



# DIALYSIS CLINIC, INC.

A Non-Profit Corporation

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August 30, 2011

Dr. Donald Berwick  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

Re: CMS-1577-P: Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014: Proposed Rule

Dear Dr. Berwick:

Thank you for the opportunity for Dialysis Clinic, Inc. (DCI) to comment on CMS-1577-P: Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014: Proposed Rule. DCI is a 501(c)(3) nonprofit dialysis provider treating approximately 13,500 patients at 207 dialysis facilities in 27 states. Eighty-seven percent of these patients are insured by Medicare, Medicaid, HMO Medicare or the Department of Veteran Affairs.

DCI's patient care is high quality and efficient. 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 2010 USRDS Annual Data Report (ADR) found DCI to be the national provider costing CMS the least, at \$2,223 per patient per month, compared to a national average of \$2,274 and an average of \$2,284 and 2,359 for the other two national providers. The 2010 ADR showed that DCI's low costs reflect the most conservative laboratory testing and drug administration practices in the field, but that DCI had the lowest proportion of patients with a hemoglobin < 10, with an average erythropoiesis stimulating agent (ESA) cost per patient per month \$482, compared to an average of \$495 and \$506 for the other national providers.

## I. Quality Measures for 2013

### A. Comments on Proposed Measures

#### 1. Anemia

##### (a) Hb < 10

**Hb < 10 should remain as a quality measure for payment in the QIP. Hb < 10 is an excellent clinical demarcation for low hemoglobin. DCI data show higher mortality and hospitalization rates for patients whose Hb is less than 10. In addition, we are concerned that patient quality of life will suffer if hemoglobin values drop.**

We strongly disagree with the proposal to remove Hb < 10 as a measure for low hemoglobin. Hb < 10 is an appropriate clinical measure for low Hb, and no data show that it is more dangerous to maintain a patient at Hb 10-12 rather than at 9-11. The fraction of patients with Hb < 10 has already increased, and without a QIP floor, patient hemoglobin values may drop further.

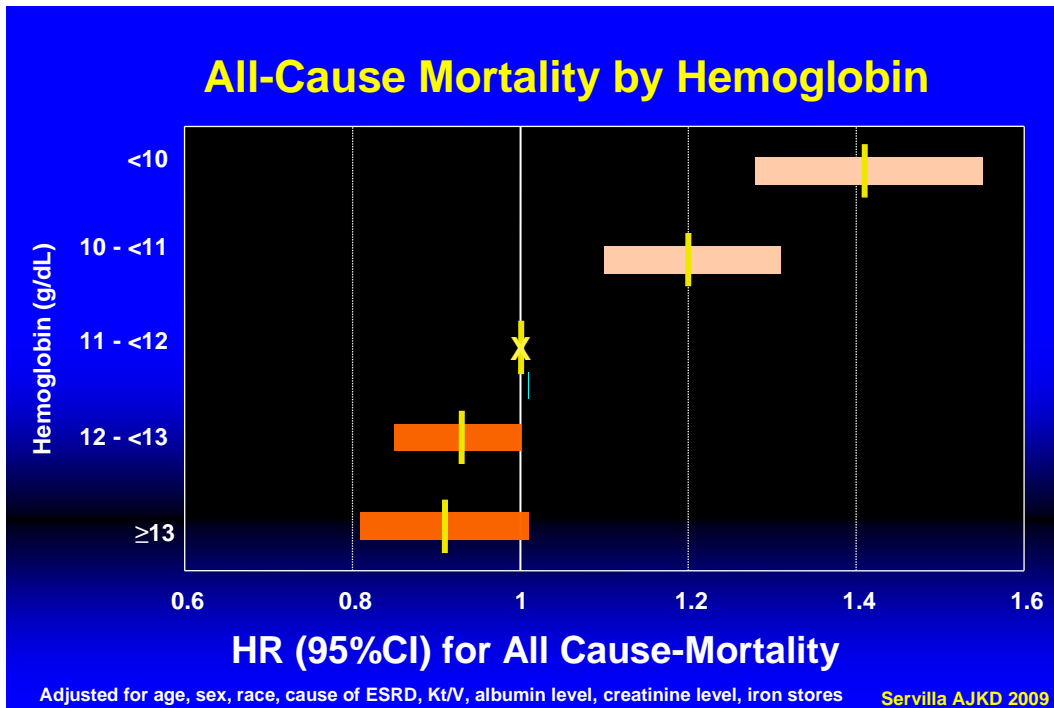
Our position to recommend the continuation of the Hb < 10 measure will economically disadvantage our facilities. Despite this disadvantage, we believe that maintaining the Hb < 10 measure is essential to optimizing the quality of life of dialysis patients. The goal of the QIP is to improve care under the bundle. We are concerned that if the lower limit Hb measure is eliminated, the bundle will have reduced the quality of dialysis patients' lives. Transfusions will increase, and mortality and hospitalization rates may also increase.

#### 1) **Hb < 10 is an appropriate clinical measure for low Hb**

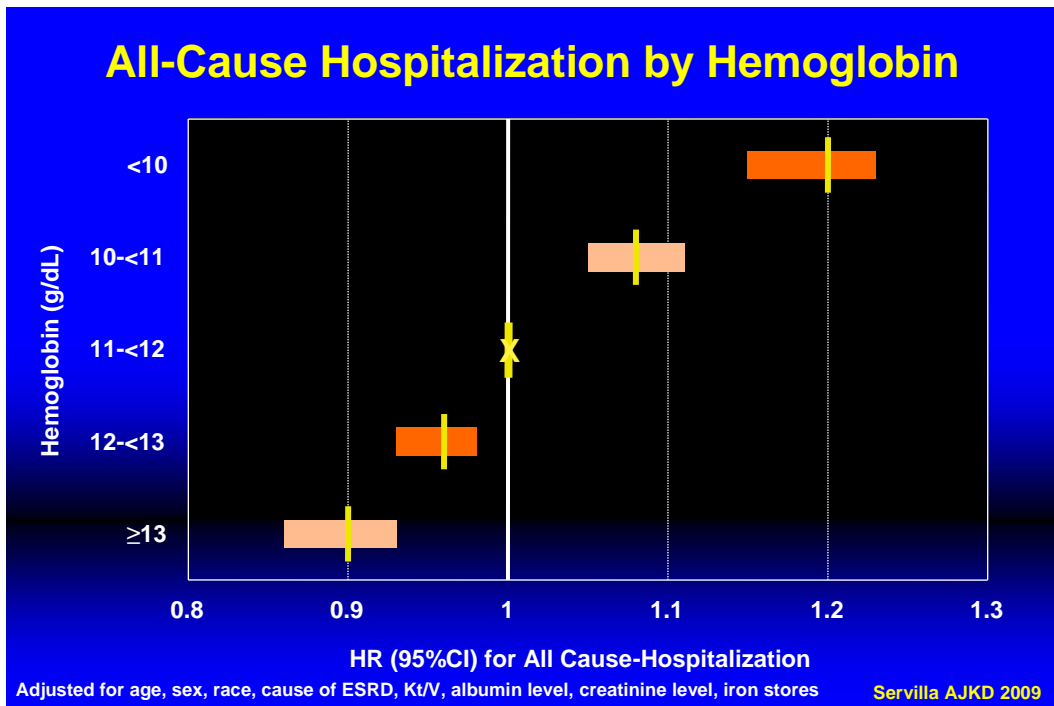
Among DCI patients, mortality and hospitalization increase as Hb drops below 10. In fact, DCI data show increased mortality for patients with Hb < 11.

