KIDNEY CARE PARTNERS

August 25, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Room 445–G
Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1628-P: Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program

Dear Acting Administrator Slavitt:

On behalf of Kidney Care Partners (KCP), I would like to thank you for providing us with the opportunity to comment on the "Proposed Rule: End-Stage Renal Disease Prospective Payment System and Quality Incentive Program" (Proposed Rule). KCP is an alliance of members of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies that support the provision of high quality care for individuals with both chronic kidney disease (CKD) and End-Stage Renal Disease (ESRD). We appreciate the opportunity to provide comments on the proposals related to the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) that are part of the Proposed Rule. We have submitted our recommendations on the ESRD Quality Incentive Program (QIP) in a separate letter.

In sum, KCP would like to work with the Agency to improve this prospective payment system, but also has serious concerns about several of the proposals outlined in the Proposed Rule. As The Moran Company analysis of the proposed adjusters shows, the policy goals of making sure that beneficiaries have access to care are not being met by the proposals. If CMS is not able to address these concerns, then it should minimize the adjusters as described in detail below for PY 2016.

In addition, we firmly believe that the Congress did not intend for new drugs or biologicals to be added to the ESRD PPS without adjusting the payment rate, once it provides CMS with the authority to do so. However, we understand that the Congress has required CMS to set forth a process for determining when certain drugs are no long oral-only and for incorporating new injectables and biologicals into the ESRD bundle. As described in detail below, we are concerned that the process and the application of the overly broad proposed functional categories would result in no drug or biological ever qualifying for the proposed

adjustment. Without ensuring the economic feasibility of the payment rate (which includes adding new dollars to the payment rate when new items or services are added), it will be impossible to maintain economic viability of this single payment rate system or to incentivize innovation in a disease state that is in need of innovative solutions. We provide recommendations as to how a process for incorporating new drugs and biologicals could be structured to address our concerns.

I. KCP Supports Refining the PPS Adjusters and Recommends that CMS Include Only Those Adjusters that Serve a Policy Purpose.

Case-mix adjusters, when appropriately defined, may serve to protect beneficiaries. As CMS has described in the context of the home health agency (HHA) prospective payment system, "[a]djusting payment to reflect the HHA's cost in caring for each beneficiary including the sickest, should ensure that all beneficiaries have access to home health services for which they are eligible."[1] MedPAC has made similar statements, defining the purpose of adjusters as ensuring access to services. This statement articulates the basic payment policy that should underlie all payment adjusters.[2] Thus, when evaluating any adjuster, the first step should be to determine whether the adjuster serves the policy purpose of ensuring that beneficiaries have access to the services for which they are eligible.

Congress understood this policy-based rationale for adjusters when it established the ESRD PPS; some of which are mandatory and others of which are permissive. Specifically, the Congress requires CMS to "include a payment adjustment based on case mix that **may** take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors."[3] The Congress requires CMS to include an 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."[4] The Congress also mandates a low-volume adjuster[5] and authorizes "other payment adjusters as the Secretary determines appropriate" including a pediatric adjuster, a geographic index adjuster, and a rural adjuster.[6]

Therefore, while CMS must include some type of patient characteristic adjusters, the Congress did not mandate the specific type(s). CMS has discretion to

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[1]CMS, "Home Health PPS," *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/index.html?redirect=/HomeHealthPPS/ (last visited July 26, 2015).
[2]MedPAC, *Report to the Congress*, 154 (June 2012).
[3]SSA § 1881(b)(14)(D)(i).
[4]*Id.* at § 1881(b)(14)(D)(ii).
[5]SSA § 1881(b)(14)(D)(iii).
[6]SSA § 1881(b)(14)(D)(iv).

determine which adjusters meet the fundamental principle that they are necessary to ensure beneficiary access to ESRD services. Additionally, while the low-volume adjuster is mandatory, a rural adjuster is discretionary.

As described in detail below, KCP supports in concept some of the current adjusters, but because of data and methodological concerns, believes that CMS should establish an interim set of adjusters until it, in consultation with the kidney care community and other stakeholders, can identify a more appropriate data source, as well as address the problems with the regression analysis, which has remained basically unchanged since it was first used to establish the ESRD PPS in 2010. In determining which adjusters are appropriate, CMS should ask: Does the adjuster center on a patient or facility characteristic that without additional dollars would limit access to patients? Additionally for patient-level adjusters, evaluating both the clinical relevance and the cost of documenting a patient's condition to claim the adjuster are critical aspects of determining whether access to services could be limited without an adjuster.

A. As a Threshold Matter, KCP Recommends that CMS Provide Greater Transparency for the ESRD PPS.

In our letter dated July 10, KCP requested data, descriptions, and explanations with regard to the proposed modifications. Without this information, it is difficult to provide a complete analysis and offer the most constructive comments possible. This type of information is routinely provided to hospitals and home health providers with their proposed rules. It is unclear why ESRD facilities are treated differently. Our request for information has become an annual request since the first ESRD PPS proposed rule, unfortunately. Therefore, we strongly encourage CMS to provide the information requested in the July 10 letter with the publication of the proposed rule in coming years.

B. KCP Remains Concerned about Using Cost Reports as a Data Source and Maintaining the Previous Methodology To Identify and Calculate the Adjusters.

For the CY 2011 Proposed Rule, KCP raised a series of concerns about the types and values of adjusters that were proposed for the ESRD PPS. We specifically noted that:

- Many of the proposed adjusters could not be directly linked to costs of providing dialysis services;
- The adjuster variables were not independent of each other; and
- Cost report data used to develop adjuster values was not appropriate because it cannot be directly linked to any patient characteristic.

While we appreciate that CMS made some modifications in response to these comments, the Agency has not required the contractor to develop a more statistically sound and robust methodology to address these problems going forward. In addition, it appears that the contractor continues to rely upon cost reports, which still do not contain appropriate data to link costs to patient characteristics.

In previous comment letters, KCP has expressed concern that the use of the current methodology, which does not accurately predict the cost of providing services, and the lack of an update to the budget neutrality standardization factor have led to adjusters that function not to ensure access to care, but rather jeopardize economic stability of providers by inappropriately functioning as a cut to the program. Comparing the 2014 final rule Impact File projected spending for 2014 and the actual spending in 2014 from the 2016 Proposed Rule Rate Setting File, The Moran Company found that CMS underpaid dialysis facilities by an average of $2.29 per treatment. These dollars are lost forever from the system and essentially amount to an inappropriate reduction in the payment rate. The Moran Company describes the losses to the base rate in the chart below.

Year	Total Underpayment 2011 - 2014	2011	2012	2013	2014
Provider Count[1]		4,820	5,036	4,987	4,987
Total Medicare Treatments[2]		*41,929,867*	*43,256,346*	*43,943,048*	*37,415,318*
Total Underpayment / Tx		7.11	5.38	5.18	2.29
Underpayment of PPS per Tx		6.09	3.57	4.46	2.01
Underpayment of Outlier Pool per Tx		1.02	1.81	0.72	0.28
Total Underpayment	$ 844,146,571	$ 298,121,357	$ 232,719,144	$ 227,624,991	$ 85,681,079
Underpayment of PPS	$ 680,968,835	$ 255,352,893	$ 154,425,157	$ 195,985,996	$ 75,204,789
Underpayment of Outlier Pool	$ 163,177,736	$ 42,768,465	$ 78,293,987	$ 31,638,995	$ 10,476,289

1. Providers found on both ESRD Final Rule Impact File and in SAF data.
2. Tx counts for 2011 - 2013 from CMS Outpatient SAF for 72x Claims, 2014 from partial year data from rate setting file.

Under the proposals in the CY 2016 Proposed Rule, the budget neutrality standardization factor is increased to almost 10 percent reflecting unnecessary adjusters and a proposal to increase the size of the patient age adjuster. This proposal will only increase the loss of dollars from the program.

While we had hoped that in revisiting the adjusters, CMS would have developed an alternative data source for patient characteristic data, as well as revised the methodology to address the concerns raised by KCP and others in previous letters, we understand that these changes are unlikely to take place before CY 2016 policies are finalized. To that end, KCP recommends that CMS commit to working with the community to develop a transparent and appropriate methodology, as well as identify and use more appropriate data sources. CMS should use cost report data only to calculate the facility level adjusters, such as the low-volume adjuster. Information about age, weight, and the onset of dialysis can appropriately come from the claims data to identify patients, but there are currently

no appropriate sources of data for calculating the values of these adjusters or identifying the other patient characteristic adjusters.

As CMS revises the adjusters, as we propose below, it should also update the budget neutrality standardization factor to ensure its accuracy. Without the additional information requested in the July 10 letter, the current explanation of the refinement adjuster that reduces the base rate does not provide sufficient information to determine the relationship between the previous standardization factor and the added refinement adjuster. It is unclear whether CMS used the actual frequency of adjusters applied to the 2013 claims to derive a standardization factor that is the sum of the previous standardization factor and the new refinement adjuster. It is critically important that CMS provide greater transparency as to both the standardization factor and the refinement adjuster.

Given The Moran Company's analysis (see Appendix B) of the adjusters and the fact that they are not paid out at expected levels, KCP is concerned that the budget neutrality adjustments have preserved an artificially and inaccurately high standardization factor that reduces the overall program budget below that prescribed by MIPPA as the basis for budget neutrality for the entire system. Thus, consistent with the comments below, CMS should provide greater transparency and also recalculate the standardization factor prior to implementing the final rule. In addition, KCP also recommends that CMS recalculate the budget neutrality standardization factor each year based on the actual prevalence of all adjusters in the most recent year of data.

C. KCP Recommends that CMS Refine the Current Set of Patient Characteristic Adjusters.

The American Taxpayer Relief Act (ATRA)[7] requires that CMS undertake the review of the patient characteristic adjusters. We are especially pleased that CMS has proposed to eliminate two of the comorbidity case-mix adjusters: bacterial pneumonia and monoclonal gammopathy. We also support the continued use of the onset of dialysis adjuster. However, we remain concerned about the methodology and data the contractor has used in its review that results in proposals that are deeply flawed.

