice.

The following chart compares DCI’s 2007 charges to CMS for erythropoietin, intravenous iron, intravenous vitamin D, tissue plasminogen activator (Activase) and carnitine (Carnitor) to the cost of oral Part D drugs used by DCI patients in 2007, the last calculated on the basis of entries in the DCI medical information system. Part D medications represent a significant cost, second only to that of erythropoietin.

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If CMS holds to the original estimate that \$14 per treatment represents an adequate adjustment to the composite rate for inclusion of Part D drugs, biologicals and their oral equivalents, dialysis facilities will be forced to take draconian measures, both to contain the expense of these essential medications, and to restrict other aspects of care. In real dollars for DCI, the CMS proposal will result in a shortfall of \$32,369,000 based on 2007 utilization of ESRD related Part D drugs, and \$34,210,000 based on 2009 utilization. We cannot sustain losses of this magnitude.

If DCI patients are representative of the dialysis population of the United States, our estimate would mean that the authors of the PPS have underestimated the cost of the Part D drugs for which dialysis facilities would become responsible by \$887,163,000 per year. Although we understand the importance of fiscal discipline, it would be a serious mistake to implement such a drastically underfunded system, and would materially change patient care for the worse. The text of the PPS proposal express the concern that if oral drugs and biologicals for which there is no injectable equivalent are excluded from the bundle, it “would defeat one of the very purposes of the new system” and “would result in the gradual growth of excluded services from the ESRD PPS payment bundle, and the progressive erosion of the payment system, as new oral-only drugs and biologicals for the treatment of ESRD emerge”. Although we recognize the dilemma, the solution proposed is beset with detrimental unintended consequences for patients.

The proposed rule will drive a wedge between patients and physicians because dialysis providers will be forced to maintain narrow formularies which will limit the discussion of choices and of the risks and benefits of treatment alternatives. Physicians will face the choice of failing to inform patients of treatment options, incurring potential liability as well as failing to fulfill their responsibility to their patients, or of telling patients that they lack access to new drugs because of rationing decisions made by the dialysis provider, or perhaps attributing the rationing decision to CMS. Patients will lose access to new and better oral drugs because the proposed rule will discourage manufacturers from bringing new oral-only drugs to market. It is well documented that

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new and second generation drugs arrive on the market at a higher cost. The pharmaceutical industry certainly will not invest research and development monies in ESRD-specific products unless they can be assured of a reasonable financial return. The proposed rule will thus introduce a new disparity in care, one reflecting the reason for Medicare entitlement. Medicare ESRD patients will not have access to new oral medications available to individuals whose Medicare entitlement is based on age or disability. Under Medicare Part D, dialysis providers presently have no financial incentive or disincentive to encourage patients to use oral drugs and biologicals for which there is no injectable equivalent. Physicians currently make these decisions in the patient's best interest. However, the proposed rule will limit patient access to oral drugs and will create a significant potential for underutilization.

Dialysis providers' administrative costs for managing and dispensing oral medications will be significant, but the proposed rule provides no reimbursement to them for assuming this responsibility. The cost of administration and oversight for dispensing oral medications for which there is no injectable equivalent must be considered if dialysis providers are to assume this added responsibility. However, one wonders whether it is wise to duplicate a functioning system that is already in place under Medicare Part D. We are concerned that superimposing a second system for the provision of oral medications will actually increase inefficiencies and ultimately be more costly to CMS.

Section 1881(b)(14)(B)(iii) of the MIPPA specifies that other drugs and biologicals that were furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, prior to the implementation of the ESRD PPS, and their oral equivalent forms, must be included in the ESRD PPS payment bundle. We acknowledge that CMS is not able to remove all oral drugs from the bundle. As an alternative, we propose that CMS limit the scope of the drugs and biologicals included in the bundle to only oral versions of injectables. The following table shows that oral drugs with injectable equivalents are primarily prescribed to patients undergoing peritoneal dialysis (PD) or hemodialysis (hemo) at home. Dialysis providers could reasonably provide such medications.

### **DCI Oral Versions of Injectable Equivalents Cost by Modality – 2009 Data (Annualized)**

Modality	Treatments	Cost	Cost/treatment
Hemo in center	1,305,075	\$310,027	<b>\$0.24</b>
Hemo home	11,403	\$124,231	<b>\$10.89</b>
PD home	98,899	\$1,029,772	<b>\$10.41</b>

Furthermore, it is important to understand that the proposed inclusion of Part D drugs in the PPS gives dialysis patients an unfunded entitlement for medications. Currently, dialysis patients only receive Part D coverage for medications if they pay a premium for Part D drugs and a co-pay for each prescription. In addition, coverage stops once a patient reaches the "donut hole." Under the proposed rule, all dialysis patients will receive Part D medications related to ESRD regardless of whether they have paid a

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premium for Part D coverage and without the continued existence of the “donut hole.” It is our opinion that this expansion of benefits for dialysis patients is beyond the scope of the bundle and is an entitlement that the Congress has not authorized.

As we have now demonstrated, the proposed regulation significantly underestimates the cost of providing Part D drugs. If this unfunded entitlement is included in the payment bundle, dialysis providers will limit the use of these medications. Such rationing would interfere with the doctor-patient relationship, would compromise the quality of dialysis care, and would be a direct consequence of CMS policy if the PPS is implemented in its present form. To avoid these unintended consequences, we recommend that CMS limit the drugs included in the PPS to the oral equivalents of injectables.

### **II. Proposed Facility-Level Adjustments**

CMS has proposed a low volume adjustment to encourage small ESRD facilities to continue providing access to care in locations in which providing dialysis care would not be economically feasible. We agree that a low volume adjustment is desirable for an essential facility that treats few patients because it is the first and only facility in a remote and sparsely populated area. However, we encourage CMS to enact controls and measures sufficient to prevent potential misuse of the 20.2% proposed adjustment. It is imperative that this modifier not be available to a provider that desires simply to open a competing dialysis unit in a market in which an existing facility is sufficiently serving the patient population. The practice of developing competing facilities for financial gain is widespread, and only serves to increase the cost of care for those facilities primarily serving the Medicare population. We also believe that it is unreasonable to require a facility that is truly isolated and low volume to operate for 3 years before qualifying for the low volume adjustment. We request that CMS reduce the qualifying operating requirement to one year for those truly isolated, essential low volume dialysis units.

We believe that elimination of the wage index floor for rural dialysis facilities would be a mistake. Rural facilities possess characteristics that result in higher cost and lower revenue. They often struggle financially because fewer of their patients have private insurance, and because their operating costs are higher. It is common for rural facilities to incur premium staffing costs, even exceeding the costs of operating in urban markets. This is not conjecture: for example, in two rural Montana DCI facilities, staff must be recruited from nearby large cities, and travel costs and wage premiums are paid to encourage employees to endure the long commutes. For skilled patient care staff, we typically pay a higher wage than if the employee worked in the large city. The wage index floor should be maintained for all non-urban geographic locations. The proposed removal of this floor will aggravate disparities in care and will impair access to care at rural facilities.