To evaluate the effect of Hb on mortality and hospitalization, we studied an incident cohort (n=14,956) which began hemodialysis at a DCI facility between January 1, 2000 and December 31, 2006. [Servilla KS, et al, Am J Kidney Dis 2009 ; 54:498-510.] Inclusion criteria included age  $\geq 20$  years at diagnosis of end stage renal disease (ESRD) and survival of  $\geq 1$  year from the first outpatient hemodialysis. We restricted the cohort to patients with  $\geq 1$  year of follow-up to allow sufficient time for epoetin dose to stabilize. Follow-up for death or hospitalization began 1 year after initiation of hemodialysis and continued until change in modality (transplant or peritoneal dialysis), transfer from DCI or withdrawal from dialysis, absence from DCI for >30 days (excluding hospitalization), or end of study on December 31, 2007. Patients who transferred from DCI or withdrew from dialysis were followed for vital status for 30 days after their last recorded visit. The following are our results.

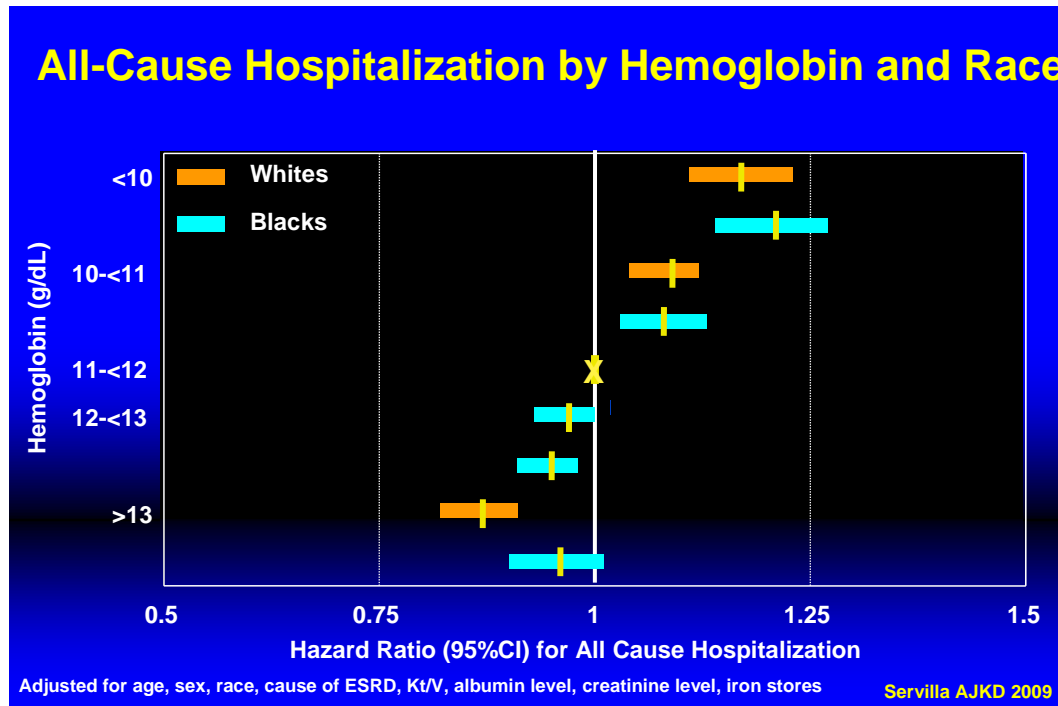
We found that all cause mortality was increased for patients with Hb < 11:



In addition, all cause hospitalization was increased for patients with Hb < 11:



All cause hospitalization is increased for both African American patients and Caucasian patients with Hb < 11:



Outside analysis supports our findings. Lacson et al evaluated clinical data, including laboratory records from October 1 to December 31, 2003, for 78,420 patients who survived until January 1, 2004. They found that “[h]emoglobin < 11 (22% of patients) added 20 to 50% to the risk of death and 18% to 38% to the hospitalization risk.” [Lacson E et al, American Journal of Kidney Diseases 2009; 53: 79-90]

We understand that analyses of observational, non-randomized data sets may be confounded, and that statistical correction does not guarantee that the effects of such confounding have been eliminated. However, in this context, it is our opinion that conclusions based on DCI observational data are as strong as conclusions based on achieved hemoglobin values in the Normal Hematocrit (NHCT), CHOIR and TREAT Studies. Analyses of achieved (rather than targeted) results of randomized trials do not have the strength of conclusions from the randomized comparison. Thus, in our opinion, the only conclusion that can be drawn with respect to hemoglobin in NHCT, CHOIR and TREAT that is stronger than the conclusions from the observational DCI data is that *targeting* hemoglobin of 13 or greater in these populations with substantial comorbidity is associated with worse outcomes than targeting a lower value. Inferences based on randomized trial achieved hemoglobin values are no stronger than inferences based on observational cohort data. Thus, the observation that, in TREAT, achieved hemoglobin values between 12 and 13 were associated with increased stroke should not carry greater weight than DCI data, which show that achieved hemoglobin values between 12 and 13 are associated with better survival than are lower achieved hemoglobin values. The fact that several randomized trials show danger at higher hemoglobin values does not mean that any higher hemoglobin is more dangerous than any lower hemoglobin. Using computerized decision support for EPO and iron dosing, DCI has demonstrated our ability to maintain 67% of our patients within a 2 g/dl

hemoglobin range between 10 and 12. If there is, in fact, a trade-off between the quality of life associated with hemoglobin in this range and safety, we believe that it is one that many patients, if informed of their choices, would gladly make. The literature shows that dialysis patients are clearly willing to trade off life years for quality of life. [Plantinga LC, Fink NE, Bass EB, Boulware LE, Meyer KB, Powe NR. Preferences for current health and their association with outcomes in patients with kidney disease. Med Care. 2007 Mar;45(3):230-7.]

## **2) Patient quality of life is related to hemoglobin concentration**

We disagree with the statement added to the Epogen package insert in June 2011 that “Epogen has not been shown to improve quality of life, fatigue, or patient well-being.” The evidence of the relationship between hemoglobin concentration and quality of life may not meet the standards that the FDA currently sets, that the effect on quality of life should be shown in a double-blinded randomized controlled trial, but many non-blinded trials show the relationship. We quote from one of them, which is particularly relevant because the hematocrit range involved, 25.5 to 29.9, is the range into which hemoglobin values will fall if the Hb < 10 standard is removed.

“Significant improvements in four of the six SF-36 scale scores and in the mental component summary score from baseline to follow-up were observed in the New-to-Epo patients (Table 4). In this group, the first follow-up assessment occurred an average of 99 days after the baseline assessment. Hematocrit levels increased from baseline to first follow-up from 25.5 to 29.9 ( $P < 0.001$ ). The vitality scale score showed the largest improvement from baseline to first follow-up, increasing 9.3 points ( $P < 0.001$ ). Physical functioning, social functioning, and mental health SF-36 scores also improved, increasing by 3.7, 7.5, and 4.1 points, respectively ( $P < 0.001$  for each). The mental component summary score also improved, increasing by 3.7 points ( $P < 0.001$ ). The proportion of patients who reported that their health was better than it was 1 yr ago increased from 40% to 56% from baseline to follow-up ( $P < 0.001$ ).”

“The average differences in SF-36 scale scores before and after treatment appear to be clinically relevant in comparison with differences observed in other populations. For example, a 9.3-point improvement in vitality represents slightly over half of the improvement in vitality observed at the 6-month follow-up among patients who received a new heart valve (24). Comparisons with differences observed between a general population sample and other samples of chronically ill patients offer additional insight on clinical relevance. For example, the 9.3-point improvement in vitality scores among the New-to-Epo patients is twice the difference in the vitality score observed in patients with Type II diabetes when compared with the general population. A 9.3-point improvement in vitality is similar to the impairments experienced by patients with chronic back pain and osteoarthritis, who exhibit differences in vitality of 8.7 and 11.5 points, respectively, from population norms (11). For social functioning, the improvement of 7.5 points observed in the New-to-Epo patients is twice the difference observed in patients with osteoarthritis compared with population norms (11). Finally, the difference of 4.1 points observed on the mental health scale in the New-to-Epo patients is 1 1/2 times greater than the decrement in mental health associated with the psychological distress caused by being fired or laid off from one’s job (25)” [Beusterien KM, J Am Soc Nephrol 1996; 7:763-73]

We also believe that CMS should consider what dialysis patients have been telling physicians for two decades now, that correction of anemia makes a difference in how they feel. CMS heard eloquent testimony on this at last year's MEDCAC meeting. We quote one speaker:

“I don't feel normal and cannot function as well if my hemoglobin level falls below 10, and I prefer to be closer to 12 simply because I feel better. At a hemoglobin below 10 I tire easily. I become short of breath walking upstairs. I have trouble sleeping, and daily activities become difficult or even impossible to perform. Frankly, I can always tell by the way I feel and how well I function that my hemoglobin has dropped before a lab test ever confirms it. And the effects of anemia in combination with the fluid filled fatigue of CKD that I experienced prior to the onset of dialysis treatments left me even more debilitated.”