Based upon both clinical experience and concerns about the methodology, we recommend that CMS retain the current age adjuster and payment multipliers, rather than adopt the proposed modifications. The continued use of both BMI and BSA is problematic because they in essence cancel each other out, and KCP recommends an interim proposal to address this problem in CY 2016. We also believe that the other comorbidity case-mix adjusters have problems similar to

[7]ATRA, Pub. L. No. 112-240, § 632(c) (42 U.S.C. § 1395rr note).

those of the two comorbidity adjusters that CMS proposes eliminating and, thus, should also be removed from the ESRD PPS.

1. While Age May Predict Higher Facility Costs, the Proposed Modifications to the Current Adjuster and Payment Multipliers Does Not Align with Clinical Experience.

Age is one of the patient characteristics for which CMS has the discretionary authority to establish an adjuster.[8] KCP recommends that CMS retain the current (CY 2015) age adjuster categories and payment multipliers for CY 2016 while working with the community and other stakeholders to identify a better methodology and data source to evaluate an age adjuster. In discussing the patient characteristic of age with the physician, nurse, and other health care professional organizations within KCP, there is a general belief that older patients have more complications and may require the use of additional labor and resources. However, it is also clear that there is not a good data set that correlates age to higher facility costs.

CMS proposes to modify the age adjuster and set the reference group at ages 70-79. The current (CY 2015) payment multiplier reference group is set at 60-69. Based upon its mostly unchanged regression analysis, the contractor has determined that the 70-79 age group does not incur significantly higher costs than other age groups. Under the proposed modifications, facilities would receive 7 percent ($16.23) more for patients who are 60-69 years old and 11 percent ($24.58) more for patients 80 years and older. Yet, there would be no adjustment for those patients who are 70-79 years old. This result implies that patients 70-79 years old require fewer services and items than those in the other age groups. This conclusion does not align with the experience of clinicians caring for dialysis patients. In fact, the choice of the 70-79 group as a reference with no adjustment appears to be a requirement of the statistical method and is not based on actual cost variation with age.

In addition, the proposed modification would add substantially more dollars into the age adjuster. The Proposed Rule would increase the estimated payment for the age adjuster from $7.47 per treatment to $19.36 per treatment.

[8]SSA § 1881(b)(14)(D)(i).

Table 1: Total Dollar Amounts Associated with Patient Adjusters for Age in the ESRD PPS 2015 Final Rule and ESRD 2016 Proposed Rule Analysis Limited to Facilities that Did Not Choose the Three Year Transition and to Adults

		Estimated Payment for Adjusters from CY 2015 Rule				Estimated Payment for Adjusters from CY 2016 Proposed Rule			
Age Band	Treatments	Adjusters from 2015 Rule	Total	Dollars per Treatment for Patients in Age Band	Dollars per Treatment	Adjusters from Proposed Rule	Total	Dollars per Treatment for Patients in Age Band	Dollars per Treatment
Total	**37,893,299**		**$ 282,951,456**		**$ 7.47**		**$ 733,767,960**		**$ 19.36**
18-44	5,010,677	1.171	$ 209,637,651	$ 41.84	$ 5.53	1.257	$ 293,513,401	$ 58.58	$ 7.75
45-59	10,828,558	1.013	$ 34,876,469	$ 3.22	$ 0.92	1.068	$ 173,036,285	$ 15.98	$ 4.57
60-69	9,888,573	1.000	$ -	$ -	$ -	1.070	$ 160,499,393	$ 16.23	$ 4.24
70-79	7,823,356	1.011	$ 21,338,257	$ 2.73	$ 0.56	1.000	$ -	$ -	$ -
80+	4,342,134	1.016	$ 17,099,079	$ 3.94	$ 0.45	1.109	$ 106,718,881	$ 24.58	$ 2.82

Source: 100% Medicare Standard Analytical Files (SAFs), January 2013-December 2013.

There are no data that validate this 159 percent increase in the average adjuster value. CMS has not provided, and KCP has not been able to identify, any reason for this substantial difference. The age distribution of the dialysis population has changed very little when comparing the 2009 age mix (which was used to finalize the 2011 base rate) to that in 2013. Similarly, there is very little difference in separately billed services by age category in 2013 data, reflecting the decrease in use of ESAs and some other drugs since 2011. There have been no concerns expressed about limited access to dialysis services for any of the age groupings. Thus, it is unclear and in fact appears inappropriate to modify the age adjusters as proposed.

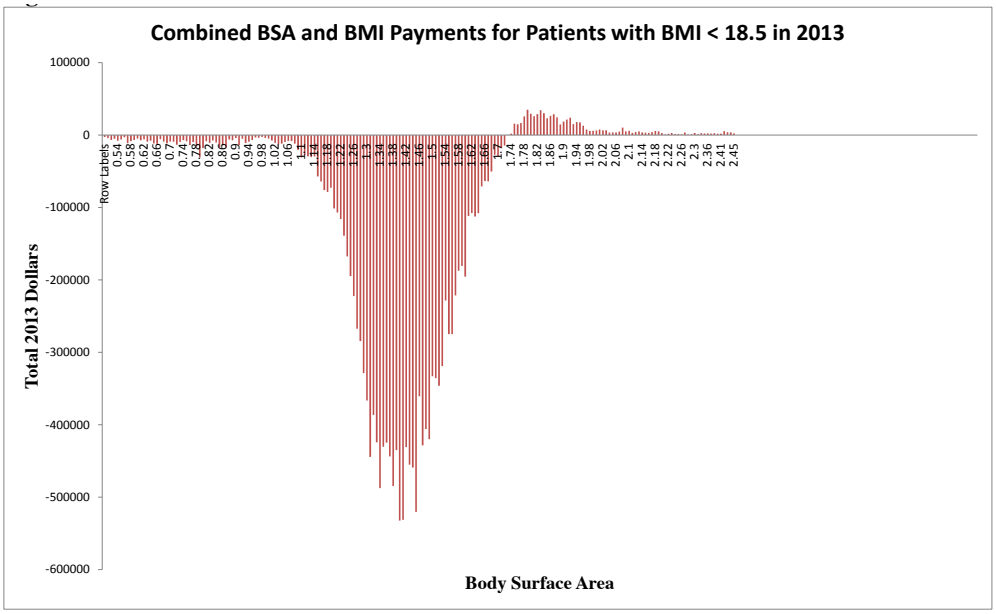
The problems with the proposed age adjuster strongly suggest that there is something wrong with the regression analysis. The Moran Company has raised concerns about using a regression analysis to determine the relationship between age and facility costs, as well as with using cost report data to establish an association of age and composite rate costs. They have found only a very limited association of age with separately billable costs. The result of the use of the age adjuster essentially randomizes payment, rather than targeting payments to patients with specific characteristics associated with higher costs.

Rather than implement the proposed modifications that are based upon inadequate data and a flawed methodology, KCP recommends that CMS work with the kidney care community and other stakeholders to identify an appropriate source of data to capture the cost of patients at various ages and revise the methodology. KCP is committed to working with CMS in this process. In the meantime, CMS should retain the CY 2015 age categories and payment multipliers.

2. Even Though a Patient's Weight May Predict Higher Facility Costs, the Current Adjusters Cancel Each Other Out and Fail To Achieve the Policy Goal.

Body Mass Index (BMI) is one of the patient characteristics for which CMS has the discretionary authority to establish an adjuster.[9] KCP supports an adjuster(s) to account for patient weight for the ESRD PPS, but has concerns about the interaction of BMI with the other weight-related adjuster, the Body Surface Area (BSA). In discussing the patient characteristic of weight with the physician, nurse, and other health care professional organizations within KCP, there is a general sense that physicians rely more often on the BMI to adjust patient treatments. BSA is important for evaluating overweight patients. However, as currently designed these adjusters cancel each other out for underweight patients and do not achieve the goal of addressing higher costs for patients with these characteristics.

BMI and BSA are both variables for the same patient characteristic. As such, they are highly correlated and should not function as independent variables in a regression analysis because they essentially measure the same thing. Patients who are underweight and qualify for a positive adjuster for low BMI are also subject to a BSA adjuster, which applies to all patients, including those with a low BMI. The BSA adjuster for low BMI patients is negative and offsets almost all of the benefit of the positive low BMI adjuster.



In this figure, the vast majority of patients with low BMI (lines below the $0 line) receive reduced payments because the BSA adjuster eliminates the value of the BMI

[9]SSA § 1881(b)(14)(D)(i).

adjuster. Only the very small number of patients with low BMI (shown above the line) are eligible for any net positive adjustment.

One reason for this problematic result is that the BSA adjuster assumes that cost increases with body size on a continuum. An alternative could be to focus on patients who are overweight and underweight. Clinicians have indicated these characteristics do require more staff time and, for overweight patients, different supplies or equipment may also be necessary. Because the BSA adjuster as currently designed applies to all patients, it does not meet the policy goal of recognizing the point at which body size results in higher staffing costs or specialized equipment.

Thus, rather than continue adjusters that cancel each other out, KCP recommends as an interim step for CY 2016 that CMS rely upon the adjusters related to underweight patients and those who are overweight. Specifically, CMS should rely upon the current (CY 2015) low BMI adjuster to address underweight patients and establish a high BMI adjuster to address overweight patients. The threshold for determining a high BMI would be tied to the National Institutes of Health guidelines for defining overweight patients using BMI. The current guidelines define overweight patients as having a BMI of 25.0 or greater. The BSA adjuster would be eliminated for purposes of this interim proposal. In addition, CMS would need to determine the amount of dollars for these adjusters by recalculating the values based upon the new parameters. To do this, KCP recommends that CMS take the CY 2015 dollars for the BMI and BSA adjusters and divide them equally over the low BMI and high BMI adjuster we propose for CY 2016. During this period, KCP would like to work with CMS and the contractor to identify a better approach that would allow the weight of patients to be incorporated into the patient level adjusters.