### **III. Proposed Patient-Level Adjustments**

We were also unable to duplicate the CMS co-morbidity findings. In developing the bundled reimbursement criteria, it appears that CMS has overestimated patient co-morbidities and consequently, overestimated reimbursement available to our dialysis facilities. The CMS data shows that the average dialysis facility across the country had a patient adjustor of 1.2870. Breaking out the 200 DCI facilities from the CY 2011 Proposed ESRD PPS Facility Level Impact File, we calculate that CMS has projected that these DCI dialysis facilities have an average patient adjustor of 1.3193. We have analyzed the patient level adjustment factors for all 10,000 DCI Medicare patients using 2007 as the examination year. Our data indicates that the average patient adjustor for that period was 1.1745. DCI co-morbidity data were obtained from the problem list in the DCI electronic medical information system and from claims data. DCI's electronic medical information system is problem-based. Problems are created from patient histories, 2728 forms, hospital discharge summaries, and physician correspondence. Problem descriptions come from the ICD-9-CM manual. All orders (medication, treatment, lab, procedures, and consultation) must have an assigned problem in order to enter them into the medical information system. This assigned problem is the reason for giving the order. For example, to create an ESA order, in addition to adding the dose, route, etc., the clinician adds the ICD-9 justification from the problem list or creates a new problem if necessary. DCI data have always been of high quality in activities such as the batch submitting process for CrownWeb, Fistula First and E-lab, therefore we believe that the information contained in our medical information system is accurate.

To further test the validity of DCI's patient level adjustment calculation, we modeled just how much sicker our Medicare patients would have to be to reach the value of 1.3193 that CMS imputes to DCI. We first determined the "demographic" adjusters applicable to DCI patients. These are conditions that are easily captured or calculated by the clinic without dependence on outside entities, such as age, sex, BSA, low BMI and onset of renal dialysis. There should be little variance between DCI data and CMS data for these conditions. We calculated this "demographic" adjuster to be 1.1581 for DCI patients. Therefore, for DCI patients to reach the CMS predicted total patient level adjustment of 1.3193, the remainder of the proposed adjusters would need to carry a total weight of  $1.3193/1.1581 = 1.1392$ . The following table shows what proportion of treatments DCI performed in 2007 on patients having the various payment multipliers, and what proportion of treatments would have been required under one simulated scenario to allow DCI to achieve the total patient level adjustment that CMS has predicted. The simulated distribution of treatments across co-morbidities is only one of an infinite number of possible combinations.

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### Actual & Simulated Treatments to Achieve Co-morbidity Score Imputed to DCI by CMS

Co morbidity	PM	Actual % of Treatments with Comorbidity	% of Treatments with Comorbidities Needed to Reach Total Comorbidity PM = 1.1392	PM Weight
Anemia (hereditary hemolytic/sickle cell)	1.226	0.10%	1.0%	0.0123
Cancer	1.128	4.40%	10.0%	0.1128
Cardiac arrest	1.032	1.43%	6.0%	0.0619
Drug and alcohol	1.150	0.96%	5.0%	0.0575
GI bleeding	1.316	0.17%	3.0%	0.0395
Hepatitis B	1.089	0.43%	4.0%	0.0436
HIV	1.316	1.44%	7.0%	0.0921
Monoclonal gammopathy	1.021	0.16%	1.1%	0.0112
Myelodysplastic syndrome	1.084	0.01%	1.0%	0.0108
Other infections	1.307	0.05%	5.0%	0.0654
Pericarditis	1.195	0.09%	5.0%	0.0598
Septicemia	1.234	2.50%	22.8%	0.2814
None of the above co-morbidities	1.000	88.26%	29.1%	0.2910
Total Payment Multiplier				1.1392

To reach the patient level adjustment factor that CMS projected for DCI, our patient population would need to possess the following characteristics:

- 22.8% of our patients would be septic (currently 2.5%) *and*
- 10.0% of our patients would have cancer (currently 4.4%) *and*
- 7.0% of patients would have HIV/AIDS (currently 1.44%) *and*
- there would be simultaneous significant increases in several other co-morbidities

The patient disease mix required to reach 1.3193 is not realistic. We believe CMS has overestimated co-morbidity patient modifiers and consequently has overestimated reimbursement under the proposed bundled reimbursement system. The financial consequence of this variance is not insignificant: DCI would be reimbursed \$15,679,000 per year less than the CMS estimate. This unintended consequence is not budget-neutral, but budget-negative. As it currently stands, the proposed PPS only predicts 46% of the variance for the case mix adjustors. Clearly, the detrimental effect of even a small difference between the CMS case mix estimates and a provider's actual case mix is of such magnitude that it would place a dialysis organization's viability in jeopardy.

Assuming that DCI data is consistent with the rest of the US dialysis population, we estimate that the current methodology for payment will underfund dialysis care by \$392,956,000 each year. We also repeated this calculation for 2009 to observe changes and determine the impact with more current data. The DCI 2009 average patient adjustor was 1.1802; a slight increase from the 2007 value, although still significantly below the estimate used by CMS to develop the proposed ESRD PPS rules.

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We believe that the CMS approach to determine co-morbidity and outlier payment adjustment is too complex, and that a different approach is warranted. Only a tiny minority of patients and family members will be able to follow the calculations determining the Medicare allowable rate, and thus determining their responsibility for the 20% not reimbursed by CMS. The PPS will thus lack face validity to the citizens whom it is designed to serve. The proposed rule adds unnecessary complexity, and will increase administrative cost as facilities hire additional billing staff. Further, the complexity could lead to billing errors. Currently, most providers accurately code all chronic ESRD problems related to routine dialysis care, and they rely on the hospital's certified coding staff to accurately code patient problems in discharge summaries to capture new and often acute and short-lived patient co-morbidities such as gastrointestinal bleeding. Under the proposed rule, the dialysis claim will need to capture all new co-morbidities in the month that they occur. Incomplete co-morbidity data will delay claims processing and result in lost reimbursement. If dialysis facilities are unable to obtain timely hospital discharge summaries (which is a frequent occurrence) to code problems beyond routine dialysis care, they will need to hire additional certified coding experts. Contrary to the primary goal of bundling, this system will be inefficient and expensive. Ultimately the increased cost for providers will be passed on to CMS, effectively increasing the amount needed to be paid for dialysis services. This represents another unintended consequence of an overly complex system.

We propose the following simplified approach to case-mix adjustment. CMS should adjust payment on the basis of patient characteristics and conditions that are chronic and thus easily captured or calculated by the clinic without dependence on outside entities, and on the basis of certain diagnosis codes. The patient characteristics would include age, sex, BSA, low BMI, and renal dialysis onset.