“So a hemoglobin of 10 to 12 seems to be the right balance to allow physicians and patients to determine what is the best level for them to maintain their well-being. Many people who have CKD can relate experiences of how anemia has affected them personally. Symptoms may include chest pain, feeling cold, feeling tired, and I'm talking about a level of tired you don't even imagine exists. Low energy levels, so that doing even routine activities of daily living become impossible. Poor appetite. Shortness of breath. Depression. A poor sense of well-being. An inability to work, manage a home, volunteer. In short, the loss of a meaningful life.” [Kathe LeBeau at MEDCAC Meeting on ESAs in Anemia Related to Kidney Disease, March 24, 2010, 00128-6 – 00129-15, downloaded from <https://www.cms.gov/mcd/viewmcac.asp?from2=viewmcac.asp&where=index&mid=52> &, September 12, 2010 ]

### **3) The fraction of patients with Hb < 10 has already increased in response to concerns about high EPO doses**

In fact, we have already seen an increase in the number of patients with Hb < 10 prior to the effect of the FDA label change. The fraction of patients with Hb < 10 has **increased by 50%** over the last 12 months. During the first 6 months of 2010, the mean percent of DCI patients with Hb < 10 was **8.2%**, in the second 6 months of 2010 **9.5%**, and in the first 6 months of 2011, **12.4%**.

*It is important to note that this change does not reflect the impact of the new FDA label because these data only extend through June, 2011. **On the basis of subsequent practice changes, we are concerned that we may see a continued increase in the fraction of patients having Hb < 10.***

We are concerned about this increase in the percent of patients with Hb < 10 and are taking numerous measures to make patients more EPO responsive, such as giving iron, removing catheters, administering nutritional supplements, treating inflammatory conditions, and encouraging patients to consider a change to peritoneal dialysis. We expect that these and other measures will limit the number of patients remaining below a hemoglobin of 10. Unfortunately, the new FDA label change adds an enormous challenge

to our ability to maintain patients above Hb 10. **If the Hb < 10 QIP measure is also removed, the challenge for maintaining patient hemoglobin values will become even more difficult.**

**4) Continuing the Hb < 10 measure is an investment in improving quality of life**

We do not make the recommendation to continue the Hb < 10 measure lightly; in fact our financial penalty for 2013 will increase substantially if the Hb < 10 measure is reinstated. Extrapolating from our Jan – June 2011 data, and assuming a baseline of 3% of patients with Hb < 10 and equal weighting for the Hb < 10 measure for 2013, we calculate that our QIP penalty will increase from **0.42%** to **1.43%** if the Hb < 10 measure is reinstated with the penalty structure proposed by CMS and from **0.20%** to **0.69%** if the penalty structure from 2012 is continued in 2013.

We are willing to accept this financial penalty because we see it as an investment in the quality of life of DCI patients specifically and all dialysis patients. As you know, there is a strong financial incentive to decrease the use of EPO because it is the most expensive medication provided under the bundle. In our opinion, it is essential to have a financial penalty for low Hb to help offset the financial incentive to decrease EPO use. When we discuss anemia management with our Medical Directors and the healthcare team at local clinics, we have been able to gain support for clinical changes to decrease low hemoglobins by showing the financial penalty for low hemoglobin; we expect that this would also be a helpful tool for other providers.

**(b) Hb > 12**

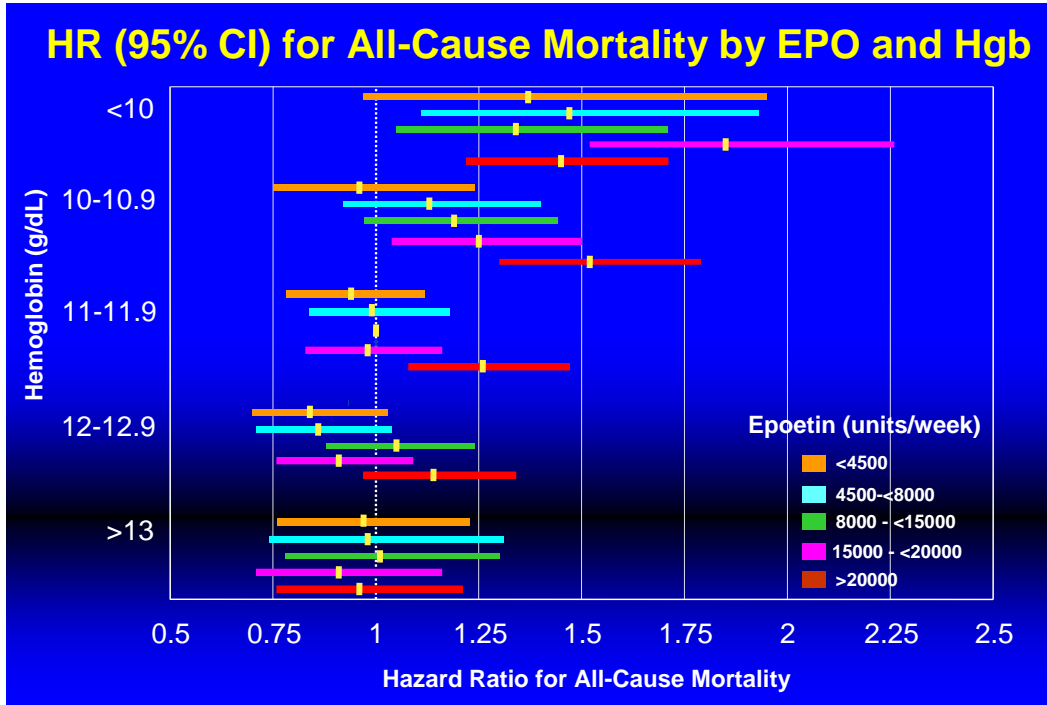
**Recent clinical practice changes have addressed the concern for high hemoglobin and high EPO doses; because of this change in practice, it may be reasonable to decrease the weighting for the Hb > 12 penalty**

In the last year and a half, we have seen a substantial decrease in the EPO dose given to patients with Hb > 12 and a substantial decrease in the percent of patients with Hb > 12. We expect to see further declines in response to the revised FDA label for EPO. We expect that similar utilization changes have occurred for other dialysis providers. Because practice has already changed to address concerns about the risk of high EPO doses and high Hb, it may be reasonable to decrease the weighting for the Hb > 12 penalty.

In our opinion, the risk of adverse events from ESAs is due to the high doses of EPO given in the past, not the attainment of a high hemoglobin. As shown previously in this comment, DCI data shows that patient mortality is *lower* for patients who are able to achieve a hemoglobin > 11. Also, as noted previously, other data support our findings.

If we are able to maintain patient Hb between 10 and 12 at a low ESA dose, we consider this a success. The patient's quality of life is improved while exposing the patient to a minimal dose of EPO.