3. KCP Continues To Support the Use of the Onset of Dialysis Adjuster.

KCP supports CMS's proposal to continue including the onset of dialysis adjuster for the ESRD PPS. We agree that when patients first begin dialysis, they often require additional resources. Given our other recommendations in this letter regarding adjusters, we urge CMS to recalculate the payment multiplier for this adjuster and appropriately adjust the budget neutrality standardization factor.

4. KCP Supports the Proposal To Remove Two of the Comorbid Case-Mix Adjusters and Recommends that CMS Remove the Other Four Because of Similar Concerns.

The comorbid case-mix adjusters are patient characteristics for which CMS has the discretionary authority to establish an adjuster; the statute does not

mandate their creation or application.[10] KCP supports the Agency's proposals to eliminate the bacterial pneumonia and monoclonal gammopathy case-mix adjusters. Despite the results of the regression analysis, CMS has correctly also evaluated these adjusters in terms of their burden on facilities and patients. As noted previously, for patient-level adjusters, evaluating both the clinical relevance and the cost of documenting a patient's condition to claim the adjuster are critical aspects of determining whether access to services could be limited without an adjuster. When applying these criteria, it becomes clear that the remaining four comorbid case-mix adjusters should also be eliminated.

The remaining four comorbid case-mix adjusters do not serve a policy purpose. In the final rule for CY 2011, CMS stated that "[t]he purpose of the co-morbidity adjustments is to provide added payment for those co-morbid diseases that result in higher dialysis costs."[11] Consistent with further statements in other payment systems, CMS presumably cares about addressing higher-cost patients to ensure they have access to medically necessary services. There is no indication that patients with any of these comorbid conditions have difficulty accessing care.

Access concerns related to patients with these comorbid conditions may have arisen in 2010 because these conditions often require greater amounts of ESAs. The Agency noted in the CY 2011 final ESRD PPS rule that "[o]ur analysis has identified certain co-morbidity diagnostic categories that have shown higher use of separately billed renal dialysis items and services, which are recognized for a payment adjustment under the ESRD PPS."[12] In this year's Proposed Rule, CMS acknowledges that "the costs were identified with increased utilization of ESAs and other services."[13] Clinical practice has changed significantly since the data used to establish these comorbid case-mix adjusters were collected and analyzed. Due in large part to changes in labeling requirements by the Food and Drug Administration, the utilization of ESAs has declined. In addition, the number of patients with these conditions is extremely small. Taken together these facts do not support the need for the comorbid case-mix adjusters.

In addition, the documentation requirements outlined in the Benefits Policy Manual for pericarditis, gastrointestinal tract bleeding with hemorrhage, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome create the same overly burdensome requirements that CMS has recognized for bacterial pneumonia and monoclonal gammopathy. The burden on facilities and, in some instances, patients make the cost of documenting the requirements greater than any potential benefit a facility might receive from claiming the adjuster.

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[10]SSA § 1881(b)(14)(D)(i).
[11]75 *Fed. Reg.* 49030, 49098 (Aug. 12, 2010).
[12]*Id.* at 49100.
[13]Display Copy pg. 43.

Part of the reason these comorbidities may have been determined to be higher cost to facilities, when they in fact do not change facilities cost in a substantial way, is that the contractor may have relied upon cost report data. This data source is not appropriate to use for this type of analysis because the data cannot be linked directly to any patient characteristics. We are also concerned that the regression analysis methodology relies upon variables that are not in fact independent of one another, but are treated as if they are. Without addressing these short-comings, it is not surprising that the contractor found a higher cost in areas where those who work in the community do not see higher costs.

Given the dramatic change in ESA utilization, as recognized by the Congress and the Agency, and the problems with using the current methodology and cost report data, KCP recommends that CMS reconsider the necessity of all of the comorbid case-mix adjusters. Simply put, with this decrease in drug utilization and given the experience of those working in the community, we believe that the outlier pool, which has otherwise not paid out as predicted, can better address the costs associated with the few patients who have these comordities, while limiting the documentation burden on facilities and patients.

a. Pericarditis

Pericarditis is the inflammation or swelling of the thin sac-like membrane surrounding the heart. This condition is one that can occur suddenly and rarely lasts long. Only a small number of patients receiving dialysis experience this condition. While patients may report atypical chest pain and nephroloists may listen to the patient's heart for the pericardial friction rub, nephrologists rarely require patients to incur the cost of having an electrocardiogram before simply treating the condition based upon the patient's report and listening to the patient's heart.

Yet, to document this condition, the Benefits Policy Manual requires "suggestive electrocardiogram changes (*e.g.*, widespread ST segment elevation with reciprocal ST segment depressions and PR depressions) not previously reported" in addition to listening for the pericardial friction rub. Thus, as with the bacterial pneumonia, the documentation requirements are inconsistent with current diagnostic practices. Because of this fact and the small number of patients with the condition and its short duration, KCP recommends that CMS eliminate the pericarditis comorbid case-mix adjuster and allow facilities to rely upon the outlier policy for those patients who may incur higher costs because of this condition.

b. Gastrointestinal (GI) Tract Bleeding with Hemorrhage

While GI tract bleeding may account for the greater use of some drugs or biologicals, the cost of meeting the current documentation requirements exceeds any potential benefit that this adjuster might provide. In speaking with nephrologists, it is clear that while many patients may experience GI bleeds, the treatment protocol is to treat to the condition rather than require patients to receive one of the expensive tests the Benefits Policy Manual sets forth. Few dialysis patients obtain an endoscopy, colonoscopy, adionuclide scan, or radionuclide imaging, and/or angiography to confirm the condition. Even if a patient does undergo one of these procedures, it can be difficult to identify the actual clumping of the arteries that cause the bleed. Additionally, once a patient has had one of these procedures, it is unlikely that a nephrologist would order a second or third one simply to confirm what he/she already knows has likely occurred again. Thus, for the same reasons that CMS proposes to remove the monoclonal gammopathy comorbid case-mix adjuster (documenting it requires patients to undergo procedures they otherwise would not), CMS should eliminate the GI bleeding comorbid case-mix adjuster. Facilities that experience higher costs related to patients with this condition can instead rely upon the outlier policy.

c. Hereditary Hemolytic or Sickle Cell Anemia

While recent studies have shown that hereditary hemolytic or sickle cell anemia result in higher ESA utilization, this condition is present in a small percentage of the ESRD population[14] and the current documentation requirements do not align with clinical practice. Nephrologists monitor patient hemoglobin levels to determine the dosing of ESAs. While it may be of interest to know definitively whether a patient has hereditary hemolytic or sickle cell anemia, the fact that a patient requires more ESA to maintain target hemoglobin levels is independent of the specific diagnosis. Thus, rather than require patients who do not already know their status to undergo one of the tests outlined in the Benefits Policy Manual, nephrologists focus on managing the patient's anemia. Thus, it becomes extremely difficult, if not impossible, for facilities to meet the documentation requirements for this condition. An approach that is more consistent with clinical practice would be to rely upon the outlier policy to address the higher costs.

d. Myelodysplastic Syndrome

The extremely few dialysis patients with myelodyspastic syndrome (MDS) are battling not only kidney failure, but also a potentially fatal blood cancer. In

[14]Vimal K. Derebail, Eduardo K. Lacson, Jr., Abhijit V. Kshirsagar *et al.*, "Sickle Trait in African-American Hemodialysis Patients and Higher Erythropoiesis-Stimulating Agent Dose" J. Am. Soc. Neph. (Jan. 23, 2014)(published online).

caring for these patients, nephrologists focus on keeping them from being uremic. Patients will indicate that they have MDS, but very few oncologists or hospitals are willing to provide dialysis facilities with the documentation of the biopsy necessary to meet the requirements of the Benefits Policy Manual and it would be wasteful to order a second biopsy merely to establish this case-mix adjuster. Given the small number of dialysis patients with MDS and the difficulties in documenting the disease, we recommend that CMS eliminate the comorbid case-mix adjuster and instead rely upon the outlier policy.

D. KCP Supports the Continuation of Including a Low-Volume Adjuster, and the Modified Criteria Set Forth in the Proposed Rule, but Cautions against Including a Rural Adjuster and Recommends Instead Expanding the Low-Volume Adjuster.

The Congress mandated that CMS include a low-volume facility adjuster as part of the ESRD PPS. This adjuster seeks to address the costs associated with facilities that do not serve large enough patient populations to benefit from economies of scale. We remain concerned that CMS has not provided more detailed information about the methodology used to determine the low-volume adjuster, but we do agree that cost report data is an appropriate data source. KCP supports the modifications CMS has proposed to the low-volume adjuster that address some of the concerns raised by the GAO, as well as the kidney care community.

The low-volume adjuster recognizes that smaller patient populations increase the cost of providing service in both rural and urban areas. Before implementing a rural adjuster, CMS should ensure that it does not overlap with the low-volume adjuster. Low volume and rural status are not independent variables and relying upon a regression analysis to generate their values is inappropriate. While it might be possible to calculate the low volume adjuster first, then remove those facilities, and calculate a separate rural adjuster, a better approach would be to increase the threshold of treatments and expand the low-volume adjuster. We believe that this approach would be more consistent with the principles that MedPAC set forth in its June 2012 *Report to the Congress*.