We believe a higher base rate with fewer adjustors will be more beneficial rather than adjustors that do not appear to have significant impact on the activities needed to dialyze patients. Should CMS deem it necessary to include adjustors other than the patient characteristics mentioned above, we propose that they be limited to the following diagnosis codes with the caveat that an appropriate recalculation of their weighted value must be made.

- Cancers
- Hepatitis B
- Hereditary Hemolytic Anemias/Sickle Cell Anemias
- Monoclonal Gammopathy
- Myelodysplastic Syndrome

**These conditions can be characterized as chronic, they can be associated with higher treatment cost, and they can be more easily and reliably captured.** We recognize that Drug and Alcohol Induced Mental Disorders and HIV/AIDS are also chronic conditions; however, these conditions are often under-coded on claims. Payment adjustment on the basis of Drug and Alcohol Induced Mental Disorders could present an opportunity to over-code anyone who had ever used non-prescription drugs or alcohol.

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Even if coding is accurate, these codes stigmatize patients. The Proposed Rule acknowledges that the diagnosis of HIV/AIDS is problematic because there are states in which this information is afforded special protection. We do not think that the public interest in modifying payment in this way is so great that it justifies CMS in establishing a regulation which is inconsistent with laws established by states to protect patient privacy. It would be inappropriate to require dialysis facilities either to violate state law, to forgo full reimbursement for treatment of potentially very ill patients, thus disadvantaging all patients in that state, or to lobby or litigate, perhaps unsuccessfully, to resolve the inconsistency. We are also concerned that clinics in states where it is allowed, may be forced to require HIV testing of all patients, not for patient care reasons, but to maximize their financial return.

We believe that a change should be made to the modifiers for BMI and BSA to avoid an unintended consequence of decreased reimbursement for malnourished patients. When a patient meets the BMI threshold, the BSA adjustor should be assigned a value of one (1.0). In the current basic case-mix system, the effective product of the two adjustors inappropriately creates a lower adjustor for patients with low BMI. CMS actually shows this in Example 5 of the proposed rule — “Aged ESRD patient with low BMI (< 18.5kg/m<sup>2</sup>) and history of hospitalization.” In this example, the PMs would reflect the applicable case-mix adjustments age, gender, BSA, low BMI, and cardiac arrest; expressed as:  $\text{PmtMult}_{age} * \text{PmtMult}_{gender} * \text{PmtMult}_{BSA} * \text{PmtMult}_{BMI} * \text{PmtMult}_{CardArrest}$ .  $Or = 1.076 * 1.132 * .8662 * 1.020 * 1.032 = 1.1106$ . The product of 0.8662 ( $\text{PmtMult}_{BSA}$ ) \* 1.020( $\text{PmtMult}_{BMI}$ ) is equal to 0.8835. This patient’s BSA negated the effect of the low BMI.

We recommend removing all proposed patient modifiers except for those noted above. The other modifiers will be very difficult for dialysis providers to capture in a timely manner. As a result, clinics would receive less reimbursement than intended by CMS. Providers would also be required to hire additional staff just to identify these modifiers. The inclusion of modifiers that are difficult to determine would change the focus from quality of care to cost of care, and will increase expenses for dialysis providers and work to the detriment of the ESRD patient.

### IV. Outliers

We understand that Section 1881(b)(14)(D)(ii) of the Act provides that the ESRD PPS must include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis-stimulating agents necessary for anemia management. Consequently, CMS is required to include a mechanism to address outliers. We agree with the allocation of 1% of annual costs to pay for outliers. However, we request that 1% be withheld *after* CMS has deducted 2% from the amount paid for dialysis for budget neutrality.

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We also believe that the current methodology in the proposed bundle is not an effective technique to reimburse providers for high cost outliers. The methodology will increase the expense of dialysis billing because providers will be required to submit itemized summaries of formerly separately billable expenses, and must analyze whether each treatment meets the criteria for outlier payment. We are concerned that smaller providers may not have the resources to be able to evaluate these costly patients. As a result, smaller providers would, in effect, lose 1% of the total Medicare reimbursement since this amount has been reserved for outlier payment. Ironically, the outlier system, which was created primarily to help small providers, could financially harm small providers. As the proposed PPS is currently written, the separately billable prediction equation only predicts 8.7% of the variance. This is extremely important in terms of the financial viability of dialysis providers. It would be a better solution to pay providers what they actually spend on high cost outliers.

We propose a simpler system which can be more efficiently administered, ultimately at lower cost to Medicare. Instead of analyzing each individual patient to determine whether that patient has additional expenses, we propose that CMS make a fixed payment for patients with certain outlier characteristics. We propose that these characteristics be (1) undergoing home training or self-care training, (2) undergoing treatment for infections or symptoms of infection, and (3) recent gastrointestinal bleeding. All patients having these characteristics have additional expenses that are not directly related to co-morbidities.

### A. Home Training

In recognition that additional expenses occur with home training, we recommend that CMS pay a fixed payment for each treatment in a month during which a patient receives home training. By removing the current reimbursement for home training, the proposed PPS redistributes training reimbursement to facilities that do not provide training. In effect, the proposed rule rewards facilities for not providing training, thus providing an incentive not to promote home dialysis. Only a minority of dialysis clinics provide home training. Currently only approximately 15% of facilities provide home hemodialysis training and fewer than 50% of clinics provide peritoneal dialysis training.

The proposed rule contains the following statement:

*“After reviewing the separately billable payment amounts for patients ranging from one month to twelve months since the onset of dialysis, we found that there was a drop in the amount of separately billable payments after four months on dialysis. These higher costs for new patients may be due to stabilization of the patient’s condition; administrative and labor cost associated with the patient being new to dialysis either in-center or home setting; or initial costs incurred to train patients and their caregivers to perform home dialysis.”*

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DCI supports the inclusion of the renal dialysis onset adjustor. However, our experience does not support the argument that the renal dialysis onset adjustor will cover the cost of training, because most training does not occur within the first 4 months of the patient's ESRD onset date. Fewer than half of DCI training and re-training sessions billed to Medicare in 2007 were performed within the first 4 months of the patient's ESRD onset date. These findings are outlined in the following table.

DCI Training and Re-training sessions in 2007

Description	Total Training and Re-Training Sessions	Within 4 Months of ESRD Date	% within 4 Months
Hemo Home Training	282	39	13.8%
Hemo Home Re-Training	6	0	0.0%
CAPD Training	938	528	56.3%
CAPD Re-Training	100	28	28.0%
CCPD Training	424	275	64.9%
CCPD Re-Training	221	52	23.5%
Total	1,971	922	46.8%

To resolve this issue, we recommend that CMS pay a fixed payment for each treatment in a month during which a patient receives home training dialysis.

### B. Treatment for infection and for symptoms of infection

We recommend that Medicare provide an additional payment for each patient month in which the patient was treated for infection or for symptoms consistent with infection. By making this payment, Medicare would be recognizing that treating infections or symptoms of infection are not routine dialysis care. The costs associated with infections include additional laboratory work, greater use of supplies, more antibiotics and higher ESA needs. Most of these expenses exist regardless of whether it is ultimately confirmed that the patient had an infection.