Our opinion that high EPO doses increase the risk of mortality is supported by our analysis of DCI data. We stratified each Hb category by EPO dose and found in each Hb category a trend exists in which higher ESA doses seem to be associated with higher mortality. This association is less clear for Hb < 10:



In the last year we have seen both a decrease in the percent of patients with Hb > 12 and a decrease in EPO dose given to patients with Hb > 12. Our average EPO dose for patients with Hb > 12 has decreased by over **57%** in the last year. From January to June of 2010, our average EPO dose for hemodialysis in-center patients was **4056** units per treatment; this dose decreased to an average dose of **3090** Units from July to December 2010 and **1721** units per treatment from January to June 2011.

In addition, we have seen a **36%** decrease in the percent of patients with Hb > 12 in the last year. For the first 6 months of 2010, the average percent of DCI patients with Hb > 12 was **32.7%**; this number decreased to **25.1%** for the second six months of 2010 and **20.8%** for the first six months of 2011.

*It is important to note that these utilization changes occurred before the FDA label change.* We expect that our EPO dose to patients with Hb > 12 will further decrease and the percent of patients with Hb > 12 will further decline now that we have implemented changes to our electronic protocol to comply with the new FDA label. All of these changes will result in an increase in the fraction of patients having Hb < 10, and a decrease in the fraction having Hb > 12.

**(c) Average hemoglobin should be rounded to one decimal place to reflect the accuracy of the laboratory test**

Hemoglobin should be rounded to one decimal place to reflect the precision of the laboratory test. Industry standard is to report Hb to one decimal place and it is our

understanding that all renal laboratories report to one decimal place. **To average hemoglobin values to more than one decimal place exaggerates the precision of the autoanalyzer.** The average hemoglobin should be reported to the nearest one decimal place, according to rounding conventions. For example, 9.96 should be rounded to 10.0, and both 11.96 and 12.04 should be rounded to 12.0

Failure to round average hemoglobin to one decimal place will have an important financial impact for dialysis providers. We calculated the difference in penalty to our clinics attributable to rounding. Twelve DCI clinics would have a lower penalty (ranging from a 0.5% to a 1.5% difference) if average Hb < 10 had been rounded to one decimal place; and two DCI clinics would have a lower penalty (0.5%) if average Hb > 12 had been rounded to one decimal place. These 14 clinics represent almost 7% of our clinics.

## **2. URR**

### **a) URR should be changed to Kt/V as soon as possible; residual renal function should be included in the determination of dialysis dose**

We are encouraged that CMS plans to change to use Kt/V as an indicator of dialysis adequacy in 2014. We also appreciate that CMS has excluded home patients from the analysis of adequacy, since the standard of URR > 65% is applicable only to thrice weekly hemodialysis, and cannot be used as a quality metric for patients dialyzed more frequently.

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\\_up\\_HD\\_PD\\_VA/hd\\_appendix.htm#hhtable19](http://www.kidney.org/professionals/KDOQI/guideline_up_HD_PD_VA/hd_appendix.htm#hhtable19)

We realize that some members of the renal community have recommended that residual renal function not be included in the calculation of Kt/V for hemodialysis. Although we appreciate their concerns about the difficulty with lengthening dialysis treatment time once a patient no longer has residual renal function, it is our opinion that a nephrologist should be allowed to include residual renal function as a part of the determination of the appropriate dialysis dose for all dialysis patients. Inclusion of residual renal function allows for a more patient-centered approach to the dialysis prescription. Shortening treatment time on the basis of residual kidney function may make the difference in allowing a patient to continue to work, one of the original goals of the ESRD program. It is true that it may be difficult to persuade a patient to increase dialysis duration when kidney function declines. However, in our opinion, few things are more worthwhile to do on hemodialysis rounds than to talk with a patient about treatment time. A significant number of DCI hemodialysis patients have their dialysis dose calculated with the

inclusion of residual renal function. As of June 2011, 3.5% of our hemodialysis patients had residual renal function measured within the last 3 months.

**b) CMS should use the last URR of the month because this value is the best indicator of actual dialysis dose received.**

If a claim has more than one URR or Kt/V, the last URR or Kt/V of the month should be used because it is the best clinical indicator of the actual dialysis dose delivered to a patient during the claims month; not the first URR that is being used by the dialysis report contractor for calculation of 2012 QIP. Using the last URR of the month is consistent with CMS policy concerning evaluation of patient URRs. The Guide to the PY 2012 ESRD QIP Performance Score Report at the following address: [http://www.dialysisreports.org/pdf/esrd/public/Guide to the PY 2012 ESRD QIP PSR .pdf](http://www.dialysisreports.org/pdf/esrd/public/Guide%20to%20the%20PY%202012%20ESRD%20QIP%20PSR.pdf). states under section *III. Inclusion Criteria; Dialysis Adequacy (URR of at Least 65%)* "If during a month, multiple claims meet these criteria for the same patient at the same facility, the last claim of the month is used".

CMS has also recognized the need to report the last reading in the billing period as shown in the Medicare Claims Processing Manual Chapter 4 - Part B Hospital (Including Inpatient Hospital Part B and OPSS) under the section Value Codes and Amounts "D5 – Result of last Kt/V reading. For in-center hemodialysis patients this is the last reading taken during the billing period. For peritoneal dialysis patients and home hemodialysis this may be before the current billing period but should be within 4 months of the claim date of service". Also in section 50.9 - Coding for Adequacy of Dialysis, Vascular Access and Infection it states "If a home hemodialysis patient is not monitored during a month, the last, most recent URR for the dialysis patient must be reported."

The last URR of the month is the best clinical indicator of the actual dialysis dose delivered to a patient during the claims month. Often facilities repeat URR measurement when they do not think the first measurement was performed properly. For example a facility could perform a measurement on the 5th day of the month and get the result of 50%. The physician knows that the patient's history shows that URR's have consistently been in the 75% range. The physician thinks this low URR is a lab error or improper removal of saline from the dialysis lines and would ask the facility to repeat the URR after the staff reviews the proper techniques and procedures of obtaining the measurement. In most case the repeat URR is higher and more accurate.

In addition, a patient's dialysis dose may be adjusted in response to a low URR. The last URR of the month is most likely to be reflective of the actual dialysis dose received by the patient after the patient's dialysis dose has been adjusted.

The choice of CMS to use the last URR of the month instead of the first or lowest URR of the month can have a large impact on the QIP penalty for a provider. In our evaluation of DCI clinics, we found that 25 clinics had a higher penalty in 2012 ranging from 1.0% to 0.5% because the lowest URR of the month was used. These 25 clinics represent 12% of DCI's clinics.

## **B. Comments on Application of 2013 QIP**

### **1. The QIP should take into account inter-laboratory variability**

At DCI we operate our own renal laboratory. We have been working with the renal community to calculate the variability of lab values between renal laboratories. We agree with the position of KCC and KCP that the QIP should take into account inter-laboratory variability. We look forward to working with the renal laboratory community to decrease inter-laboratory variability.

### **2. CMS should reinstate the 2012 Penalty Structure**

We agree with KCP and KCC that the 2013 and 2014 penalty structure should be the same as the 2012 penalty structure.

We were surprised to find that, based on DCI data from January to June 2011, we estimate our penalty will increase in 2013 even though our performance improved in the last year for the two measures proposed to be evaluated for 2013.

Comparing our quality of care for the first six months of 2011 to the first 6 months of 2010, we found that the number of DCI clinics that did not meet the URR goal for the QIP decreased from **55** to **54** clinics. We also evaluated our overall URR results as a company (all patients, not just those qualifying to be evaluated by for the QIP) and found that the percent of patients not meeting the goal decreased from **9.5%** to **8.1%**, representing a **15%** decrease in patients not meeting the URR goal.

Concerning the Hb > 12 measure, we found that the number of DCI clinics that did not meet the Hb > 12 goal for the QIP decreased from **7** to **3** clinics.<sup>1</sup> We also compared our overall Hb > 12 results as a company (all patients, not just those qualifying to be evaluated by for the QIP) and found that the percent of patients with Hb > 12 decreased from **32.7%** to **20.8%**, representing a **36.3%** decrease.

