



August 10, 2018

The Honorable Alex M. Azar, II  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

Kidney Care Partners (KCP) appreciates the opportunity to provide comments on the Proposed Rule entitled “End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS” (Proposed Rule).<sup>1</sup>

KCP is an alliance of members of the kidney care community that includes patient advocates, kidney care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with both CKD and irreversible kidney failure, known as ESRD.<sup>2</sup>

In this letter, KCP focuses on the drug designation process and the payment adjuster proposals of the CY 2019 ESRD PPS. We are providing our comments on the other PPS proposals and the ESRD Quality Incentive Program (QIP) proposals in separate letters.

In an overarching manner, the kidney community is concerned about the fact that the ESRD PPS does not cover the cost of providing services. The problem is two-fold. First, the Medicare rates are inadequate to cover the cost of providing services. MedPAC in its most recent *Report to the Congress* estimated that the margin is 0.5 percent. This estimate is high in our view because it does not account for actual revenue reductions, such as the Network Fee that reduces each payment by \$0.50 and the substantial amount of unrecovered bad debt. If just these two amounts were taken into account, the average margin would be several points negative. Using CMS data, The Moran Company estimates that 55 percent of facilities have negative margins – their revenues do not cover the cost of providing services already. The second problem is that the federal government has relied upon the historic cross-subsidization through Medicare Secondary Payer (MSP) and commercial payers to compensate for the underfunding of the Medicare ESRD program. This system is under attack; the historic balance that allowed facilities to maintain services

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<sup>1</sup>83 *Fed. Reg.* 34304 (July 19, 2018).

<sup>2</sup> A list of KCP members is provided in Appendix A.

has ended. This economic instability means that it is critically important that the ESRD PPS be allowed to evolve to support innovative products and services, while also eliminating policies that take money out of the system inappropriately.

**I. KCP Supports Efforts to Incentivize Innovation in the Treatment of ESRD, but Is Deeply Concerned that the Proposed Changes to the Drug Designation Process Are Incomplete and Would Stifle Innovation.**

KCP supports the efforts to incentivize innovation in the treatment of ESRD and commends the commitment by HHS to this goal, as evidenced by the launch of the Kidney Accelerator (KidneyX). When HHS launched it, Bruce Greenstein, then HHS Chief Technology Officer, indicated that “KidneyX will create a sense of urgency in the innovator community by spotlighting the immediate needs of patients and their families.”<sup>3</sup> He further noted that:

KidneyX is designed to accelerate the development of drugs, devices, biologics and digital health tools spanning **prevention, diagnostics, and treatment** with the aim of giving patients with renal failure better treatment options and ultimately, to reduce the need for dialysis.<sup>4</sup>

Most importantly, he promised that HHS would prioritize patients’ access to clinical innovation. He recognized that for those living with kidney failure and relying upon dialysis treatment the innovations seen in other areas of health care had passed them by. “Some 30 million Americans suffer from kidney disease, yet the solutions are nearly identical to what they were decades ago.”<sup>5</sup>

KCP agrees and is pleased that HHS has launched this effort to promote innovation. Our members have been supporting and advocating for federal policies that would address this problem. While these efforts have included advocating for early detection, increased patient education through the Chronic Kidney Disease (CKD) Education Benefit, and developing innovative payment models that support care coordination, the root of the lack of innovation in this space is the fact that the current payment system stifles innovation. The lack of the potential for new money for new technology within the ESRD PPS bundle for advances in this area keeps investors from investing and companies from innovating in this space. To ensure the success of KidneyX, it is crucial that sensible payment policies be implemented. The comments that follow reflect this shared goal.

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<sup>3</sup>Bruce D. Greenstein, “KidneyX: A new wave of innovation to treat kidney disease,” HHS Blog (April 26, 2018) (available at: <https://www.hhs.gov/blog/2018/04/26/kidneyx-new-wave-innovation-treat-kidney-disease.html>).