In that report, MedPAC identified few differences among urban and rural populations. As the preamble to the Proposed Rule notes, MedPAC has considered the need for adjusters in rural areas. MedPAC has indicated that:

> A key objective of rural payment adjusters is to maintain access to care. Areas with low population density may have only one small, low-volume provider. In these cases, costs may be above traditional PPS rates because the low population density prevents economies of scale, and the low volume and high costs may be beyond the providers' control. Special

> payments by federal or local sources may be needed to maintain access to care in these communities.[15]

In this report, MedPAC criticized rural adjusters as often being too broad and recommended a more targeted approach: "Payment adjusters should be targeted to providers that are necessary to preserve beneficiaries' access to care."[16] Of particular interest to the Commission is the use of low-volume adjusters. Maintaining specific distance requirements, which CMS has established for the ESRD low-volume facility adjuster, is a critical component of MedPAC's recommendation.[17] In evaluating the then current rural adjusters, MedPAC noted:

> In general, most adjusters succeed in increasing payments to rural providers, which is important for keeping access to care in certain isolated areas (Medicare Payment Advisory Commission 2005). However, the programs are rarely targeted to isolated providers, and in some cases the magnitude of the payment is not empirically justified.[18]

To be consistent with MedPAC's more targeted approach, KCP recommends that CMS rely upon a two-tiered low-volume adjuster policy. The current low-volume adjuster (as modified by CMS in the Proposed Rule) would constitute tier one. As an interim step (before the methodology for adjusters can be addressed fully), the dollars for this adjuster should be set at the CY 2015 level.

Rather than adopt a less-specific rural adjuster, CMS could create a second low-volume adjuster. As an interim step, CMS should use the dollars allocated in the Proposed Rule for the rural adjuster for this second tier low-volume adjuster. This second tier adjuster would apply to facilities with 4,001-6,000 treatments per year. The other low-volume adjuster requirements would also apply.

We believe that the 4,001-6,000 range is appropriate based upon an analysis prepared by The Moran Company. While it is not possible to replicate the geographic isolation criteria, The Moran Company was able to perform an analysis of the 2013 cost report data to show the distribution of low treatment volumes in relation to facilities' margins. Based upon this analysis, it is clear that facilities with 4,001-6,000 treatments per year also experience significantly negative margins per treatment and rural facilities with more than 6,000 treatments generally exhibited normal Medicare margins, making it inappropriate to provide them with a low-volume adjustment. This second tier low-volume adjuster would allow CMS to

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[15] MedPAC, *Report to the Congress*, 154 (June 2012).
[16] *Id.*
[17] *See id.* at 155.
[18] *Id.*

target the dollars directly to those facilities that struggle because of a smaller patient base.

E. KCP Supports Patient Access to All Modalities

KCP feels it is important to reiterate the community's support for ensuring patient choice and informed decision-making as patients seek treatment for kidney disease and kidney failure. One important decision patients must make is which dialysis modality is best suited to their needs. KCP believes that patients must have access to the full range of treatment modalities, including home-based and in-center options. KCP also believes that it is important to address barriers to patient access to preferred modalities, including home dialysis. However, KCP does not support removing funds from the base payment rate to address these issues, as those funds are crucial to ensuring that high quality care is available to all patients.

II. KCP Recommendations Regarding the Standardization Factor, Outlier Policy, and Wage Index.

A. KCP Urges CMS To Recalculate the Standardization Factor and the Base Rate To Account for the KCP Recommended Changes to the Adjustors; CMS Should also Adjust the Standardization Factor Each Year.

KCP is deeply concerned by the reduction of the base rate for CY 2016. Consistent with our concerns about the lack of transparency described in Section I, the Proposed Rule does not contain sufficient information to determine the relationship between the previous standardization factor and the added refinement adjuster. For example, it is not possible from the preamble to determine whether the contractor used the actual frequency of adjusters applied to the 2013 claims to derive a standardization factor that is the sum of the previous standardization factor and the new refinement adjuster. It does appear that the significant reduction in the base rate is due to the inappropriate increase in the age adjuster. Therefore, we strongly recommend that CMS recalculate the standardization factor and base rate by taking into account the changes in the adjusters that KCP has recommended in Section I. In addition, it would be extremely helpful if CMS would include with the final rule sufficient information to allow the community and other interested parties to understand the interaction of the standardization factor and the new refinement adjuster.

Additionally, KCP strongly recommends that CMS recalculate the standardization factor annually. This approach would allow CMS to update the standardization factor using the most currently available data. As The Moran Company has shown in the past, the standardization factor becomes a source of dollars being inappropriately removed from the payment system if it is not adjusted

to take into account the actual prevalence of the adjusters each year. Therefore, we think that it is imperative to recalculate the standardization factor for each calendar year to protect the integrity of the payment system.

B. KCP Recommends that CMS Rely upon the Outlier Adjuster Instead of Reducing the Base Rate through the Comorbid Case-Mix Adjustors.

Historically, KCP has raised concerns about the fact that the outlier expenditures have not met the one percent target. To this end, we have recommended setting it at zero. However, we do believe that the outlier policy could be useful to address high costs related to certain dialysis beneficiaries. As we describe in Section I.C.4., we recommend that CMS eliminate all of the comorbid case-mix adjusters and instead rely upon the outlier adjuster to fine-tune the payment to facilities caring for the small number of beneficiaries who may incur higher costs. This would ensure that facilities experiencing higher ESA costs for certain patients would be appropriately compensated, while preserving the base rate to cover the costs associated with the vast majority of patients.

C. KCP Supports the Wage Index Proposals.

KCP continues to support the methodology for determining the wage indices and the continued application of the wage index floor of 0.4000 to areas with wage index values below the floor.

III. KCP Recommends Narrowing the Functional Categories of ESRD Drugs and Biologicals, as well as Revisions to the Process Outlined in the Proposed Rule for Incorporating New Injectable or Intravenous Drugs and Biologicals into the ESRD PPS.

As described in detail in our comment letter from last year, KCP continues to have concerns about the authority to incorporate new injectable and intravenous (IV) drugs and biologicals into the ESRD PPS. We reiterate those concerns here and note that KCP believes that CMS does not have broad authority to incorporate new drugs and biologicals into the ESRD PPS, as has been indicated in the Proposed Rule. Additionally, the Congress did not intend for the Agency to add new items or services to the bundle without increasing the overall Medicare spending for ESRD.

We also recognize that in the Protecting Access to Medicare Act of 2014 (PAMA), the Congress mandated that as part of the CY 2016 rulemaking CMS "establish a process for—(1) determining when a product is no longer an oral-only drug; and (2) including new injectable and IV products into the bundled payment

under such system."[19] In doing this, KCP appreciates that CMS has taken into account the principles the kidney care community set forth in our comment letter last year.

We are concerned about the overly broad definitions of the functional categories and the proposal to categorize injectable and IV drugs and biologicals as within the bundle if they seem to fit into one of the functional categories when launched. It is even more concerning that the preamble states that new categories will be added if the current broadly defined categories do not incorporate new injectable and IV drugs or biologicals. These policy choices would result in no such drug or biological being defined as "new," which is inconsistent with the Congressional interest in establishing a process for "including new injectable and intravenous products into the bundled payment."

Additionally, CMS may consider itself to be under a constraint to apply the concept of budget neutrality within the ESRD PPS given current Office of Management and Budget (OMB) policies. The ESRD statute itself requires that budget neutrality apply only in 2011, during the first year of the ESRD PPS.[20] The Congress did not apply a budget neutrality policy to any subsequent payment year. Given the clarity of the statute, we do not believe that the Congress intended for the Agency to add new items or services to the bundle without increasing the overall Medicare spending for ESRD. In other words, the Congress has not required CMS to reduce spending on currently bundled items and services when it adds new items or services to the bundle.

In fact, unlike statutes authorizing other prospective payment systems, MIPPA does not provide an express mechanism for incorporating new injectable and IV drugs or biologicals to the bundle and adding new – not budget neutral – dollars to the payment system. The lack of a clear statutory policy related to expanding the bundle is likely because the Congress did not contemplate that the ESRD bundle should be expanded to include new injectable and IV drugs and biologicals beyond ESAs. Thus, the proposed methodology to incorporate new drugs and biologicals into the ESRD PPS should not be implemented.

If the process that the Congress has asked CMS to describe in PAMA were authorized to be implemented, it is essential that it be done in an economically feasible manner to ensure that all services are adequately funded. Without ensuring the economic feasibility of the payment rate (which includes adding new dollars to the payment rate when new items or services are added), it will be impossible to incentivize innovation in a disease state that is in need of innovative solutions. Continued investment in innovation will depend on the availability of appropriate

[19] PAMA § 217(c).
[20] 42 U.S.C. § 1881(b)(14)(A)(ii).

reimbursement for using advanced therapies. In addition, lack of adequate payment to recognize new therapies will diminish the ability of facilities to use them and in turn denying patients' timely access to them. This history of the ESRD payment system demonstrates how little innovation has occurred, unless the item or service had been designated as separately billed. There have been fewer than five novel ESRD therapies approved in the last decade, whereas advancements in phosphate binding therapies have been significant. This difference might quite possibly be related to the reimbursement of these treatments outside of the current PPS.

While it is laudable that CMS proposes a mechanism for adding new items to the ESRD PPS, the proposed construct would diminish the ability for any new ESRD products in development to qualify for the transitional payment. Therefore, we urge CMS to refine the approach as outlined below and apply the transitional payments even if new products at launch would suggest that they be classified in one of the functional categories. Without a change in the proposed policy, patient access to new technologies will be severely limited.

In addition, it is important to recognize that the ESRD PPS is unique in the Medicare program. It is the only payment system that is based on providing a single set of services. Just as other providers have a mechanism to evaluate new items before they are added to their bundles, so should dialysis facilities. The Congress did not intend dialysis facilities to absorb increases in cost within a budget neutral way. The ESRD PPS by design cannot function in this manner. This structural difference makes the ESRD PPS particularly vulnerable if new and costly items or services are added to it and a budget neutrality construction is applied.