Despite this improvement in care relative to the two continued measures of the QIP, we were surprised to find that our estimate of our QIP penalty for 2013 actually *increased* by more than **14%**. Our estimate for DCI's QIP penalty for 2013 using data from January to June, 2011, is **0.474%**, compared to our previous estimated QIP penalty for 2012 of **0.415%** using data from January to June, 2010.

We estimated our penalty for 2013 using the 2012 penalty structure and found that our penalty would decrease by more than **42%** from **0.474%** to **0.272%**. This change is significant, representing a greater than **\$500,000** decrease in the 2013 QIP penalty for DCI. We consider this penalty, based on the 2012 penalty structure, to be a more appropriate penalty for the two quality measures proposed to be used for the 2013 QIP since our overall performance improved for these measures in the last year.

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<sup>1</sup> All three DCI clinics that currently do not meet the Hb > 12 had a temporary increase in hemoglobin from change in iron therapy. We anticipate that all of the facilities will meet the Hb > 12 criteria after the full 12 months of 2011 are analyzed.

### 3. CMS should change the weighting of the QIP Measures for 2013

As we have noted previously, we strongly disagree with the decision by CMS to remove the Hb < 10 measure from the 2013 and 2014 QIP. At the same time, we recognize the concerns of the kidney community that the baseline for the Hb < 10 measure does not take into account practice changes over the last few years. Members of the kidney community have proposed that the Hb < 10 measure be kept in the QIP for reporting purposes only until a new baseline can be determined. For the reasons noted previously in this comment, we recommend that the Hb < 10 measure continue as a payment measure.

We propose that Hb < 10 remain in the QIP, but that the weighting for this measure be decreased until an accurate baseline is determined which reflects change in practice over the last few years, including the new FDA label. In our opinion, anemia practices in 2012 will reflect the change in practice in response to the FDA label change. Consequently, we recommend that the Hb < 10 measure be included with a decreased weighting for the QIP in 2013 and 2014. For the QIP in 2015, we recommend that Hb < 10 receive increased weighting, similar to the weighting in 2012, since a new baseline and performance period can be utilized for the QIP at that time.

It is not clear what the appropriate weighting for Hb < 10 should be for 2013 and 2014. One compromise may be to select a weighting formula that gives dialysis providers the same average penalty in 2013 and 2014 as in 2012. As noted previously, we recommend using the same penalty scale as 2012 to allow for a better comparison of future care to the care provided under the first year of the QIP.

In the remainder of this section, we will compare our data from the first six months of 2010 with our data from the first six months of 2011 in an attempt to further the discussion concerning the appropriate penalty formula including Hb < 10 for 2013 and 2014. In our opinion, our penalty for the QIP in 2013 should be marginally higher than the penalty in 2012 because our performance in 2011 with respect to Hb < 10 is worse than our performance with respect to Hb > 12.

The following is a summary of the change in the DCI penalty from 2012 to 2013 for a number of different penalty allocations. In this analysis, we used the same payment reduction scale as applied in the 2012 QIP and looked at the effect on DCI's estimated penalty if the weighting were changed for the Hb < 10, Hb > 12 and URR >= 65 measures:

Hb <10	Hb > 12	URR >= 65	Estimated reduction based on Jan - Jun 2011 data	Increase/Decrease in penalty compared to 0.415% in 2012
50%	25%	25%	0.78%	88%
33%	33%	33%	0.61%	46%
25%	25%	50%	0.52%	26%
10%	40%	50%	0.31%	(25%)
20%	40%	40%	0.42%	2%

Based on the above summary, it seems that, based on DCI data, the formula that would provide for a minimal increase in the QIP penalty for 2013 would be:

Hb < 10	20%
Hb > 12	40%
URR	40%

We look forward to working with CMS to determine the appropriate penalty for a Hb < 10 measure for the 2013 and 2014 QIP.

#### **4. CMS should exclude clinics with fewer than 20 Medicare patients from QIP analysis**

We support the recommendation of KCP and KCC that clinics with fewer than 20 Medicare patients should be excluded from QIP analysis. For the 2012 QIP, small DCI clinics were disproportionately affected by the QIP. Thirteen DCI clinics with only one patient with an average Hb < 10 had a score reduction for the Hb < 10 measure in the QIP. Twenty one DCI clinics with only two patients with an average Hb < 10 had a score reduction for the Hb < 10 measure. We are concerned that the disproportionate impact of the QIP on small facilities, which are often rural, could adversely affect access to dialysis care for kidney patients and hope that CMS will accept this recommended change to promote improved patient access to dialysis services.

#### **5. The QIP should not be used to decrease total funding for dialysis care**

The primary purpose of the QIP should be to improve the quality of dialysis care. We do not believe that a quality improvement program should decrease total funding for the care of dialysis patients. Although the overall Medicare cost for ESRD care is far greater than anticipated in 1972, bundled payment since the early 1980s has constrained the cost per beneficiary more effectively than for any other patient population. In 1983, before erythropoietin was introduced, the composite rate was \$127; inflated by the Consumer Price Index, this would be \$278 in 2010 dollars. In its current form, the QIP will penalize our underperforming facilities, but excellent performers will not be rewarded, and overall funding will decline. Small facilities, in which statistics are more volatile, will be more vulnerable; these are disproportionately rural.

It is our opinion that the current model actually risks *decreasing* the quality of care in dialysis because it decreases the amount of resources provided for dialysis care. We strongly recommend that the system be changed so that funds that are not given to underperforming providers will be returned to support care provided to dialysis patients. Many different techniques could be used, including making additional payment to high performing providers or giving additional payment to those providers who show the greatest improvement in their care. We welcome the opportunity to work with CMS in conjunction with other members of the dialysis community to help develop a program in which the funds removed from the dialysis industry with the QIP are utilized in such a way to *further improve* the care provided to dialysis patients.

## **II. Quality Measures for 2014**

### **A. Comments on Specific Measures**

#### **1. CMS should continue the Hb < 10 Measure**

For the reasons stated previously in this letter, we strongly recommend that CMS continue the Hb < 10 measure in 2014.

#### **2. CMS should include residual renal function in the Kt/V measure**

As noted previously in this letter, we recommend that residual renal function should be included in calculation of Kt/V. It is our opinion that inclusion of residual renal function in Kt/V allows for a more patient-centered approach to determination of dialysis dose.

#### **3. CMS should change the weighting for the vascular access measure to emphasize the importance of catheter reduction**

We recommend that weighting for the vascular access measure be changed such that the catheter measure would be weighted 66% and the fistula measure would be weighted 33%. In our opinion, the most important intervention in the change of a dialysis access is the removal of a catheter. However, we also consider a fistula to be the optimal access for a patient and therefore it is our opinion that a fistula measure should also be included in the 2014 QIP.

#### **4. CMS should not include the vascular infection measure using the V8/V9 modifiers**

We agree with the KCP and KCC position that the vascular infection measure using V8/V9 modifiers should not be used. As there is no standardization in reporting, different results for facilities may not represent a difference in infection rates.

#### **5. SHR should not be used as a QIP measure at this time**

We agree that it is important to decrease hospitalization rates and commend CMS for proposing to use hospitalization rates as a QIP measure. However, the process for calculation of SHR currently has not been shared with the dialysis community. In addition, it seems that the current measure may include hospitalizations that are not related to kidney disease and therefore are outside the control of dialysis providers. As result, we agree with the KCP and KCC position that SHR should not be used as a QIP measure at this time.

We support the use of an SHR measure in the future, once the provider community has had an opportunity to learn more about the measure and propose changes to the measure.

#### **6. CMS should maintain the NHSN Measure, but should take into account the expense for NHSN application and participation in any future recalculation of Medicare payments for dialysis**

We support the NHSN reporting measure and plan to enroll all DCI clinics in NHSN. However, we note that the clinics will have substantial expenses from enrolling and participating in NHSN. We ask that CMS take these expenses into account when calculating the base rate for dialysis care for future years.