<sup>4</sup>*Id.*

<sup>5</sup>Bruce D. Greenstein, “Putting patients at the center of KidneyX,” HHS Blog (May 16, 2018) (available at: <https://www.hhs.gov/blog/2018/05/16/putting-patients-at-the-center-of-kidneyx.html>).

CMS has an opportunity in this rulemaking, as it refines the drug designation process, to support the Department's efforts and incentivize the development and integration of new technology for the care of dialysis patients. KCP asks CMS to balance the pressures of reducing drug costs with the desperate need for innovative treatment options in this population to ensure patients with kidney failure who rely on dialysis – and Medicare – to stay alive are not left out of the future that medical innovation promises.

**A. KCP Supports the Application of TDAPA to New Drugs and Biologicals and Recommends that the Reimbursement Rate Be Set at ASP+6 percent.**

KCP appreciates that CMS heard our previous comments that TDAPA has been too narrowly defined in the context of functional categories. Therefore, we support its application to any new renal dialysis drug or biological approved on or after January 1, 2019. However, as described below, we recommend that CMS not apply TDAPA to generics (which as we understand the proposal it already does not) or to biosimilars. The rationale for TDAPA is to allow the community and CMS to better understand the appropriate utilization of new products and their pricing. Generics and biosimilars seek to provide the same type of treatment and patient outcomes as existing drugs in the bundle. Thus, the additional time is unnecessary for these products. KCP would prefer to have CMS appropriately incentivize innovative products and appropriately pay for them.

As KCP has indicated previously, and expands on in subsequent sections in this letter, we agree with CMS's statement that the base rate "may not directly address the total resource use associated with the newly launched drugs trying to compete in the renal dialysis market."<sup>6</sup> TDAPA does play the important role of allowing the kidney care community and CMS to collect sufficient data about how new drugs are utilized and priced.

CMS also seeks comments on modifying the basis of TDAPA from payment at ASP+6 percent to ASP+0 percent. While KCP recognizes the Administration's goal to reduce overall drug spending, the ESRD program, which serves some of Medicare's most vulnerable beneficiaries, needs innovation and investment – not cuts. As the preamble to the Proposed Rule states and the Department's KidneyX program recognizes, there has been no significant non-service innovation in this space in decades. There are also fewer health care professionals interested in making nephrology and the care and treatment of this population their life's work. When breakthrough technologies, such as CAR-T cells and personalized medicine, dominate the headlines in oncology and other disease states, there is little to attract and keep health care professionals in this space. It is not appropriate to assume that because a functional category exists there is sufficient funding for all future drugs and biologics developed to treat such conditions. Providing low payment rates in a system in which dialysis facilities, on average, are paid less than the cost of providing

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<sup>6</sup>83 *Fed. Reg.* at 34313.

services<sup>7</sup> will only make this problem worse. Thus, if CMS is trying to find ways to reduce overall spending on Part B drugs, the already under-funded Medicare ESRD program is not where it should start. Promoting innovation in kidney care requires taking into account patients, providers, and manufacturers. In addition to the activities around KidneyX, CMS needs to make sure that its policies also promote innovation and advances in care across these stakeholder groups. Properly aligning the payment component is essential to advancing innovation as well.

While it is true that MedPAC has raised concerns about the continued use of ASP+6 percent in the broader context of the Medicare Part B program, it did not recommend setting the rates at ASP+0 percent.<sup>8</sup> MedPAC's specific concern as expressed in the June 2015 *Report to the Congress* was that:

The 6 percent add-on to the ASP may create incentives for use of higher priced drugs when lower priced alternatives are available. Since 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selection of the higher priced drug may generate more profit, depending on the provider's acquisition costs for the two drugs.<sup>9</sup>

However, it recognized as well that this concern was theoretical: "Currently, it is difficult to know the extent to which the percentage add-on to ASP is influencing drug prescribing patterns because few studies have looked at this issue."<sup>10</sup> Thus, MedPAC modeled two options for addressing the problem. The Commission modeled two policies that would:

convert part or all of the 6 percent add-on to a flat-fee add-on for each day the drug is administered to a beneficiary. Our modeling demonstrates that a flat-fee add-on would increase payment rates for lower priced drugs and reduce payment rates for higher priced drugs compared with current policy.<sup>11</sup>

MedPAC reviews the potential benefits of these options, but also notes their potential downsides.