Therefore, the KCP recommendations related to the process for incorporating new injectable and IV drugs and biologicals into the ESRD PPS seek to provide CMS with a clear policy pathway for recognizing the unique nature of the ESRD payment system and providing a method for evaluating such new drugs and biologicals under Part B until there is sufficient information to determine their use within the ESRD program.

A. KCP Recommends Refinements to the Process for Incorporating New Injectables and IV Products into the ESRD Bundle.

CMS has set forth a framework for adding new injectables and IV products to the ESRD bundle consistent with its statutory obligation. We are deeply concerned, however, that the proposal that would place an injectable and IV drug or biological into the bundle based upon a conclusion made when such a drug or biological is launched, rather than after data about the utilization and cost are gathered, would result in virtually no drugs or biologicals being defined as new. Perhaps more importantly, it would inappropriately place CMS in the position of making a clinical judgment – namely, that a particular injectable and IV drug or biological will be

related to the treatment of ESRD – before clinical professionals using medical judgment have made that determination.

When trying to determine whether an injectable and IV drug or biological is added to the bundle, CMS will need to determine whether it is substantially similar to a drug currently paid within the ESRD bundle. For example, a generic of a current drug could be added to the bundle without a transition period. If, however, an injectable and IV drug or biological is not substantially similar to an existing drug or biological, the process for incorporating new injectable or IV drugs and biologicals into the bundle should ensure that the bundle payment rate will be adequate to cover the cost of the new item being added to the bundle.

As a threshold matter, we strongly urge the Agency to state clearly in the final rule that any decisions related to adding a new drug or biological to the ESRD bundle, as well as items believed to be substantially the same as other drugs or biologicals currently in the bundle, be presented through notice-and-comment rulemaking with complete and transparent data to allow all interested stakeholders to evaluate the proposals before they are finalized. While we acknowledge that there may be a gap between the launch of a drug or biological and a final rule, we strongly recommend that CMS use an interim rulemaking process or allow the item to be paid for separately outside of any ESRD budget neutrality construction until the rulemaking process can be completed. We do not believe that such substantive changes in policy and payment rates should be adopted through sub-regulatory guidance.

1. KCP Strongly Urges CMS To Rely upon the Same Process for all New Drugs and Biologicals unless They Are Substantially the Same as Drugs or Biologicals Currently Reimbursed under the ERSD PPS Payment Rate.

While KCP agrees with the process that new injectable and IV drugs and biologicals should be transitioned into the ERSD bundle over a defined period of time, we are concerned that the Proposed Rule outlines an approach that would define a drug or biological as new only if it did not already fall within one of the ESRD functional categories. It is not appropriate to add such drugs and biologicals to the bundle without first learning about their utilization patterns or their costs and without adjusting the payment rate in a non-budget neutral manner. The proposed distinction makes it extremely unlikely that any injectable and IV drug or biological would be considered new and creates a disincentive for developing innovative products for ESRD patients. It also presumes that CMS can exercise clinical judgment as to what drugs or biologicals will be related to the treatment of ESRD even before the majority of clinical professionals have had the opportunity to use them.

We appreciate that the outlier policy could address some of the costs associated with these new injectable and IV drugs or biologicals that would be defined as within an existing ESRD functional category, but relying upon the outlier pool alone is not sufficient. First, the outlier pool does not make providers whole, but rather only covers a portion of the costs that are above a certain threshold. Second, it would be extremely difficult to set the outlier pool at the appropriate level without first knowing the utilization patterns and the cost of an item. Finally, the purpose of the outlier pool is to address the small number of patients who may require additional items or services. It would be inappropriate to use it to offset the costs associated with a new drug or biological that a substantial portion of ESRD patients may require.

A better approach would be to address all new injectable and IV drugs and biologicals using the same methodology. Under this approach, CMS would add a new drug or biological to the bundle only after a transition period during which its utilization and costs would be determined. During this period, the drug or biological would be paid at ASP+6 percent under Part B, not as an ESRD service. There should also be an opportunity to extend this period if CMS does not believe it has sufficient information about cost and utilization.

At the end of the transition period, CMS would have sufficient information to determine whether the drug or biological fits within the ESRD functional categories. As part of this determination, CMS should review the utilization data. If the item has a very low frequency utilization and very high price with no alternatives or substitutes, it should be excluded from the bundle in the way that other high cost, but low frequency items are.

Once it is clear that an injectable and IV drug or biological is appropriate to add to the bundle, CMS would value the cost of the item (determined at the time the item is added to the bundle and based upon the Part B (not as an ESRD service) and beneficiary coinsurance costs) and add that amount without application of the budget neutrality construct to the base rate.

Any new drug or biological that does not come within an existing ESRD functional category would be paid for separately if administered in an ESRD facility.

As noted above, some injectable and IV drugs or biologicals may be substantially the same as injectable and IV drugs or biologicals that are already paid for within the ESRD PPS. In these instances, we support incorporating these items into the PPS on a case-by-case basis using notice-and-comment rulemaking and foregoing the full transition period if it can be shown that the injectable and IV drug or biological is substantially the same and that the PPS rate is adequate to cover the cost of providing the injectable and IV drug or biological.

This approach would ensure that all new injectable and IV drugs and biologicals that are used for the treatment of ESRD are appropriately evaluated with sufficient information before they are added to the ESRD bundle. It would also provide medical professionals with time to evaluate how to appropriately use new drugs and biologicals prior to the decision being made by government officials.

2. KCP Recommends that CMS Align the Definitions of the ESRD PPS Functional Categories for Drugs and Biologicals with the Statutory Requirement.

One critical aspect of the analysis that should be undertaken prior to adding a drug or biological to the ESRD bundle is determining if it is a renal dialysis service, meaning it is directly related to dialyzing a patient.[21] CMS has established the following chart that outlines the framework for considering when a particular drug or biological could be considered to be a renal dialysis service. It is important to emphasize that this chart provides guidance as to this determination and should not replace the case-by-case evaluation of each new drug or biological prior to a determination of whether it should be added to the bundle or not.

KCP is concerned that the language in the chart and in other regulatory guidance inappropriately extends the scope of the bundle beyond the Congressional definition of ESRD services by defining the functional categories in a way that includes drugs and biologicals that are not renal dialysis services. Therefore, KCP strongly recommends that CMS align the "Rationale for Association," which functions as the definition of the much more general categories, with the statutory requirement that the bundle include only drugs and biologicals that are renal dialysis services. Our recommendations for refining these definitions are highlighted in red in the following chart.

Category	**Rationale for Association**
Access Management	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.
Bone and Mineral Metabolism	Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics.
Cellular Management	Drugs used for deficiencies of naturally occurring substances

[21] SSA §§ 1881(b)(14)(A)(i) & 1881(b)(14)(B).

Category	Rationale for Association
	needed for cellular management. This category includes levocarnitne.
Antiemetics	Used to prevent or treat nausea and vomiting ~~secondary~~ directly related to the delivery of dialysis. Excludes antiemetics needed for any other purpose not related to dialysis, such as antiemetics used in conjunction with chemotherapy or oral-only drugs outside of the bundle as these are covered under a separate benefit category.
Anti-infectives	Used to treat vascular access-related and peritonitis infections. May include antibacterial and antifungal drugs. All other uses of these drugs should be separately billed.
Antipruritic	~~Drugs in this classification have multiple clinical indications and are included for their action~~ Used to treat itching when ~~secondary~~ directly related to the delivery of dialysis.
Anxiolytic	~~Drugs in this classification have multiple actions but are included~~ Used for the treatment of restless leg syndrome when ~~secondary~~ directly related to the delivery of dialysis.
Excess Fluid Management	Drug/fluids used to treat fluid excess/overload.
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs/fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs used to treat ~~graft~~ vascular access site pain and to treat pain medication overdose when related to medication provided to treat vascular access site pain.

This narrowing language is necessary to link the functional categories to the activities directly related to dialyzing patients. Without the language modifications, it is easy to see how the bundle could be expanded beyond the scope of renal dialysis services. For example, the functional category of anti-infectives is explained as drugs "[u]sed to treat infections. May include antibacterial and antifungal drugs." Without the clarification that the infections being treated are related to vascular access and peritonitis, this category could be read to include any type of infection that a patient might develop regardless of its relationship to the dialysis treatment. While KCP supports efforts to improve care coordination, the Congress clearly did not define the ESRD PPS to include all health care services that dialysis patients might incur.

KCP also recommends that CMS clarify in the final rule and relevant guidance documents that any drug that is administered in a dialysis facility, but does not fit within one of the functional categories and is not a new drug within the ESRD functional categories, subject to the process described below, should be defined as a separately billed drug under Part B and identified as such by using the AY modifier on the claims.

To the extent that clinical practice changes over time, CMS should work with the kidney care community to revise the ESRD functional categories through notice-and comment rulemaking. We also suggest that CMS rely upon notice-and-comment rulemaking to address new drugs or biologicals that could be defined to fit into more than one of the ESRD functional categories.

3. Example of the Recommended Process.

It may be helpful to provide an example of the process KCP is recommending. The determinations would be made through notice-and-comment rulemaking with CMS providing sufficient data to allow interested stakeholders to fully evaluate the proposals.

Step 1: Determine if the injectable and IV drug or biological is substantially the same as a drug or biological that is related to the treatment of ESRD and currently within the ESRD PPS. In our example, the new drug is an anti-infective that would likely be used to treat vascular access-related infections. If the anti-infective is substantially the same as drugs currently used to treat infections related to a patient's catheter (for example), then it would be added to the bundle. If, however, the PPS rate is likely insufficient to cover the cost of providing the drug it should be evaluated through a transition period.

Step 2: Determine the utilization and cost of the injectable and IV drug or biological before incorporating it into the bundle. In our example, if the new anti-infective drug were not substantially the same as an existing drug in the bundle, CMS would establish a two to three year transition period during which facilities would be paid separately for the drug at ASP+6 percent under Part B and not as an ESRD service.