**7. CMS should modify the ICH-CAHPS survey to allow it to be administered in three parts and should take into account that expense for administering the CAHPS survey in any future recalculation of Medicare payments for dialysis**

At DCI we value input from our patients about the care that we provide and have used an internally designed patient satisfaction survey for the last fifteen years. In our experience, it is difficult for patients to complete a lengthy questionnaire. We therefore agree with the recommendation of KCP and KCC that the ICH-CAHPS survey be split into three distinct pieces and that each patient take a portion of the survey so that 1/3 of each clinic's patients take a different portion of the survey.

In addition, we note that there will be a substantial cost for implementing the ICH-CAHPS survey in our clinics. It is our understanding that CMS is requiring that each clinic use a third party vendor to evaluate the results of the CAHPS survey. According to the proposed rule for the 2013 and 2014 QIP, the "total cost for ESRD providers/facilities to comply with the collection of information requirements associated with administering the ICH CAHPS survey each year would be approximately \$3,264.29, or \$17.1 million across all ESRD providers/facilities." We ask that CMS take these additional new expenses into account when calculating the base rate for future years.

We also have two questions/comments about the application of the ICH-CAHPS quality metric:

1. The proposed Rule does not make clear the contemplated administration procedure and the basis of estimation of cost of administration; we are not sure that the two are internally consistent. The Rule refers to the AHRQ website, where documents state that a 3d party vendor must administer the ICH-CAHPS. However, the proposed Rule makes reference to administration in the facility, and the time and cost estimates seem to be based on administration by facility staff. Thus, the proposed Rule may underestimate the true cost to the facility of administering ICH-CAHPS properly.
2. ICH-CAHPS was developed for and tested among adult in-center hemodialysis patients being treated three times a week. The AHRQ website mentions scoring modifications for peritoneal dialysis and pediatric patients, respectively, but the validity of these modifications is unknown. There is no reference to home hemodialysis. Thus, ICH-CAHPS may not reliably capture the experience associated with home dialysis, a form of treatment that is associated with lower cost to CMS, and potentially perpetuates disparities in care related to patient age.

## **B. Comments on Application of 2014 QIP**

### **1. Average hemoglobin should be rounded to one decimal place to reflect the accuracy of the laboratory test.**

As noted previously in this letter, we agree with KCP and KCC that the average hemoglobin should be rounded to one decimal place to reflect the accuracy of the laboratory test.

### **2. The QIP should take into account inter-laboratory variability**

As noted previously in this letter, we agree with KCP and KCC that the QIP should take into account inter-laboratory variability.

### **3. CMS should reinstate the 2012 Penalty Structure**

As noted previously in this letter, we agree with the KCP and KCC position that the penalty structure for 2012 should be included for 2014.

### **4. CMS should exclude clinics with less than 20 Medicare patients from QIP analysis**

As noted previously in this letter, we agree with the KCP and KCC position that CMS should exclude clinics with less than 20 Medicare patients from QIP analysis.

### **5. If new penalty methodology is implemented by CMS in 2014, changes should be made to equitably address clinics that have maintained their quality of care.**

We agree with the analysis of KCP and KCC concerning the effect of the proposed new payment methodology on clinics that fall in the middle for performance. According to the new penalty scale, a clinic that consistently performs in the middle, and has better quality results than a clinic with improving care, could receive a lower score than the improving clinic. If the new CMS methodology is adopted, we recommend that a change be made so that a clinic that is performing consistently is not penalized.

### **6. Hb < 10 should receive a lower weighting in 2014 QIP**

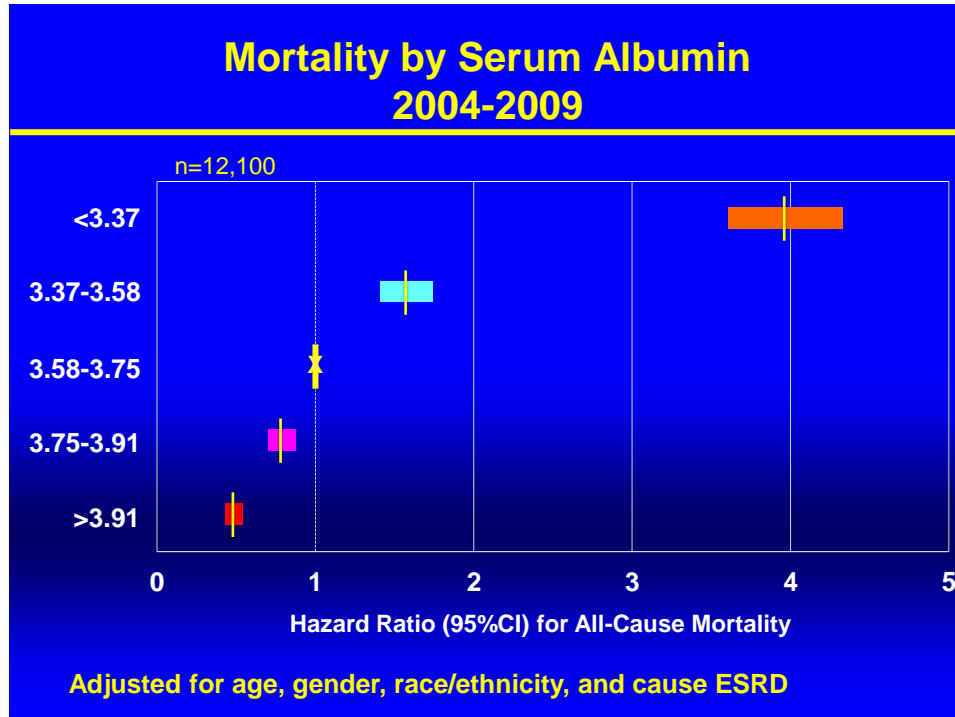
As stated previously in this letter, we strongly recommend that the Hb < 10 measure be continued in the QIP. However, we recognize the concerns of the kidney community, stated in the KCP and KCC comment letters, that the current baseline for Hb < 10 does not take into account changes in practice over the last few years, and specifically does not take into account potential changes in practice in response to the new FDA label. We therefore recommend that CMS consider decreasing the weight of the Hb < 10 measure until baseline data is available that accurately takes into account change in practice after the new FDA label. Once new baseline data is available, we recommend weighting Hb < 10 more heavily than other measures, as was done for the first year of the QIP.

### III. Future Quality Measures – CMS should add serum albumin as a future quality measure

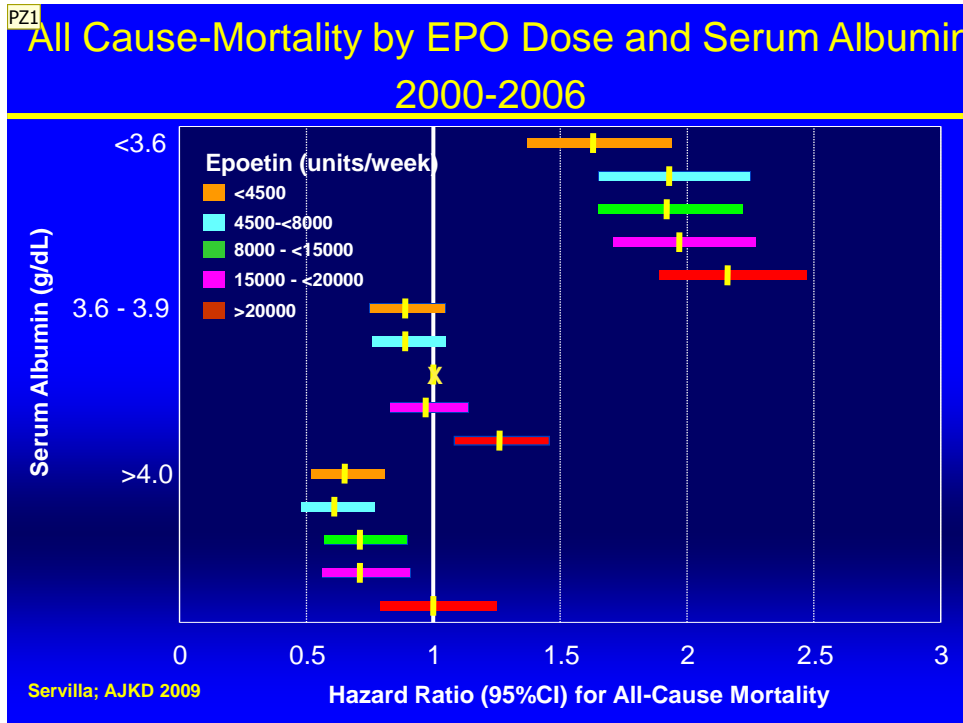
Serum albumin has long been recognized as a powerful, independent predictor of mortality and hospitalization. Therefore, we strongly recommend that CMS include serum albumin as a quality measure in the future.