We propose that this payment be made for any patient with infection symptoms characterized by ICD-9 codes 780.60, 780.64, 780.99, 789.07 and 792.5 for hemodialysis patients, and ICD-9 codes in the range of 567.0 to 567.89 for peritoneal dialysis patients. In addition, we recommend that CMS evaluate the impact of vancomycin resistant infections and consider increased outlier payment for patients with these infections.

### C. Gastrointestinal Bleeding

We recommend that a fixed outlier payment be made for any patient with gastrointestinal bleeding. Due to increased ESA expense and the possible expense for transfusions, patients with gastrointestinal tract bleeding would clearly meet the legislative intent for an outlier payment since they represent "high cost outliers due to

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unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis-stimulating agents necessary for anemia management”.

We also propose that CMS return any unanticipated decrease in reimbursement to providers on a *pro rata* basis at the end of each year. The goal of the bundle is to provide efficient treatment and to be budget neutral, not budget negative. CMS proposes many adjustments to ensure that dialysis care will not be more costly than under the current methodology for reimbursement, and we share their concern regarding the increasing cost of healthcare. However, we are also concerned about the effect on patient care if, as an unintended consequence, the proposed bundle methodology actually decreases payment for dialysis care below the anticipated funding level. We have documented examples of unintended decreases in reimbursement which can be anticipated under the rule as currently proposed. We have also explained our concern that, under the current methodology, clinics may not receive adequate payment for outlier expenses. If our actual reimbursement is decreased by the anticipated amount, we will be forced to change our patient care. We anticipate that these changes will damage patients’ relationships to the doctors, nurses, social workers, dieticians and other staff who take care of them, and that they will limit our ability to continue to provide excellent patient care. To protect its beneficiaries against this eventuality, and to ensure truly beneficiary-centered care, CMS should develop a process to return any unanticipated funding shortfalls to dialysis providers.

### **V. Diagnostic Laboratory Tests and Other Items and Services**

Section 1881(b)(14)(B)(iv) of MIPPA requires that diagnostic laboratory tests and other items are to be furnished to individuals for the treatment of end stage renal disease. We agree with the concept of bundling certain ESRD lab tests, however, CMS has proposed an interpretation of the language “for the treatment of end stage renal disease” to include all separately billable labs ordered by a physician who receives monthly capitation payments (MCP) for treating ESRD patients.

At a time when coordination of care is a national priority, the PPS as proposed will disrupt the coordination of dialysis patient care by nephrologists. Many nephrologists also serve as dialysis patients’ primary care physicians. Tests they order as part of primary care will become the financial responsibility of the dialysis facility, broadening the bundle of services beyond what was contemplated. The harder nephrologists try to coordinate their patients’ care, the more conflict they will encounter with dialysis facilities. Nephrologists may stop providing primary care, or may send their patients to physicians who do not bill Medicare for dialysis treatments solely for the purpose of ordering diagnostic laboratory tests. Those physicians, in turn, will be obligated to examine the patient, and bill Medicare, thus increasing the overall cost of care while inconveniencing patients and delaying and disrupting care.

Because it promotes phlebotomy outside the dialysis facility, the PPS as proposed is also inimical to the goals of the Fistula First Breaththrough Initiative. The internists,

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family practitioners and subspecialists outside nephrology to whom patients will be referred, so as to save the dialysis facility the cost of testing, will generally have the blood samples drawn in their own offices or by a hospital or free-standing laboratory. The staff of these offices and laboratories are rarely qualified to draw blood from a hemodialysis fistula or graft. They may damage the access, and if they puncture a vein in the contralateral arm, they may damage veins that could be used for future hemodialysis vascular access. Minimizing venipuncture outside the dialysis facility is one of the cornerstones of vein preservation. The additional discomfort and inconvenience to the patient also conflicts with the express intention of the PPS to promote patient-centered care.

We are also concerned about the coordination of diagnostic laboratory tests required for kidney transplant listing and maintenance of the patient's status on the transplant list. If the cost of these tests is added to expenses for dialysis clinics, these clinics would have a financial disincentive to refer patients for kidney transplant evaluations and to maintain their active status on the list. The proposed regulation would also effectively require nephrologists who evaluate patients for transplantation to stop taking care of chronic dialysis patients, since facilities could not afford to pay for tests ordered as part of transplant evaluations. Alternatively, pre-transplant evaluation would become exclusively the province of transplant surgeons. These possibilities will either degrade patient care or limit patient choice.

The proposed rule will give dialysis facilities an incentive not to support their hemodialysis patients' efforts to travel. Dialysis providers often require proposed transient patients to submit Hepatitis B Surface Antigen and Surface Antibody results which are more recent than required by CDC guidelines, and may require testing for Hepatitis C and HIV antibody. Under current practice, the patient is generally responsible for the cost of this testing; the proposed rule will shift the cost to the home dialysis facility, representing another unfunded entitlement to dialysis patients. Assisting patients in identifying facilities for transient treatments is a time-consuming activity for dialysis social workers, entailing not only internet searches and telephone negotiations, but faxing of patient information; without the active support of the home facility social worker, many patients will not be able to make the arrangements. Either they will not travel, or they will skip treatments increasing the likelihood of medical complications and hospitalizations. Patient travel already represents an administrative burden and economic loss to the home unit; the proposed provision makes it even less attractive. Furthermore, less educated patients who require the most help in arranging transient dialysis will be disproportionately affected, thus exacerbating disparities in care.

Nine dollars per treatment is inadequate reimbursement for all diagnostic tests that may be ordered for an individual who happens to have ESRD. If the nephrologist is also serving as the patient's primary care physician, she or he might order many additional tests that are not specifically related to the ESRD condition. The proposed rule will limit access to new laboratory tests because dialysis providers will be reluctant or unable to assume the cost of newly developed diagnostic tools. The physician will face

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choices whether or not to ration the patient's care and whether or not to tell the patient that care is being rationed.

The incorporation into the proposed bundle of all currently separately billable labs ordered by a physician who receives monthly capitation payments for treating ESRD patients will cause patients' co-payments to rise. People with ESRD will become the only class of patient in the Medicare system required to make co-payments for diagnostic laboratory tests.

We recommend that CMS use the list of ESRD specific diagnostic laboratory tests that are identified in the Conditions for Coverage to establish coverage under the bundled payment (ATTACHMENT 3). It is reasonable to include such tests in the bundled rate; however, laboratory tests performed for the purpose of patient travel should be separately billable. We also believe that it is important that bacteriology laboratory tests not be included in the bundled rate. The identification and treatment of infection is not routine care.