It would be important in structuring a flat-fee add-on to consider its effect on providers' ability to purchase drugs within the Medicare payment amount. A

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<sup>7</sup>The ESRD PPS was not structured based on the cost of providing services, which in part has resulted in substantial negative Medicare margins, as MedPAC has recognized and The Moran Company has identified repeatedly based on its analysis of CMS cost report data.

<sup>8</sup>MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, "Ch. 3: Part B drug payment policy issues" (June 2015).

<sup>9</sup>*Id.* at 61.

<sup>10</sup>*Id.* at 61-62.

<sup>11</sup>*Id.* at 62.

flat-fee add-on would reduce payment rates for very expensive drugs. With a flat-fee add-on, some providers might have difficulty purchasing very expensive drugs within the Medicare payment rate, but that would depend on how the policy is structured and how manufacturers' pricing decisions respond to the policy.<sup>12</sup>

MedPAC clearly suggests that any changes to the rate setting for Part B drugs needs to be evaluated closely *before* being implemented. But even with the modifications suggested, MedPAC recognizes that there needs to be an add-on above the basis on which the reimbursement is based.

As MedPAC recognizes, there are several costs that facilities incur when providing drugs and biologicals beyond the cost of the product. In addition, there is a high rate of unrecoverable bad debt associated with drugs and biologicals. Many patients are unable to pay the cost-sharing obligations for many reasons; for example, not all States require insurers to provide access to Medigap insurance and other States do not pay the beneficiary's 20 percent when the beneficiary is a dual eligible.

The proposal to set the basis for TDAPA at ASP+0 percent would most likely disincentivize the adoption of new drugs. In setting payment policy for outpatient drugs, CMS should consider the 20 percent co-payment exclusion from bad debt recovery and the impact of sequestration on reimbursement. Given these factors, ASP+0 percent would actually result in the payment amount being less than ASP, and even adjusting for these factors will leave most providers' reimbursement below the ASP.

ASP is driven by the "average" sales price for a drug to all purchasers, including hospitals and large purchasing groups. Many dialysis facilities may not be able to purchase at or below ASP. This approach would under-fund the use of any new drug even during the TDAPA period. It is clear from MedPAC's discussions about Part B drugs, as well as the basic structure of ASP, that there needs to be an additional amount above the average price.

While KCP supports efforts to try to address the cost of new drugs, given the nascent state of innovation in the ESRD space, we believe it is too soon to experiment with any policy other than ASP+6 percent. While it might be possible to craft another approach, in the short-term at least, CMS should review the example of what happened in the hospital outpatient setting when it tried to shift to ASP+4 percent. Between 2009 and 2012, CMS struggled to establish the appropriate payment rate for separately paid drugs in the hospital outpatient setting.<sup>13</sup> During this time, CMS made various shifts in the percentage added to the ASP, but eventually for CY 2013 concluded that the only way to establish a predictable and accurate payment for these drugs that recognized the real overhead costs

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<sup>12</sup>*Id.*

<sup>13</sup>77 *Fed. Reg.* 45061, 45137-40 (July 30, 2012).

associated with providing them was to set the amount at ASP+6 percent. Perhaps most importantly, none of the proposals in the outpatient setting over the years ever suggested setting the rate at 100 percent of ASP.<sup>14</sup> While the actual items and services that drive the overhead costs of providing new drugs and biologicals to patients may vary when comparing outpatient departments to dialysis facilities, these costs are real and ones that other parts of the Medicare program have studied and affirmed over the years.