DCI data shows that mortality rates are lower for patients with a higher serum albumin. We studied the association between serum albumin and mortality in 12,100 incident HD patients (2004 – 2009). Cox model regression analyses were used and adjusted for age, gender, race/ethnicity, year HD initiated, and cause of ESRD. Time-varying 3-month average serum albumin levels were categorized before analysis: one analysis used quintiles and the other grouped patients based on cut-points of 3.5 and 4.0. Strength of associations was summarized as hazard ratios (HR) and 95% confidence intervals.

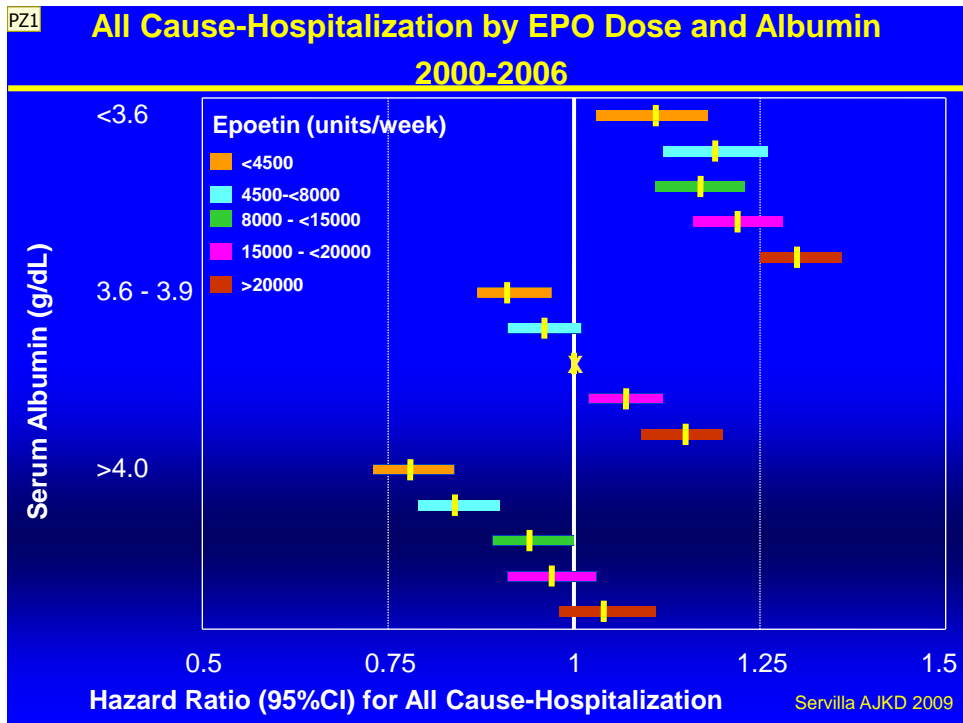
Applying this analysis, we found a strong, negative, association of serum albumin with mortality.



We have previously published our results on mortality and hospitalization rates by EPO dose and serum albumin. [Vide supra, Servilla Am J Kidney Dis 2009] We found a strong inverse relationship with serum albumin and mortality and an increased risk of mortality with increased EPO dose.



We found the same relationship with both serum albumin and EPO dose and hospitalization rates.



These findings are in concert with a report by Owen et al. conducted in patients receiving care from Fresenius Medical Care, North America. These investigators observed that compared to the referent group (serum albumin >4.0 g/dL) the odds ratios for mortality associated with serum albumin concentrations 3.5-3.9 g/dL and 3.0-3.49 g/dL were 1.48 and 3.13, respectively. [Owen et al, New England Journal of Medicine 1993; 1001-1006]]

Given the strong predictive power of serum albumin, it seems prudent to postulate that administration of oral nutritional supplements may increase serum albumin and thereby decrease mortality and hospitalization rates.

To begin to explore this hypothesis, in May 2010 we began a program in which all dialysis patients with a serum albumin  $\leq 3.5$  g/dL were eligible to receive oral nutritional supplements three times a week on dialysis. We stopped nutritional supplements when the serum albumin concentration  $\geq 4.0$  g/dL and did not restart them until the serum albumin was  $\leq 3.5$ . Nutritional supplements were treated as a medication. The patient's nephrologist wrote an order for the supplements in the clinic and the DCI patient care staff recorded the supplement dose as an administered medication in the DCI electronic medical record if the patient drank the supplement during a treatment. In the month of July, 2011, 4130 DCI patients, representing 30% of all DCI patients, received a total of almost 40,000 doses of nutritional supplement during dialysis.

A preliminary analysis conducted in January, 2011 had encouraging results. Among 487 patients who had received supplements for  $\geq 4$  weeks and had subsequently stopped therapy the mean serum albumin concentration increased by 0.47, from 3.33 to 3.80 g/dL. Among 2038 patients who had received supplements for  $\geq 4$  weeks and were continuing to receive therapy the mean serum albumin concentration increased by 0.17, from 3.28 to 3.45.

Since the inception of the supplement program we have observed a favorable change in the distribution of serum albumin among DCI patients, as a whole (for all DCI patients, not just Medicare patients). Between June 2010 and June 2011, the percentage of patients with a serum albumin concentration  $< 3.5$  g/dL decreased from 23.5% to 21.4%. The percentage of patients with serum albumin concentration  $>4.0$  g/dL increased from 30.9% to 35.0%.

We recently implemented two changes to increase the number of patients receiving supplements. First, we introduced an electronic nutritional supplement protocol, which now covers over 62% of DCI patients. Second, we added a better tasting supplement to the DCI formulary and 72 DCI clinics are currently using this supplement.

A recent analysis of July 2011 data revealed that the percentage of patients with a serum albumin concentration  $< 3.5$  g/dL had decreased to 19.1% and the percentage of patients with serum albumin concentrations  $> 4.0$  g/dL had increased to 38.9%. It is unclear whether this change represents monthly variation or reflects the recent changes in our program.

We will continue to follow the change in DCI patient serum albumin distribution and look forward to sharing our results with you in the future. We are also currently

undergoing a more thorough analysis of our nutritional supplement program and hope to publish our results later this year.

#### **IV. Comments on End-Stage Renal Disease Prospective Payment System for 2012**

We want to acknowledge CMS's responsiveness to our concerns and to those of the dialysis industry as a whole. We very much appreciate the correction to the transition adjustor in April 2011, and agree with the proposal to maintain the transition adjustor at zero for 2012. The clarifications in the proposed rule regarding the low volume determination and emergency services to ESRD are also helpful.

All of DCI's facilities elected to enter the ESRD PPS (the bundle) without transitioning. So far, this choice has not affected our ability to care for our patients. We are glad to see that the proposed rule addresses many of the issues that have posed considerable challenges to our facilities. These areas are: (1) co-morbid adjustors, (2) laboratory related issues, (3) antibiotic treatments, (4) proposed revisions to the outlier policy, (5) the wage index, and (6) cost reports.