CMS should not use the identity of the physician ordering tests as the basis for determining which laboratory tests are included in the bundle. Instead, we recommend that the claims processing system be utilized to identify ESRD patients. This should be easily accomplished by asking the facility to include the 585.6 ICD-9 code on the claim and using the claims processing system to verify ESRD status within the common working file. The Medicare Administrative Contractor (MAC) would make a determination of tests drawn in the dialysis facility that are included in the bundled rate and those that are excluded. This is very similar to how CMS is already applying Automated Multi-Channel Chemistry (AMCC) tests for ESRD beneficiaries (Section 30.2.2 in the CMS Beneficiary Manual). Tests outside of the defined ESRD bundle list would be paid separately if they meet the normal frequency and reasonableness requirements.

Finally, we point out that by including \$9 per treatment in the bundled rate, CMS is not maintaining budget neutrality. Currently there are no co-pays for laboratory services. If CMS proposes to include \$9 per treatment in the bundle, when the patient's 20% co-pay is considered, CMS will only be paying \$7.20 per treatment, and will have removed \$1.80 per treatment from the system.

### **VI. Pediatric Patient Adjustment**

Dialysis is even harder for children than for adults, and occasions yet greater anxiety and more dramatic psychosocial changes and trauma for them and their families. Children with kidney failure require more time and effort by specialized pediatric ancillary staff, and increased coordination with pediatric medical and surgical specialists, developmental specialists, psychologists and school personnel.

The unintended consequences of the PPS proposal for adult patients discussed earlier will be magnified for children. As noted above, the proposed bundled

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reimbursement is insufficient for dialysis providers to provide high cost pharmaceuticals to adults. The cost of oral drugs which must be compounded in liquid form for a child would be prohibitive. The consequences of including all laboratory tests ordered by dialysis nephrologists would be even worse for children than for adults. In adults, one minimizes venipuncture to be kind and to save veins for future vascular access. The proposed bundle in essence tells the parents of a child with kidney failure that although the blood could be taken painlessly from the vascular access at the hemodialysis treatment, or without additional discomfort at the time of a peritoneal dialysis monthly visit, they must take the child to a different office, and explain why he or she must endure yet another venipuncture. We reiterate our recommendation that CMS identify a list of tests related to ESRD that will not be separately reimbursable, and abandon the plan to bundle all tests ordered by nephrologists billing Medicare for outpatient dialysis.

As a pre-requisite for a payment adjustment, the proposed rule requires providers billing for pediatric dialysis to use two co-morbidity categories, different from adult co-morbidities, to classify patients into one of eight groups. This distinction is overly complicated, and undervalues the complexity and additional facility costs for dialyzing children, regardless of age. Children should not be subdivided by age. Furthermore, pediatric facility payments should not be adjusted for dialysis modality. At least forty percent of prevalent pediatric dialysis patients receive maintenance peritoneal dialysis, as compared to approximately two percent of adults. The incidence of peritoneal dialysis initiation is higher in pediatric patients. Peritoneal dialysis avoids the difficulties of obtaining hemodialysis vascular access in small children, permits less dietary restriction, and makes home dialysis and regular, uninterrupted school attendance practical. The proposed rule undervalues staffing support needed for home peritoneal dialysis and actually provides a payment disincentive to provide home peritoneal dialysis for children. This would be a terrible side-effect.

The conditions proposed to trigger an outlier payment do not have face validity in children. Diabetes and primary hypertension, which are the common causes of ESRD in adults, rarely cause ESRD in childhood. As for adults, the main causes of increased cost for children on dialysis are training and infections, and the infection burden is increased by virtue of the frequent requirement for hemodialysis catheters in children. Small vessels and childrens' difficulty accepting repeated large gauge needle sticks make fistulas and grafts more problematic than in adults.

The proposed rule will unreasonably disadvantage facilities taking care of children. CMS has calculated that 24% of pediatric outpatient dialysis treatments were provided in facilities that would qualify for a low-volume adjustment, and has cited this fact as one of the justifications for lowering the proposed pediatric payment adjuster. However, providing care for children is more costly regardless of whether the facility is low volume. We have calculated that a DCI facility that is 100% dedicated to pediatric patients (Austin, TX), and qualifies as low-volume, would sustain an average rate *decrease* of 12% under the proposed rule. Further, the pediatric reimbursement in DCI's larger facilities with a mixed pediatric/adult population would sustain an average rate decrease of approximately 44% under the proposed rule.

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### DCI Pediatric Facility Reimbursement : Annualized 2009 vs. Projected Bundled 2011

Clinic Location	# of Pt-Months	Average Total PM	Low Volume PM	Current Reimbursement 2009	Predicted Bundled Reimbursement 2011
TENNESSEE	8	1.13		\$17,899	\$14,470
NEW YORK	17	1.01		\$166,379	\$122,533
CALIFORNIA	3	1.06		\$62,257	\$17,928
SOUTH CAROLINA	1	1.35	Yes	\$2,599	\$1,530
NEW JERSEY	4	1.01		\$52,489	\$32,309
MASSACHUSETTS	8	0.96		\$77,982	\$61,472
ARIZONA	2	1.09		\$17,762	\$12,747
NEW YORK	8	1.06		\$90,117	\$61,784
TEXAS	30	1.23	Yes	\$277,634	\$247,617
CALIFORNIA	1	1.13		\$11,203	\$8,380
PENNSYLVANIA	14	0.97		\$126,957	\$101,669
TOTAL				\$903,278	\$682,439

Approximately 68% of pediatric patients treated by DCI do not receive treatment in a facility that would qualify for the low-volume adjustor, and even those facilities that do qualify as low-volume will lose revenue under the bundle proposal. The proposed bundled rate methodology for pediatric dialysis is unreasonable and will hurt children who need dialysis.

Pediatric dialysis patients represent fewer than 0.6% of chronic dialysis patients in 2007 (USRDS 2009 Annual Report). This complex dialysis population will not have any significant impact on budget neutrality. CMS should retain the current modifier for pediatric dialysis in facilities treating a mix of pediatric and adult patients, and should introduce payment methodology to provide increased reimbursement to dialysis facilities that are 100% dedicated to pediatric treatment.

## **VII. Quality Standards**

### **Anemia**

As noted earlier, USRDS data show that DCI has been more successful than other providers in meeting the target of maintaining hemoglobin values between 10 and 12 g/dl. We agree that it is a reasonable approach to evaluate quality by measuring separately the proportion of hemoglobin values below 10 g/dl and exceeding 12 g/dl. However, in formulating these standards, it is important to understand that the two

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measures must be linked, and that the distribution of hemoglobin values cannot be made arbitrarily narrow. The Elab project has found that in 2008, 5.9% of hemodialysis patients' hemoglobin values fell below 10, 56.8% were 10-12, and 37.3% exceeded 12 g/dl. We are not at all sure that the distribution can be made substantially narrower. We urge CMS to use caution in setting these standards, and to understand that although the measurable quality standards it sets are important, the attention staff pay to them is inevitably diverted from other aspects of the quality management. If the hemoglobin distribution required is too narrow, dialysis facility staff time will be consumed with ultimately futile attempts to control these values, at the expense of other important activities.