The Moran Company also modeled the impact of valuing drugs at ASP+0 percent instead of ASP+6 percent to provide an illustration of the impact of using ASP+0 percent in this area. They analyzed the amounts added for the top drugs in the bundle in the 2011 final rule when CMS established the ESRD PPS. They found that “In 2011, a switch from ASP+6 to ASP+0 would have reduced the total value of the bundle by \$157 million per year, or \$4.28 per treatment.”<sup>15</sup> Such a decrease in value would have overwhelmingly destabilized the system. Given current negative margins, it is difficult to see how facilities would have continued to operate if such a policy had been implemented at that time. If CMS were to finalize the 100 percent ASP policy for TDAPA, and that amount were used to fold drugs and biologicals into the ESRD PPS, there will simply be insufficient dollars available to provide access to these products for patients.

While the preamble states that the proposed drug designation changes would not apply to the use of ASP+6 percent for calcimimetics, the regulatory text is less than clear. KCP supports the statement in the preamble that CMS has not changed the oral-only with new intravenous drug policy and strongly support maintaining the policy as it is today, with the recommendation about its timing described below. However, it is critical that this intent be reflected in the regulatory text as well. If ASP+6 percent is appropriate for these drugs, which we believe it is and as CMS states in the preamble, we do not understand why it is also not appropriate for future drugs in this space.

**B. KCP Recommends that CMS Adopt a Policy that Allows Certain Drugs that May Be Classified as within Existing Functional Categories to Be Added to the ESRD PPS with New Money.**

KCP is troubled by the proposal to establish a one-size-fits all policy for new drugs or biologicals that CMS determines to be within a functional category. This policy seems to contradict the intent behind extending TDAPA to all new drugs and biologicals. While it may be true that current funding within the ESRD PPS would be sufficient to cover the costs for some new drugs or biologicals within an existing functional category, that fact would not be true for all new drugs and biologicals. For these other drugs and biologicals, having guaranteed access to TDAPA is only part of the solution. Innovation requires appropriate and sustainable long-term funding as well.

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<sup>14</sup> *Id.* at 45140.

<sup>15</sup>The Moran Company, “2019 ESRD NPRM Decision Memo #1: TDAPA Issues and Drug Trends,” (June 25, 2018).

CMS seemed to understand that such a distinction could arise between different types of new products that would enter the ESRD functional categories in previous rulemaking. In the CY 2016 ESRD PPS Final Rule, CMS took a more nuanced position than the one proposed in the CY 2019 ESRD PPS Proposed Rule. In the CY 2016 Final Rule, while CMS stated the general position that it would not add new money to the bundle for drugs and biologicals it concluded were in existing functional categories, it did recognize that unique circumstances might arise.

We do not believe it is necessary to add injectable and intravenous products to the bundled payment using notice-and-comment rulemaking because we have already included dollars in the base rate to account for products used to treat or manage conditions associated with ESRD for which we have adopted functional categories—consistent with the process we adopted through notice-and-comment rulemaking—and we believe that new drugs used to treat or manage the same conditions will be adequately accounted for by those categories.<sup>16</sup>

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For drugs that are used to treat or manage a condition for which we have a functional category, we note that we have not encountered high cost drugs that we believe would not be accounted for by the existing functional categories. We do, however, appreciate the commenters' concerns and we anticipate addressing the possibility of the unique situations they have identified in future rulemaking.<sup>17</sup>

This language suggests that CMS would address the rate if high-cost drugs that would come to market and be within an existing functional category.

While CMS may not have been aware of new products in 2015 that were distinct from those already in the bundle, today there are several in the pipeline. These drugs are not generics or biosimilars. They may treat the underlying conditions that relate to the functional categories, but are not simple substitutes for drugs or biologicals in the bundle.

When CMS developed the initial policy, it likely anticipated a new round of ESAs then in development. For example, when Peginesatide came to market, it was a type of ESA and that would provide physicians an alternative choice to the existing ESAs in the bundle. While a novel product, CMS could rightly assume that the dollars in the bundle for existing ESAs should be sufficient to cover a new ESA.

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<sup>16</sup>80 *Fed. Reg.* 68968, 69017 (Nov. 6, 2015).

<sup>17</sup>*Id.* at 69018.