Step 3: Determine if the injectable and IV drug or biological is a renal dialysis service. Based upon the information collected during the transition period, CMS through notice-and-comment rulemaking would determine whether the item is a renal dialysis service. If so, CMS would value the Part B and beneficiary costs of the item (determined at the time the item is added to the bundle) and add that amount to the base rate without applying the budget neutrality construct.

B. KCP Recommends a Transition Process when an IV Version of a Current Oral-Only Drug becomes Available.

KCP appreciates that CMS recognizes the need to reassess the payment rate in the situation when an IV version of a currently oral-only drug used to treat bone mineral metabolism conditions of ESRD patients becomes available. We are aware that this situation could occur within the coming years. Thus, we appreciate the

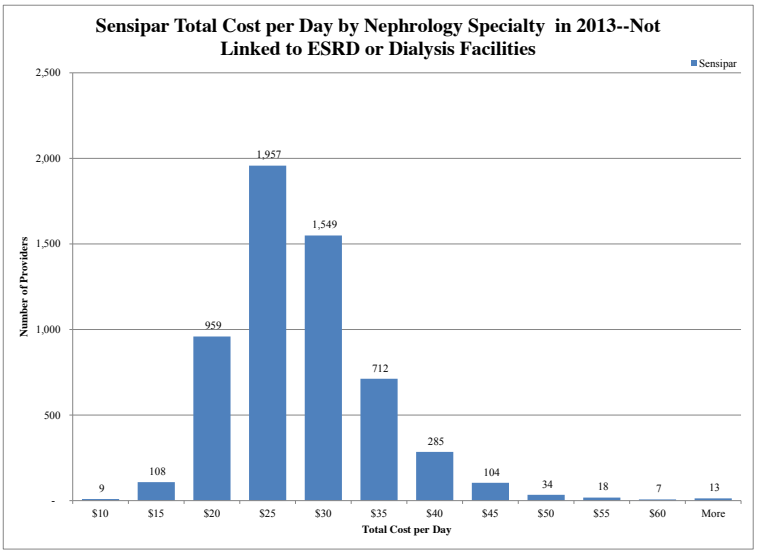
recognition in the preamble that the costs of both the IV and the oral medications are currently not within the bundled payment.

To fully address this potential change in the bundle of items and services, we recommend that CMS follow the process set forth in preceding paragraphs for the introduction of the IV calcimimetic as well. Specifically, there should be a two to three year transition period during which facilities are paid separately for the IV calcimimetic. The payment rate would be set at ASP+6 percent and provided under the Part B program, not as an ESRD service. This approach would ensure that the budget neutrality construct does not apply.

During this period, CMS could work with the community to better understand the clinical practices and utilization patterns associated with the IV calcimimetic. Very little is known about how this drug will be used in the ESRD population. For example, it is not clear whether the drug will have a similar clinical protocol, how it will be administered, or which patients could benefit from it use.

At the end of the transition period, CMS would value the cost of the IV calcimimetic under Part B, including the beneficiary costs, and add that amount to the base rate, if utilization warrants the costs to be spread across all patients. Using Part D spending data is not sufficient for purposes of addressing the increases in cost in the ESRD payment rate. Relying upon that information alone would assume that oral drug spending is the same as it would be for an IV. We simply do not know the answer to this question. This approach would allow the IV calcimimetic to be appropriately evaluated and understood before they are added to the bundle.

During this period, the oral calcimimetic would also remain outside of the bundle, consistent with the Congressional requirement set forth in PAMA. We note that CMS views oral-only drugs as technically within the bundle already, but not paid for under the PPS rate because the Congress has suspended the implementation of this policy. However, the utilization and cost of the oral calcimimetic may change with the introduction of an IV calcimimetic. From historic data, it is clear that the distribution of the cost varies across facilities.



To ensure the accurate assessment of these drugs, it is important to collect the cost and utilization data during a short period (consistent with the Agency's proposal for new drugs). This process should occur through notice-and-comment rulemaking, with the methodology and underlying data available to all interested stakeholders.

The value of these drugs should be determined by examining not only the Medicare spend, but also the costs incurred by beneficiaries and other payers. Focusing on only the Part D expenditures will be insufficient to cover the cost facilities will incur when providing these drugs.

As noted previously, if the IV calcimimetic would become available outside of the regular rulemaking cycle, CMS should use an interim rulemaking process or allow the item to be paid for separately outside of any ESRD budget neutrality construction until the rulemaking process can be completed.

Once the IV and oral calcimimetics are incorporated into the bundle, it will be important to reassess the utilization and cost patterns as well. To measure adherence, CMS will need to access both prescribing data and precise information about the frequency with which prescriptions were filled, which is the only measure of adherence that could be documented. This information and the methodology for determining the dollars being added to the bundle should be available to all interested stakeholders and changes should be made through a transparent notice-and-comment rulemaking process.

IV. KCP Supports Efforts To Increase Transparency of Facility Cost Reports.

KCP supports the Agency's proposal to eliminate the medical director fee limitation on the cost report and urges CMS to similarly recognize the statutorily required Network Fee on the cost reports as well.

A. KCP Supports Elimination of the Medical Director Fee Limitation in the ESRD Facility Cost Reports and Requests the Change Apply for 2015 Cost Reports

KCP strongly supports the proposal to eliminate the current limits on reporting medical director fees on the cost reports. As CMS notes in the preamble, the application of the reasonable compensation equivalency (RCE) limits applied to Medicare providers when they were reimbursed on a reasonable cost basis. Because CMS has removed the limitation for other Part B providers when they transitioned to prospective payment systems,[22] it makes sense to remove the limitation for ESRD facilities, which are now paid under a prospective payment system as well.

Given the importance of understanding the actual compensation of medical directors, we recommend that CMS apply this policy change to 2015 cost reports as well. Compensating medical direction is a significant cost incurred by facilities. Thus, having an accurate assessment of these costs is critical to ensuring an accurate evaluation of the appropriateness of the base rate. This information should be available as soon as possible and not delayed until 2016.

B. KCP Supports Incorporating the ESRD Network Fee into the Facility Cost Reports.

As noted, KCP strongly supports the elimination of the RCE limitation on the medical direct fees for facility cost reports because it will allow all interested parties to better understand the cost of providing care. Similarly, we encourage CMS to allow facilities to include the 50 cents per treatment Network fee on the cost reports. For example, in 2013 there were 43,737, 848 dialysis treatments

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[22]Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program, 79 *Fed. Reg.* 27978, 28174 (May 15, 2014).

administered. This means that CMS and other policy-makers were not taking into account $21,868,924 million of costs incurred by dialysis facilities.

Historically, there may have been concerns about whether the statute permits such recognition. A closer review of the statute and legislative history, however, shows that the Congress was silent on the question. The Congress established the Network Fee as part of the Omnibus Budget Reconciliation Act (OBRA) of 1986. It specifically states:

> The Secretary shall reduce the amount of each composite rate payment under this paragraph for each treatment by 50 cents (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis) and provide for payment of such amount to the organizations (designated under subsection (c)(1)(A)) for such organizations' necessary and proper administrative costs incurred in carrying out the responsibilities described in subsection (c)(2).[23]

The statute includes no express language that states whether or not the fee should be incorporated into the cost report.

While the legislative history provides a clear description of the rationale behind the changes made to the ESRD Networks in the OBRA '96, it is equally silent as to how CMS should treat these fees on the cost reports. The only reference to the fee states:

> Beginning on January 1, 1987, networks would be funded by HCFA taking 50 cents from the payment that would otherwise be made to a dialysis facility for dialysis services under the prospective, composite rate payment method. This would replace the current method of funding from the Medicare trust funds, subject to a specific appropriation.[24]

Given the text and the legislative history's silence on this point, KCP believes CMS has sufficient authority to allow facilities to include the Network Fee in their cost reports.

To achieve this goal, KCP recommends that CMS add the Network Fee as a revenue reduction on Worksheet D. CMS already includes the Network Fee on the PS&R, which facilities can use to obtain accurate and verifiable data, along with beneficiary coinsurance amounts. CMS addresses the coinsurance amount through Worksheet E, but the Network Fee is currently left off of the cost reports.

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[23]Social Security Act (SSA) § 1395rr(b)(7), as added by section 9335(j)(1) of OBRA '96.
[24] H.R. Rep. No. 727, "Omnibus Budget Reconciliation Act of 1986," 99th Cong., 2d Sess. 78 (1986).

Given the reliance of the Congress and its advisory commission, MedPAC, on the cost reports for determining appropriate reimbursement policy, it is important that the cost reports include costs that are related to the care of Medicare beneficiaries. The Network Fee is such a cost. Without including that amount, policy-makers cannot calculate correct margins. It is in the interest of all policymakers that the information provided is as accurate as possible. Therefore, we encourage CMS to add the Network Fee on the facility cost reports beginning in 2016.

Given the changes in the scope of work of the Networks, we also encourage CMS to review the scope of work and the appropriateness of the Network fee.

V. KCP Supports the Removal of the Lipid Panel from the ESRD PPS.

KCP is pleased that CMS is recognizing the importance of allowing dialysis facilities to draw blood for laboratory testing for reasons other than for the treatment of ESRD. We also support the Agency's conclusion that lipid panels are not routinely furnished for the treatment of ESRD, but instead to monitor cardiac conditions. Thus, these panels should be excluded from the ESRD PPS and paid for separately. CMS has taken the appropriate approach of working with stakeholders to determine whether there is consensus as to what tests are or are not furnished for the treatment of ESRD. We encourage CMS to maintain this ongoing dialogue as well. KCP also supports the clarifications that "a laboratory test [that] is performed to monitor the levels or effects of any of the drugs that [CMS has] specifically excluded from the ESRD PPS" will be "separately billable [and] not be considered to be furnished for the treatment of ESRD."[25]

VI. Conclusion

KCP looks forward to working with CMS on the proposals described in this letter. Please do not hesitate to contact Kathy Lester at 202-534-1773 or at klester@lesterhealthlaw.com if you have any questions.