The width of the hemoglobin range, and the specific targets for proportions of values below 10 g/dl and above 12 g/dl, respectively, must be defined in terms of the data set to be used in evaluating facilities. The choice of values and the choice of data set are inextricable. *The differences in values among data sets are non-trivial, and the choice among data sets should not be deferred.* **Table 1** below, provided by the Forum of ESRD Networks, compares USRDS data, Dialysis Facility Report data, and Elab data. The Elab project is described at <http://www.esrdnet11.org/Elab/index.asp>

It is important to note that USRDS data are available only with a 2 year lag, and that Dialysis Facility Report data become available only once a year. Furthermore, Dialysis Facility Report data cannot, by definition, be predicted, because inclusion in that data set depends on a count of how many claims were submitted for the patient. It is essential to patient care that the standard used for evaluating and reimbursing facilities be one that facilities can use real-time to manage care. Facilities can anticipate the distribution of their hemoglobin values in the Elab data set. They cannot anticipate the distribution of hemoglobin values in the Dialysis Facility Report data set, because they cannot anticipate for which patients at least 4 claims will have been submitted.

Therefore, CMS should use data from the Elab project as the standard by which to measure hemoglobin values.

**Table 1**

	<b>USRDS</b>	<b>Dialysis Facility Report</b>	<b>Elab</b>
New patients	ESRD for 90 days	ESRD for 90 days and 4+ claims	All patients included
Payment source	Medicare only	Medicare only	All patients regardless of payment source
Hb values included	Average of 12 months	Average of 12 months	Average of 3 months (Oct, Nov, Dec)
ESA use	ESA treated patients	ESA treated patients	All patients regardless of ESA use
Hb selected	Last of the month	Last of the month	First of the month

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We believe that table 42 on page 404 of the proposed rule, “Model Scoring Methodology for Proposed Anemia Management Measures using National Performance Rates in 2007 as the Performance Standards”, is out of date, and should be revised. **Table 2** below, also provided by the Forum of ESRD Networks, shows 2007 hemoglobin distributions as reported in the 2009 USRDS Annual Report, Volume 2, Table 10.5 and in the 2008 CMS Dialysis Facility Report (DFR); 2006-2008 hemoglobin distributions as reported by the Elab project; and 2008 hemoglobin distributions as reported in the 2009 Dialysis Facility Report.

**Table 2**

<b>Chains 2007</b>	<b># in cohort</b>	<b>&lt;10</b>	<b>10-&lt;12</b>	<b>&gt; 12</b>
All	219,793	3.0	50.7	46.3
Fresenius	67,236	2.2	53.5	44.3
DaVita	71,338	2.2	41.7	56.1
DCI	10,132	2.5	69.3	28.2
Small dialysis organizations	14,983	3.0	57.3	39.7
Independent	38,359	4.9	58.0	37.1
Hospital-Based	16,533	6.1	57.9	36.0
Unknown	1,212	8.5	49.3	42.2
Dialysis Facility Report 2008 (2007 Data)		1.7	54.3	44.0
Dialysis Facility Report 2009 (2008 Data)		2.3	71.3	26.4
Elab 2006		4.6	43.3	52.1
Elab 2007		5.6	49.2	45.2
Elab 2008		5.9	56.8	37.3

According to CMS Table 42, payment will be withheld from facilities in which more than 2% of patients have hemoglobin values below 10 g/dl. Given the most recent Elab data, many dialysis facilities would receive decreased reimbursement under this proposed plan, as 5.9 % of patients nationally had a hemoglobin less than 10.

For reasons outlined above, we recommend that CMS restate the goals of Table 42 in terms of Elab data, recognize that the standards for hemoglobin below 10 and above 12 g/dl must be linked, and take into account empiric findings as to the width of the hemoglobin distribution that can be achieved using current technology. DCI’s own experience in this regard is reported by [Miskulin \*et al.\*, Am J Kidney Dis. 2009 Dec;54\(6\):1081-8. Epub 2009 Sep 25.](#) Our most recent experience, not published, shows 7.6% of our hemoglobin values fall below 10 g/dl. These are not first-of-the-month values only, like Elab, but are probably comparable. We believe that our publications and USRDS reports allow us to claim to represent best practice using current technology. It would be improper to penalize the dialysis providers who achieve superior quality with the implementation of an overly narrow standard.

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Hemodialysis patient hemoglobin values must be measured before the hemodialysis treatment. Failure to standardize this measurement would not be in patients' best interest and will not produce consistent data.

Finally, we wish to call attention to the effects of altitude on hemoglobin in the general population. Hemoglobin values of people without kidney disease in the communities surrounding our rural New Mexico, Colorado and Montana clinics are demonstrably higher than those of people living at sea level. Dialysis patients' hemoglobin values should be allowed to be correspondingly elevated.

### **Hemodialysis adequacy**

The proposed measure for hemodialysis adequacy is the proportion of patients achieving URR > 65%. We recommend that CMS utilize Kt/V to evaluate adequacy and that CMS should take this opportunity to state a more comprehensive standard for hemodialysis adequacy, in such a way as explicitly to take account a) residual kidney function and b) the frequency of hemodialysis treatment. In addition, to assure that hemodialysis adequacy calculations use accurate data, CMS should mandate adherence to the standards for postdialysis blood sampling set forth by the KDOQI Work Group on Hemodialysis Adequacy in 2006.

[http://www.kidney.org/professionals/KDOQI/guideline\\_upHD\\_PD\\_VA/hd\\_guide3.htm](http://www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/hd_guide3.htm))

**a) The standard for hemodialysis adequacy should take account of residual kidney function.** Especially in the first months of dialysis treatment, residual kidney function is often substantial, and should properly be taken into account in assessing the adequacy of hemodialysis treatment. Kt/V values may be calculated which include residual urea clearance, as described the KDOQI Work Group on Hemodialysis Adequacy in 2006. If, as the Work Group recommended, residual urea clearance values are used only for three months, requiring quarterly remeasurement, patients will be protected against inadequate dialysis. CMS should explicitly sanction the reporting of Kt/V values incorporating residual kidney function, provided that they have been calculated according to the methods outlined by the KDOQI Work Group.