However, not all new drugs mirror that circumstance. There are new drugs and biologicals in the pipeline that, while likely to have an FDA label indication focused on treating conditions in an existing functional category, will not be clinically substituted with drugs currently in the functional categories or will provide a more effective treatment option than what is currently used as the standard of care. These products are true innovations.

In some instances, such as with a new anti-inflammatory, the only FDA pathway available for approval would result in label indications within a functional category, namely for managing anemia for certain pre-disposed ESA hypo-responder patients. In other instances, the innovation may be a precision therapy with notable effectiveness for a sub-population yet would still fall within a functional category. Lastly, innovative medicines that fall within a functional category based on their primary indication may in the clinical trial portion of the FDA label (Section 14) may show notable improvements in other conditions not within the functional category, such as inflammation-malnutrition, physical functioning, symptoms, or cardiovascular disease. Under the proposed policy, such medical advances in the standards of care would likely be categorized as within a functional category akin to the current standard of care, and no new dollars would be added to the bundle.

Another new drug promises to offer the first FDA-approved treatment for pruritis in hemodialysis patients. Current treatment options (antihistamines, creams and ointments) do not provide patients with an effective treatment option. Yet, again under the proposed policy, this drug would likely be viewed as coming within the functional category of antipruritics, with no new money being added to the bundle.

While the initial language around the TDAPA policy and the recognition that there could be unique circumstances encouraged some innovation, if the proposed policy were finalized, it would stop new products from being developed going forward.

These examples highlight the problem with the functional categories as currently defined and may offer insight as to why the other prospective payment systems have not used a similar mechanism when addressing new drugs and biologicals. While we appreciate that CMS has tried to narrow the functional categories, they remain overly broad and are likely to incorporate any new innovative product. As CMS has noted in the passage above, the history of this area of health care has focused on generics and biosimilars, rather than the true innovation seen in other areas of health care. If CMS were to adopt a blanket policy of adding no new money to the bundle for any drug or biological that comes within one of these categories, it will stifle innovation and leave patients with the same standard of care that existed in the 1990s.



The need to take a more nuanced approach is also critical in light of the fact that the ESRD PPS is also unique from other Medicare prospective payment system because the ESRD has one payment category. The hospital inpatient PPS has more than 460 MS-DRGs, with subgroups in each one. The hospital outpatient PPS includes more than 150 APCs, which are aggregated into families. The single payment category means that the system cannot balance itself out in the short or long term. Unless there is adequate reimbursement for new products, they simply will not be used. Patients will lose access to them, even if these products are used during the TDAPA period.

This concern is real, as hospital outpatient data shows. Drugs receiving pass-through status in the outpatient setting since 2010 that are separately paid after the pass-through status expires continue to have evolving utilization patterns and increased utilization of a product that is clinically valued. Yet drugs that are packaged after the pass-through status expires show immediate depressed utilization, very slow growth in utilization, when much more rapid growth in utilization would be expected, and, in the case of biologic tissues (a class of hybrid products granted pass-through status), no new innovations since the packaging policy was implemented. This experience shows that packaging of new drugs after 2-3 years does not support innovation and does not allow sustained diffusion into clinical practice. Specific examples are listed in Appendix A.

Moreover, these policies will disincentivize the utilization of new drugs or biologicals where physicians and providers know there will be insufficient funding available the TDAPA period.

CMS suggests in the Proposed Rule that extending the outlier policy to composite rate drugs and new drugs or biologicals in the functional categories would be sufficient to cover the cost associated with these drugs. It would not. The outlier amount only applies if the per-treatment imputed Medicare allowable payment (MAP) amount for ESRD outlier services exceeds the adult or pediatric predicted ESRD outlier services MAP amount plus the fixed-dollar loss amount. The per-treatment imputed MAP is calculated by dividing the monthly imputed MAP amount of providing ESRD outlier services by the number of dialysis treatments furnished to the beneficiary.<sup>18</sup> As noted above, The Moran Company's illustrative example shows, while the outlier policy does provide additional dollars, it is not a substitute for an appropriate bundled payment rate. After all, the purpose of the outlier policy in the ESRD PPS – or any other Medicare program – is to provide a payment adjustment for high-cost outliers due to unusual variations in the type or amount of medically necessary care. It is not meant to be the sole pathway for reimbursing an innovative drug or biological just because it did not exist and was not considered in 2009 when the ESRD PPS was first proposed.