Sincerely,

Edward R. Jones, M.D.
Chairman
Kidney Care Partners

[25]Display Copy pg. 112.

Appendix A: KCP Members

AbbVie
Akebia Therapeutics, Inc.
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
AstraZeneca
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners, Inc.
Dialysis Patient Citizens
Dialysis Clinic, Inc.
Fresenius Medical Care North America
Fresenius RTG
Greenfield Health Systems
Hospira
Keryx Biopharmaceuticals, Inc.
Kidney Care Council
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Renal Physicians Association
Renal Ventures Management, LLC
Rogosin Institute
Sanofi
Satellite Healthcare
U.S. Renal Care

Appendix B: Technical Appendix

Critique of ESRD PPS Adjuster Methodology by The Moran Company

Introduction

The purpose for development of payment adjusters in a Medicare PPS is to target additional payment to providers incurring higher cost due to either facility conditions or patient characteristics. When adjusters target higher payment to patient characteristics, this needs to be done based on reliable data documenting that higher costs are consistently incurred by providers treating patients with the target characteristic. When adjusters target higher payment to facilities, this needs to be done based on reliable data demonstrating that facility characteristics are the source of higher costs that disadvantage those facilities in the payment system, and that those characteristics are outside the control of the facility. The over-arching purpose of payment adjusters is to ensure patient access to care.

In the development of payment adjusters for the End Stage Renal Disease Prospective Payment System (ESRD-PPS), CMS and its contractor used statistical methodologies and identified adjuster variables in a manner that cannot produce valid or reliable adjuster values, and does not serve the above policy purposes. The discussion that follows explains why the chosen methodology and its implementation cannot produce valid adjusters. Statistical methods are only valid if the data to which they are applied are a fit to the methods. Statistical methods applied to data that do not meet the requirements for reliability and validity will produce results that are not accurate, may not be meaningful, and can be volatile from year to year: the resulting adjusters will target funds in ways that have no relationship to the policy that the methodology is designed to implement. Fundamental requirements of a regression model were not met in the analyses used to design the ESRD-PPS payment adjusters.

To produce valid and reliable results, a regression analysis must be based on a sound research design and must adequately address the assumptions made by the mathematical properties of the regression analysis. The major assumptions we will discuss are noted below and are commonly documented in many standard texts on regression methods.

1. Regression assumes that the model is correctly specified. If a regression model is not correctly specified, the results will be biased, and will not reflect an accurate impact of the predictor variables (also called independent variables) on the dependent variable. Correct specification requires:

   a. All variables that could predict change in the dependent variable (cost per treatment first equation, cost of separately billed items in second equation) were included in the regression model. The process for selecting variables and evaluating them for inclusion in the regression model was not comprehensive and there is considerable reason to believe that the variables that were selected were not those that drive cost variation.

   b. All variables must be statistically or theoretically related to the dependent variable in the regression model.

   c. The coefficients of the predictor variables (the value assigned to the adjuster as a result of the regression) are assumed to not change during the period of analysis.

2. The observations, in this case treatments, are uncorrelated with each other. This means that all treatments are assumed to be independent of each other. In this context, treatments occur in a sequence linked to an individual patient such that treatment cost for one treatment may be related to prior treatment, the duration between treatments, events that interrupt treatments such as hospitalization, and the patient's health status at the time of treatment. Therefore, treatments are not independent of each other.

   a. If ordinary least squares (OLS) is used, the result will be that it is no longer possible to trust significance tests.

   b. If observations are, in fact, correlated as is the case with dialysis treatments, then this correlation between observations should be modeled in the regression using generalized least squares (GLS). This would require modeling the variation within the series of treatments for each patient. GLS could not be done using cost report data as these data have no link to the patient. GLS could be done in the separately billed data. We found no documentation to suggest that this method was used.

3. Regression assumes that there is not random error built into the predictor or independent variables.

   a. Because regression assumes that the data contains no erroneous values, the data is modeled as if all values are correct. If data has a great deal of error contained in it, the result is that the coefficients of the predictor variables will be biased and will not reflect the effect of the predictor variable on the dependent variable. There is considerable error in the cost report data used. The separately billed data may meet the conditions for this assumption.

4. The predictor variables are not correlated with each other.

a. Correlation of predictor variables will increase the variability associated with a coefficient, and will reduce the accuracy of the adjuster. This will increase the degree to which small changes in the data can create large changes in the results. It will also make the interpretation of correlated variables unclear. We find that there is considerable correlation among the predictor variables.

In the discussion that follows, we will demonstrate that the regression methodology used, to the extent that it has been explained in the original 2008 Report to Congress, or in the 2016 Proposed Rule, includes multiple violations of these core assumptions.

In addition to violation of the core requirements of the regression methodology, we assert the following problems with the application of the methodology:

- Average facility cost per treatment based on cost report data (excluding drug cost) has no relationship to patient characteristics. It is not possible to distinguish variation in cost per treatment that is associated with patient characteristics from facility treatment volume and a number of corporate financial, clinical, purchasing and labor policies that dominate the ultimate cost per treatment at the facility level. Reliance on cost report data to construct adjusters for patient characteristics is inappropriate and results in an invalid model.
- Because the adjuster variables explain less than 10% of the variation in cost, the model should have been re-evaluated before being used.
- The selection and omission of variables in the regression model was not transparent. Variables known to affect cost were omitted and variables of questionable importance were included.
- Exaggerated statistical significance of variables based on a universe, not a sample, has resulted in adjusters with questionable statistical or clinical significance.
- The combination of the coefficients from the two regressions into a single adjuster is problematic. The weighting is not described, but it would not be correct to assume that the distributions for the two regressions are the same. If the distributions are not the same (which we believe is certainly the case), then the accuracy of the resulting adjuster will be compromised. Also there are costs that are duplicated in both regressions, particularly for laboratory tests, further muddying the analysis and eroding accuracy.
- Because of the poor fit of the model to appropriate data, and the high level of correlation among the adjuster variables, we do not believe that this regression model can be fixed.

Variation in average facility cost per treatment derived from cost reports does not represent variation in the cost associated with treating patients with different characteristics, such as those CMS identified for adjusters.

An analysis must use data that measures the concept under analysis. The relevance and construction of the facility level variables used by CMS have not been explained, nor has CMS explained whether other variables were considered. The only facility level variable that we agree may be linked to variation in average facility cost per treatment is treatment volume.

We disagree, and have data to demonstrate, that size of company and non-profit/for-profit status have no bearing on variation in treatment cost. In our analysis of cost report data, we find that the following characteristics of owner entities drive most of the variation in treatment cost:

- Overall financial policies
- Labor policies which may vary geographically
- Allocation of overhead to facilities
- Purchasing policies which may vary for sub-sets of facilities
- Contracting practices

Even at the local facility level, our understanding from company leaders is that variations in staffing intensity, the source for cost variation in cost report data, are not related to patient characteristics, but that more time-intensive patient care is, for the most part, integrated into the standard scheduling and operation of the clinics. In any case, the aggregate data in cost reports is not in any way directly associated with variation in patient characteristics. Because of this, the variable concepts for adjusters cannot be measured by these data.

The specific regression models used have negligible power to explain variation in cost, and therefore should not have been used to estimate adjusters.

The results from the regressions reported in the 2008 Report to Congress indicate that the adjuster variables explain little of the variation in cost – less than 2% of the total variation in composite rate costs, and less than 8% of separately billable costs. This level of explanatory power of the adjuster variables is very low, only marginally greater than zero. Variables with such low impact on cost may not have been included if the volume of claims and of facilities had not been so large as to result in statistically significant results. Because a population is used rather than a sample, we believe that more restrictive requirements should be used for determination of statistical significance.

Model Specification and Variable Selection

Inclusion of relevant variables and exclusion of irrelevant variables is vital to producing a valid model. In each of the proposed and final rules published since the publication of the 2011 proposed rule, CMS has stated that a stepwise regression was used to arrive at the adjusters. Stepwise regression is a method of adding variables to a regression equation in turn, based on statistical significance or in some predetermined order of entry. The criteria used for entry and exclusion of variables into the regression models used to create the adjusters was not explained, and it is unclear why some variables that may affect cost were excluded from consideration, while other variables were included. The issue of variable selection is magnified by the difficulties of interpreting statistical significance in data sets as large as those used. Because statistical significance alone is not a dependable method of variable selection, the judgment of the researchers becomes paramount in the selection of variables.[26]

In discussions with ESRD facility operators and clinicians, alternative variables are viewed as clinically significant and potentially relevant to the variation in the costs of delivering dialysis services. In CMS's discussion, age and body size are referred to as useful variables, largely because they are easy to record reliably in claims. It is true that clinicians would agree that body size, specifically severe underweight and significant overweight may be related to the level of effort in caring for patients, and therefore costs. However, clinicians are not suggesting that any continuous variable for body size that provides a payment adjustment for all patients is appropriate. Similarly, body size is actually a proxy for the reason for expecting more intensive care needs, and, as a proxy for underweight and overweight, the referents are different. In the case of underweight patients, the needs of the patients are associated with malnourishment and frailty and the care needed to support stability in the patient's health. Underweight patients will not use more separately billed services than overweight patients, nor will they use more dialysis time. Overweight patients may require more dialysis time, use more drugs due to dosing related to body size, and, for the morbidly obese, may require the facility to purchase special equipment such as lifts and larger sized dialysis chairs.

In the case of age, clinicians also view age as a proxy for factors that increase the cost of care and do not suggest that a continuous or tiered age variable is appropriate. Their concerns for patients with advanced age is not based strictly on age, but the correlation between age and certain characteristics that limit the patient's ability to participate in his or her own care (e.g., nursing home residency, non-ambulatory, paralysis, dementia). They note that it is common for dialysis

[26] Kennedy, P. *A Guide to Economics 1st Edition,* MIT press.

patients, due to their generally compromised health, to acquire these characteristics before the age threshold of 80.