[http://www.kidney.org/professionals/KDOQI/guideline\\_upHD\\_PD\\_VA/hd\\_appendix.htm#hdtable19](http://www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/hd_appendix.htm#hdtable19))

**b) The standard for hemodialysis adequacy should take account of the frequency of hemodialysis treatment.** More frequent hemodialysis treatment appears to offer outcomes which are at least as good, and for some patients substantially better, than conventional thrice weekly hemodialysis treatment. However, treatment given more frequently will often be associated with URR < 65% or Kt/V < 1.2, although the total weekly dose of dialysis is actually greater than delivered by thrice weekly hemodialysis meeting these standards. There are several techniques to calculate what the Kt/V would be if the patient were dialyzed three times a week from the Kt/V observed from measurements taken at hemodialysis performed 4, 5, 6 or 7 times a week. More precise methods are described by the KDOQI Work Group

[http://www.kidney.org/professionals/KDOQI/guideline\\_upHD\\_PD\\_VA/hd\\_appendix.htm#hdtable19](http://www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/hd_appendix.htm#hdtable19)), but a simple and conservative estimate, which will protect patients by

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underestimating the dialysis dose the patient receives, is a linear extrapolation from single pool Kt/V (spKt/V):

HD Frequency	Measured	Extrapolated for reporting	Minimum measured value required to meet standard of extrapolated spKt/V = 1.2
3	spKt/V	spKt/V	1.2
4	spKt/V	$(4/3)*spKt/V$	0.9
5	spKt/V	$(5/3)*spKt/V$	0.7
6	spKt/V	$(6/3)*Kt/V$	0.6
7	spKt/V	$(7/3)*Kt/V$	0.5

### **VIII. Unit of Payment**

We agree that a per-treatment basis for the unit of payment should be maintained. This will allow for easier patient travel and facilitate implementation of the transition requirements.

### **IX. Bad Debts**

Currently CMS reimburses providers for any unrecovered co-pays that relate strictly to the dialysis treatment. There is no reimbursement for unrecovered co-pays for biologicals and other services provided to Medicare beneficiaries. Under the proposed bundling rules, how will “dialysis treatment related” bad debts be determined? Will unreimbursed co-pays for laboratory services and Part D drugs be reimbursed? If these services remain in the bundle then they should be included in the bad debt reimbursement available to providers. If CMS does not intend to include these services in the bad debt reimbursement, then this represents another unintended consequence that adds additional complexity and financial burden to providers.

### **X. Effect on Small Dialysis Providers**

We are concerned about the effect of the proposed bundle on small providers. As a non-profit organization, DCI has a mission different from that of publically-held corporations, which have fiduciary responsibilities to maximize financial return to shareholders. We have always supported decentralization, to provide our medical directors and local staff the flexibility to provide the best possible care, tailored to local conditions. In healthcare, one size fits all does not make the best patient care.

Similarly, we believe that increased diversity of ownership of dialysis clinics promotes better patient care. With more providers, the number of ways in which care is provided increases. In addition, small providers are often the only providers of essential services in isolated areas. We are concerned that these services to remote communities

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will no longer be provided if small providers are no longer able to operate. Finally, all other non-profit dialysis providers are smaller than DCI, and because they are small, will be disadvantaged by the PPS as proposed. Their presence in the community matters. A decade ago, Garg found that in the early 1990s, the presence of a non-profit dialysis facility was associated with higher patient survival and higher rates of transplant listing than at the *for-profit* facilities in the same county. (Garg, *et al.* N Engl J Med 1999;341:1653-60.) On the national level and in the current era, the USRDS reports that DCI, a national non-profit dialysis organization, has patient mortality, hospitalization rates and cost to Medicare significantly lower than those of national for-profit providers. We have also shown that it is possible to achieve a narrower hemoglobin distribution than exhibited by patients treated by the large dialysis organizations.

Non-profit dialysis providers thus serve not only individual patients but the community, by setting a standard for quality. Market forces subsequently eliminate some of the differences; Garg found that in the early 1990s, “In the United States, for-profit ownership of dialysis facilities, as compared with not-for-profit ownership, is associated with increased mortality and decreased rates of placement on the waiting list for a renal transplant.” Analyses of later periods did not show the same overall discrepancy between for-profit and non-profit facilities, although at the level of individual organizations, differences remain. The market is doing its work. Likewise, after several years of USRDS reporting at the provider level, the major for-profits’ hemoglobin distributions are becoming more narrow. There is a public interest in preserving economically viable non-profit dialysis organizations, and because most of these organizations are small and local, there is a public interest that the reimbursement environment should allow them to survive.

The adoption of the currently proposed bundle will create a financial environment in which small providers may not be able to survive. The new rules threaten to shift providers’ focus from quality of care to cost of care. In addition, because of the numerous miscalculations, the proposed rules will essentially decrease reimbursement to providers while significantly increasing the number of administrative responsibilities.

In a bundled environment, large providers, which are able to obtain medical supplies at a discount and provide national services with improved economies of scale, will be better able to continue to provide care. DaVita and Fresenius, in particular, are large enough that they are able to obtain discounts that no other provider can achieve. Even a company the size of DCI, with 13,000 patients and annual EPO purchases approaching \$100,000,000, is not able to obtain a contract directly with Amgen. The net result is that DaVita and Fresenius are able to provide EPO, one of the most expensive components of dialysis, at a lower cost, while all other dialysis providers must use a less favorable contract, resulting in an increased cost per treatment compared to the two very large providers.

We are also concerned about the increased administrative expenses for the numerous additional requirements of the proposed bundle. Many of these requirements must be administered centrally. For larger providers this cost can be spread over many

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patients and centers; for smaller providers the net cost per treatment is higher. These increased administrative expenses include the cost of providing Part D drugs, the cost of completely collecting patient comorbidities, and the cost of providing information to establish that a patient is an outlier. For the outlier provision, we are concerned that small providers may not have the necessary resources available to identify outliers. This could result in the provision that was established to help providers actually harming them, as they in effect will lose the 1% of reimbursement that has been removed from the dialysis system to pay for outliers.

We have made a number of recommendations in this response addressing the increased inefficiencies of the proposed bundle. We believe that all of these provisions disproportionately negatively impact small dialysis providers. We ask that CMS evaluate each of these provisions with its effect on the small dialysis provider and dialysis patients in mind. The small provider, already challenged by current financial constraints, will be excessively impacted by the bundle as proposed.

We understand that there are benefits to providing services more efficiently and realize that increased efficiencies are available to larger providers. An argument could be made that an industry with a few large companies is beneficial because services can be provided at less cost. In certain circumstances there may be some support for this concept. However, we are talking about the future care of over 350,000 dialysis patients. Although the bundle may allow for more cost efficient provision of dialysis care, as proposed, the rules will be detrimental to patient care, especially if the net effect is that future dialysis care is provided by an oligopoly of only a few large companies.

### **XI. Interim Final Rule**

The proposed rule represents a significant change without administrative or judicial reviews. The potential detrimental effects may jeopardize a dialysis organization's viability and will impact the lives of all dialysis patients. We request that CMS publish an interim final rule with an appropriate period for public comment.

### **XII. Conclusion**

Thirty eight years ago DCI opened one dialysis clinic in Nashville, Tennessee to provide life saving dialysis care to five patients. At the time, dialysis care was not covered by Medicare; the only other outpatient dialysis facility in Middle Tennessee was a chronic unit at the Nashville Veterans Administration Hospital, and patients with kidney failure died. Medicare does now cover dialysis care, and DCI treats approximately 13,000 patients at 209 facilities in 26 states. Despite our growth, we are still non-profit, and we dedicate ourselves to the mission with which the first clinic was dedicated. We are a service organization. The care of the patient is our reason for existence.