##### **A. Co-morbid Adjustors**

We regret to observe that our comment letter on the ESRD PPS of December 4, 2009 accurately predicted the problems that would arise with respect to the reporting of co-morbid adjustors. The overriding billing issue is that the dialysis claim must capture all new co-morbidities in the month in which they occur. Our dialysis facilities are unable to obtain hospital discharge summaries and physician notes to code problems beyond routine dialysis care in a timely fashion. Even in the cases in which the discharge summaries and notes are available quickly enough, they often only suggest the possibility that the co-morbid adjustor may be appropriate, without including enough detail to allow definitive coding. It is also not uncommon to encounter cases in which the standard of care does not comprise testing which would be required to allow coding of the adjustor.

Two of the acute conditions, gastrointestinal hemorrhage and bacterial pneumonia, create most of the difficulty. These conditions are relatively numerous, may prompt hospitalization, or may complicate admission for another reason. The gastrointestinal hemorrhage adjustor requires specification of the anatomic source of bleeding, which would usually require upper and/or lower gastrointestinal endoscopy. Even with endoscopy, the diagnosis may not be definite, and endoscopy is not always appropriate, particular in frail and elderly patients with many co-morbid illnesses. Thus, the requirements for coding the gastrointestinal hemorrhage adjustor tend to promote testing which may not be necessary, and which will increase the cost of care.

The most challenging condition to document is bacterial pneumonia. The adjustor requires both an infiltrate on chest x-ray and a positive sputum culture result. The requirement that a radiographic infiltrate be present is consistent with generally accepted standards of pneumonia diagnosis. However, the requirement for a positive sputum culture is not consistent with the limited sensitivity of sputum culture in bacterial pneumonia. [Mandell LA, Wunderink RG, Anzueto A, et al. Infectious Diseases Society of America/American Thoracic Society consensus guidelines on the management of community-acquired pneumonia in adults. Clin Infect Dis 2007; 44 Suppl 2:S27.] Even if

sputum is available, antibiotics have often been administered before the specimen is obtained, further limiting its sensitivity.

The process for adjusting claims for acute conditions is more complex than for chronic conditions. Consider, for example, a hypothetical patient who has been receiving treatment at a DCI facility since February 3, 2011. The patient is admitted to a hospital with a suspected GI bleed on March 10. The facility begins the process of obtaining the appropriate documentation from outside entities at the time of discharge on March 14, and on May 4 finally receives the documentation to place in the facility chart to support this diagnosis. Because of the lack of documentation from outside entities, the facility does not add the modifier to the March or April bill. If, on May 4, the facility logs onto the Medicare Claims system for March, adds the diagnosis code, and resubmits the claim, the system will create billing errors because it does not currently automatically adjust payment for April and it is still unclear whether May and June will be paid correctly. Therefore, the only way to adjust these claims is through an appeal to the MAC. Because of these administrative burdens, many facilities are probably not requesting additional payment for patients with these two acute co-morbidities.

It is less difficult to adjust claims for chronic conditions than for acute conditions, but still complicated. For example, a patient with sickle cell anemia started treatment at a DCI facility on February 3, 2011. The facility began the process of obtaining the appropriate documentation from outside entities, and on April 4<sup>th</sup> finally received the documentation of sickle cell disease to place in the facility chart to prove this diagnosis. Because of the lack of documentation from outside entities, the facility did not add the modifier to the February or March claims. With documentation in hand, the facility logged onto the Medicare Claims system for February, added the diagnosis code and resubmitted the claim. This process was repeated for the March claim. In response to these changes, Medicare takes back the money already paid, and then makes payment for the February and March claims at a higher rate.

We suggest that to remedy the problems with acute co-morbid conditions, CMS should remove the culture requirement for pneumonia, and should allow a facility to apply the acute co-morbidity adjustor to the claim month in which the facility receives the documentation, not to the month in which the acute condition actually occurred.

## **B. Laboratory Related Issues**

We appreciate CMS' clarification that legitimate non-ESRD lab tests performed in emergency rooms, hospitals, and ambulatory surgical centers are not part of the ESRD PPS. These are the tests hospitals have been billing and continue to bill to our facilities in error.

The proposal to eliminate the 50/50 rule for the AMCC tests is welcome. However, the statement that, "[t]he elimination of the 50 percent rule for the ESRD PPS outlier payment policy with respect to the AMCC panel tests would result in the de facto treatment of those tests as composite rate tests" is problematic. Of the 23 AMCC tests, the original rule lists 12 AMCC tests that were part of the ESRD composite rate prior to January 2011. It is our opinion that the other 11 tests (total and direct bilirubin, cholesterol, CPK, glucose, gamma GT, LDH, AST/SGOT, ALT/SGPT, triglycerides, and

uric acid) should not be considered part of the composite rate (i.e. ESRD-related). These 11 tests are not routinely performed for evaluation of ESRD. From our experience so far under the ESRD PPS, we are seeing only two to five of the 11 tests ordered in the same month. It is rare to see all 11 tests ordered on one patient. We urge CMS to keep these 11 tests separately billable when appropriately justified and consistent with any NCD frequency guidelines, without applying any of the previous 50/50 modifiers (CD, CE, or CF), and to pay according to the existing ATP codes (\$82.75 CLFS amount if all 11 tests ordered vs \$9.71 for the 11 tests payment amount).

### **C. Antibiotic Treatments**

We agree with the proposal to allow facilities to receive separate payment for vancomycin by placing the AY modifier on the claim when vancomycin is furnished to treat non-ESRD related conditions. However, we also believe that a provider should receive separate and additional payment for all medications administered for a condition other than ESRD.

### **D. Proposed Revisions to the Outlier Policy**

We agree with the proposal that antibiotic drugs used at home to treat catheter site infections or peritonitis associated with peritoneal dialysis will qualify as separately billable and eligible as ESRD outlier services. Antibiotics furnished in facility would continue to be recognized as separately billable for ESRD outlier payment purposes.

We are still concerned that small providers may not have the necessary resources available to identify outliers and place them on their claims. We urge CMS to show data that this provision, which was established to help small providers, is in fact helping them. If small providers are not receiving outlier payments, then the provision is actually working to their detriment, since 1% was removed from the base rate to cover outlier payments. After reviewing requests for outlier payment in 2011, it may be best for the funds allocated for outlier payments to instead be made a part of the base rate.

### **E. Wage Index**

We request that the wage index floor be maintained for rural dialysis facilities. Rural facilities possess characteristics that result in higher cost. It is common for rural facilities to incur premium staffing costs, even exceeding the costs of operating in urban markets. In some instances, staff must be recruited from nearby large cities, and travel costs and wage premiums are paid to encourage employees to endure the long commutes. We are concerned that the proposed removal of this floor could aggravate disparities in care and may impair access to care in rural areas.

### **F. Cost Reports**

We believe the cost report form should be revised to capture all real cost data reflecting the full and reasonable costs of services related to the care of covered beneficiaries. Items that need to be added to the cost report form are medical director fees, currently non-covered items/services, and ESRD Network fees.

## V. Conclusion

Over forty years ago DCI opened one dialysis clinic in Nashville, Tennessee to provide life saving dialysis care to five patients. At the time, Medicare did not reimburse dialysis treatment; the only other outpatient dialysis facility in Middle Tennessee was a chronic unit at the Nashville Veterans Administration Hospital. Unless a living kidney donor was immediately available, a uremic patient died.

Medicare does now cover dialysis care, and DCI treats approximately 13,500 patients at 207 facilities in 27 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 non-profit service organization. The care of the patient is our reason for existence.

As an organization committed to provide the best patient care possible, we are concerned that CMS is proposing to remove the Hb < 10 measure. If this measure is removed, we fear that patient hemoglobins will drop, patient quality of life will be diminished, and patient mortality and hospitalization rates may increase. **We are concerned that patient quality of life will not be maintained to pre-bundle levels if the Hb < 10 measure is removed.**

Thank you for the opportunity to comment on the proposed QIP. Feel free to contact Doug Johnson at 615-342-0435 with any questions.

Sincerely yours,



H. Keith Johnson, M.D.  
Chairman



Douglas S. Johnson, MD  
Vice Chairman