CMS's criteria that the identification of the characteristic is easy to document does not result in accurate specification of the most relevant variables. Documentation of the characteristic also has no relation to whether there are any available data for the costs associated with those characteristics.

It does not appear that the development of the model was based on input from dialysis providers who are most aware of those factors that influence the cost of dialysis treatment. In the 2008 analysis, the research team appeared to generate a list of conditions that could potentially be related to dialysis costs, and using many years of historical claims, performed statistical significance tests (which we note were not likely meaningful due to their application to a large population). In response to criticism of the list of comorbidity adjusters in the proposed 2011 rule, CMS reduced the list considerably, and agreed with the critics that the conditions could not be determined to meet the criteria for independence of variables. The response in the final rule was to allow for only one—with the highest value--adjuster to be paid if the patient qualified for multiple comorbidity adjusters. This action in no way corrected the fundamental flaw in the methodology that made the adjuster values invalid.

Large number of ERSD claims and facilities exaggerate statistical significance.

The large number of facilities (most of the universe) and treatments used in the two regressions have resulted in exaggerated statistical significance of coefficients. This is because coefficients become more statistically significant as the size of a "sample" increases. Statistical significance is most useful to evaluate selection of variables when actual samples are being used. In these regressions, CMS uses as much of the universe as it can, rather than having statistically sampled the universe. As a result, statistical significance as used by CMS no longer has the meaning it does with actual samples. In the 2008 report to congress, the authors note this problem, stating:

> *…given the very large number of ESRD patients with Medicare claims, statistical significance is a necessary but not a sufficient condition for including a potential patient characteristic as a case-mix adjuster. Even variables with very small relationships to costs or payments are likely to be statistically significant in patient-level analyses.*[27]

[27] A Design for a Bundled End Stage Renal Disease Prospective Payment System: Report to Congress 2008, p 27.

UM-KECC, despite correctly identifying the problem of large sample size and statistical significance in its 2008 report, employs variables with indeterminate statistical significance. A categorized age variable is consistently used as an independent variable in these regressions. In the report to Congress, CMS provides detail on statistical significance of the regression coefficients associated with these variables. In the 2008 report, the age categories 45 to 59 and 70 to 79 were not significant at the .05 level, and in the case of separately billable services, the category 18 to 44 was not statistically significant at the .05 level. Only pediatric patients and patients over 80 were consistently statistically significant in these analyses. Given the large sample size, if age were an independent driver of cost, we would expect a greater level of significance. Note that none of these specifications were disclosed for the updated regressions used to estimate the proposed 2016 payment adjusters.

There is no stated clinical or economic rationale for the selection of control variables

Given the lack of information that statistical significance provides in large populations such as these, the model specification must be made on the basis of clinical or economic theoretical criteria. Of the seven control variables, no link in the dialysis literature, and no analyses confirm a link between the variables and the actual costs of dialysis. There is no theoretical argument for the use of these control variables that might provide a case for assuming a link to cost.

It is not acceptable to omit variables from the regression model that are related to costs.

While a decision to not create an adjuster from a regression coefficient can be defended on policy grounds, the exclusion of an important variable from the regression analysis cannot. The first assumption of regression modeling is that all relevant predictor variables are included in the model and irrelevant ones excluded[28] If a variable that has an effect on the cost of treatment is not included in the equation, and this variable is not perfectly uncorrelated with the remaining variables, the coefficients for the remaining variables will reflect the variation that they have in common with the omitted variable. Race of the patient, while not an adjuster, has been demonstrated to effect cost, for example. Other examples of variables that may affect cost, as identified by clinicians, include patient characteristics that interfere with the patient's ability to participate in his/her own treatment (e.g., nursing facility residents, paralysis, dementia). The category of age over 80, is essentially a proxy for these elements as discussed above. Because CMS has not reported the full results of the regression equations used to derive the

[28] Kennedy, p.A G*uide to Economics 1st Edition*, MIT press, p. 57.

adjusters for the 2016 proposed ESRD rule, it is impossible to assess the degree of misspecification of the regression model.

Non-independence of predictor variables results in imprecise parameter estimates[29,30].

In the regressions on composite rate costs and separately billable services on age, body mass index (BMI), body surface area (BSA), comorbidities, and new patient status, that were conducted by UM-KECC and reported to Congress in 2008, the level of correlation between the independent variables is severe. Body surface area and BMI are both estimated using height and weight, and are by definition, highly correlated, and therefore, not independent of each other. Older dialysis patients tend to have smaller BMI/BSA and lower rates of obesity than younger dialysis patients[31]. "New to dialysis" correlates with all other variables. There are three consequences of these correlations that we believe make these adjusters unreliable and unsuited for use in a reimbursement system.

Adjusters derived from correlated "independent" variables are imprecise.

Significant correlation between predictor variables will force the regression to only use variation unique to a variable, ignoring the variation that is correlated with another predictor variable. This results in variables with less precise adjuster values. Because the value of the adjuster is based on only the variation of the "independent" variable unique to that variable, confidence intervals around that adjuster, the range of possible values, is larger than it would be if the variable were truly independent of the other variables.

The adjusters derived from correlated variables no longer have meaning.

A regression coefficient, and the derived adjuster, represent the change required in an independent variable (e.g. age) to create a change in the dependent variable (e.g., composite rate services), holding all other independent variables constant. However, when two predictor variables are highly correlated, as are BSA and BMI, it makes no sense to state that a decrease in BSA, holding BMI constant, creates a change in cost. Because older patients tend to have smaller body size and younger patients larger body size, it makes little sense to model age and body size as if they are independent of each other. Therefore it is quite possible that the significant results obtained for age may be related to body size or some other un-specified variable.

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[29]Kennedy, *A Guide to Economics 1st Edition,* MIT press, p 129.
[30] Neter, J. and Wasserman W. *Applied Statistical Models Regression, Analysis of Variance, and Experimental Designs* 1974 Richard D. Irwin Press Homewood, Illinois, p. 344
[31] Kramer, H., Saranathan, A., Luke, A., et al. Increasing Body Mass Index and Obesity in the Incident ESRD Population *J Am Soc Nephrol 17: 1453-1459.*

Small changes in the data can result in large changes in the adjusters.

When predictor variables are correlated, even small changes in the data can result in large changes in the adjusters. There has been no demonstrated shift in either the distribution of the age of dialysis patients, nor would the effect that age has on cost over the past ten years have changed. The shift in the age category associated with the lowest cost from 40 to 59 in the proposed 2011 rule, to 60 to 69 in the final 2011 rule, and now to 70 to 79 in the proposed 2016 rule, is an indication that the age variable, highly correlated with other variables included in the regression, is unreliable, and is sensitive to small changes in the data.

The problem of correlated independent variables cannot be solved by omission of a variable

Because it is unacceptable to omit variables that are related to the dependent variable from the regression equation, any attempt to repair this regression by omitting some of the correlated variables will create new problems. The remaining coefficients and resultant adjusters will be biased, and will no longer reflect an accurate effect that the remaining variable has on cost.

Conclusion

The regression analyses used by CMS for the proposed 2016 ESRD PPS Rule violates the core assumptions for a valid analysis. We have demonstrated that:

- The regression analyses used to produce the adjuster values included in the ESRD PPS are not correctly specified: there is inadequate rationale provided to explain the selection of the variables and no discussion of other variables that clinicians would suggest better explain variation. Based on our research and expert knowledge of those delivering services, the selection of variables is certainly incomplete.
- The assumption regarding the independence of observations is not anywhere discussed by CMS or its contractor. The unit of observation (the dialysis treatment) is not independent: treatments are linked to individual patients, and one treatment and its costs may very much depend on the results of the last treatment and the interval between treatments. We see no evidence that the required statistical modeling was used to account for this lack of independence among observations.
- Our analysis of cost reporting documents reveal that there is a large amount of error in the data that is unrelated to actual variation in cost. There are large amounts of missing data in the fields that are rolled up into the total

cost field used by the researchers. CMS has not disclosed how it handled trimming data for unbelievable values and other types of error. We know that hospital cost reports are frequently highly inconsistent with independent facility cost reports, and are often missing, or have large amounts of missing data. Without addressing the known significant level of error in the data source, the assumption that the data are error free is violated.

- Virtually all of the patient level predictor variables are correlated, with different levels of correlation between pairs of variables:
    - BSA and BMI measure exactly the same characteristics, are entirely correlated and their adjusters cancel each other out.
    - Age is correlated with both BSA and BMI, particularly the lower body size and advanced age. The BSA adjuster cancels out part of the age adjuster for patients over 70.
    - Age is correlated with new patient status, as new patients are more likely to be younger, though patients start dialysis at all ages.
    - New patient coefficients are based on exactly the same data as the other patient characteristics, thereby duplicating cost variation and muddying the cost variation for other coefficients.
- Low volume and rural status are correlated, as well, as acknowledged in the proposed rule by CMS.

Therefore, the adjuster values that are generated by this model are not valid or accurate.

Furthermore, the cost report data upon which the analyses rely represents a poor fit to the task of explaining variation in cost associated with patient level characteristics. When the meaning of "higher cost care" is reflected in more intense staff time, a more expert mix of staff time, longer duration of dialysis, or special equipment, then these are the sources of data that should be used to develop adjusters, not total facility average cost without drugs. The costs of facility operations for capital, overhead, contracting, labor and benefit policies, and purchasing, are driven by corporate policies that cannot be accounted for by any of the variables included in the regression analysis. There may well be a better way to design a model to produce adjuster values that are valid, once an acceptable model can be specified. The Kidney Care Partners (KCP) and The Kidney Care Council (KCC) are available to assist CMS in formulating a statistically valid approach to developing payment adjusters.