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As an organization committed to provide the best patient care possible, we are concerned about the impact that the proposed bundle will have on the lives of all dialysis patients. The existing reimbursement system has allowed us to take excellent care of patients at low cost to the public, and to make care accessible to rural communities. The PPS, as proposed, would threaten our ability to maintain the quality of our care, and would jeopardize the survival of some of our facilities. We believe that the new rules will shift providers' focus from quality care to cost containment. For some providers this shift will be necessary to survive, for others possibly to maximize profits. We also believe that the bundle as proposed contains many serious miscalculations which will expand services provided to patients while decreasing overall reimbursement for dialysis services.

We do not believe that the proposed bundle is budget neutral: it is budget negative. The unfunded expansion of Part D coverage will shift to DCI more than \$32 million of expenditures a year that were not accounted for in the bundled rate calculation. Likewise, the over-estimation of payment modifiers will take from DCI more than \$15 million of revenue a year, revenue that CMS intended to be utilized to care for patients. If these provisions remain in place as currently proposed, we will be forced to implement severe cost reduction measures in order to be able to continue to care for our patients. We believe that these measures will interfere with the doctor-patient relationship and will hurt patients.

We encourage CMS to consider these issues seriously, and modify the Proposed Rule to achieve productive and fair change for dialysis providers and patients.

Sincerely,

H. Keith Johnson, M.D.  
Chairman

Ed Attrill  
President

Chris Lovell  
Director of Medical Informatics and Systems/Government Liaison

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ATTACHMENT 1

<b>Part D Drugs Summary 2007</b>			
Drug	Strength	Jan - Dec 2007	
		Quantity Ordered for the Year	Total Cost for the year
CALCITRIOL	0.25 MCG	50035	\$36,526
CALCITRIOL	0.5 MCG	36899	\$46,492
CALCITRIOL	1 MCG/ML	992	\$6,597
CALCIUM ACETATE	667 MG	189828	\$98,710
CALCIUM ACETATE	1000 MG	1417	\$737
ELIPHOS	667 MG		
FOSRENOL	250 MG	64078	\$62,796
FOSRENOL	500 MG	894072	\$5,078,329
FOSRENOL	1000 MG	685419	\$3,893,180
FOSRENOL	750 MG	59139	\$335,910
HECTOROL	0.5 MCG	24049	\$117,119
HECTOROL	2.5 MCG	34321	\$581,055
PHOSLO	667 MG	9406586	\$6,437,913
RENAGEL	403 MG	56731	\$34,039
RENAGEL	400 MG	312408	\$324,904
RENAGEL	800 MG	10375415	\$21,684,617
REVELA	800 MG	1512	\$2,525
ROCALTROL	0.25 MCG	44089	\$60,402
ROCALTROL	0.5 MCG	37525	\$82,180
ROCALTROL	1 MCG/ML	1918	\$22,882
SENSIPAR	30 MG	771153	\$8,660,048
SENSIPAR	60 MG	128170	\$2,878,698
SENSIPAR	90 MG	48556	\$1,635,852
ZEMPLAR	1 MCG	15578	\$110,760
ZEMPLAR	2 MCG	4973	\$70,766
ZEMPLAR	4 MCG	285	\$8,111
<b>2007 Yearly Cost</b>			\$52,217,148
<b>Per Treatment</b>			\$36.77

ATTACHMENT 2

<b>Part D Drugs Summary 2009</b>				
Drug	Strength	Annualized		Change Multiple 2007 - 2009
		Quantity Ordered for the Year	Total Cost for the year	
CALCITRIOL	0.25 MCG	73740	\$53,820	1.47
CALCITRIOL	0.5 MCG	70512	\$88,836	1.91
CALCITRIOL	1 MCG/ML	1176	\$7,824	1.19
CALCIUM ACETATE	667 MG	471204	\$245,016	2.48
CALCIUM ACETATE	1000 MG	780	\$408	0.55
ELIPHOS	667 MG	92652	\$51,888	n/a
FOSRENOL	250 MG	14412	\$14,112	0.22
FOSRENOL	500 MG	483420	\$2,745,828	0.54
FOSRENOL	1000 MG	865284	\$4,914,816	1.26
FOSRENOL	750 MG	55488	\$315,132	0.94
HECTOROL	0.5 MCG	30324	\$147,648	1.26
HECTOROL	2.5 MCG	37284	\$631,164	1.09
PHOSLO	667 MG	9592644	\$6,618,924	1.02
RENAGEL	403 MG	23604	\$14,160	0.42
RENAGEL	400 MG	217236	\$225,924	0.70
RENAGEL	800 MG	7568568	\$15,818,316	0.73
REVELA	800 MG	3460068	\$5,778,312	2288.40
ROCALTROL	0.25 MCG	35736	\$48,948	0.81
ROCALTROL	0.5 MCG	28176	\$61,704	0.75
ROCALTROL	1 MCG/ML	2664	\$31,704	1.39
SENSIPAR	30 MG	884568	\$9,933,636	1.15
SENSIPAR	60 MG	167052	\$3,751,920	1.30
SENSIPAR	90 MG	63336	\$2,133,588	1.30
ZEMPLAR	1 MCG	25152	\$178,848	1.61
ZEMPLAR	2 MCG	10104	\$143,820	2.03
ZEMPLAR	4 MCG	2664	\$75,816	9.35
<b>2007 Yearly Cost</b>			\$54,032,112	
<b>Per Treatment</b>			\$38.17	

ATTACHMENT 3

Tests listed in the sections § 494.80 of the Conditions of Coverage: Patient Assessment	
CPT code	Test
82947	Glucose
82310	Calcium
82040	Albumin
84155	Total Protein
84295	Sodium
84132	Potassium
82374	CO2 (carbon dioxide, bicarbonate)
82435	Chloride
84100	Phosphorous
84520	BUN (blood urea nitrogen)
82565	Creatinine
84075	ALP (alkaline phosphatase)
84460	ALT (alanine amino transferase, also called SGPT)
84450	AST (aspartate amino transferase, also called SGOT)
84478	Triglycerides
82465	Cholesterol
83615	LDH
82247	Bilirubin, Total
85027	Total red blood cells
85027	Hemoglobin
85027	Hematocrit or packed cell volume (PCV)
85027	Mean corpuscular volume (MCV)
85027	Mean corpuscular hemoglobin (MCH)
85027	Mean corpuscular hemoglobin concentration (MCHC)
85027	Red blood cell distribution width (RDW)
85027	Total white blood cells
85027	Platelet
82728	Ferritin
84466	Transferrin saturation
83970	Parathyroid hormone (PTH)
86706	Hepatitis B antibody
87340	Hepatitis B antigen