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<sup>18</sup>42 C.F.R. §413.237(b).

KCP recognizes as well that the Administration is trying to design policies that reduce the overall expenditure for drugs and biologicals, particularly in Part B. As noted earlier, the ESRD PPS is unique in that it is an already extremely narrowly defined payment system with only one payment category that makes it impossible to shift cost across multiple payment categories. In addition, it is an area that the Department recognizes lacks innovation, as evidenced by the support of KidneyX.

In light of these facts, KCP believes the most appropriate approach would be for CMS to review each new drug that is not a generic or biosimilar to determine based on the FDA documents (including the clinical pharmacology and study portion of the FDA label) whether the drug should be included in the bundle and, if so, then new money should be added. The intent would be to provide adequate funding to support the use of drugs and biologicals that are different from those already in a functional category.

We appreciate the administrative burden that this type of a case-by-case review might entail, even though there are only a handful of drugs that would even need to be considered under such a methodology today. To that end, we recommend that CMS modify the current language in the proposed rule and indicate that it will evaluate whether new drugs and biologicals that come within functional categories should be added to the bundle with certain guardrails in place. While we believe the guardrails below are appropriate for the time being, we ask CMS to provide in regulation that there may be instances in the future that we cannot anticipate today that may not be within these guardrails, but that would also warrant adding new money to the bundle.

Specifically, KCP recommends that CMS outline the following guardrails and provide an opportunity for the community to comment on these as part of a final rule with comment. It is important to signal this approach in the final rule rather than wait for next year because the current proposal, if finalized, will have a devastating impact on the ability of patients to access the current innovative treatments currently in the pipeline, some of which may come to market as early as 2019, if the appropriate payment policies are in place. Unless there is a clear policy that new money will be added for such products, investors have already told KCP members that they will no longer fund products in this space.

KCP suggests the following guardrails for drugs and biologicals that are within a functional category:

- Generics (which we understand CMS already has excluded from TDAPA) and biosimilars should be folded into the current functional categories without new money.

- New money should be added to the bundle for new drugs and biologicals that CMS determines are in existing function categories,<sup>19</sup> but that are differentiated from existing therapies, to account for their utilization and cost once added. “Differentiation” may be considered on the basis of the following:
  - Drugs and biologicals that fill a treatment gap (address an unmet medical need) in an existing functional category; or
  - Drugs or biologicals that treat conditions in dialysis patients for which no FDA-approved product in an existing functional category may be used consistent with the drug’s label; or
  - Drugs or biologicals for which there are multiple clinical outcomes as stated in the FDA labeling material (including within the clinical pharmacology and study portion of the FDA label, sections 11 and 14); or
  - Drugs and biologicals that based on FDA labeling<sup>20</sup> that have demonstrated clinical superiority to existing products in the bundle; or
  - Drugs and biologicals that improve priority outcomes, such as:
    - Decreasing hospitalizations;
    - Reducing mortality;
    - Improving quality of life (based on a valid and reliable tool);
    - Creating clinical efficiencies in treatment (including but not limited to reducing the need for other items or services within the ESRD PPS);
    - Addressing patient-centered objectives (including patient reported outcomes once they are developed and used by the FDA in its review of drugs and biologicals); or
    - Reducing in side effects or complications;<sup>21</sup> or
  - Drugs and biologicals that demonstrate a significant improvement in safety over products currently available in the bundle.

This review can be based on the FDA labeling information, which includes specific statements in these areas that CMS should consider when determining whether to provide new money for a drug or biological it has decided to fold into the bundle. This evaluation would not be unlike the decision CMS will have to make as to whether a drug or biological comes within a functional category in the first place.

This is not an all-inclusive list and we urge CMS to provide in regulation that new areas may arise in the future that it cannot anticipate today. These guardrails should promote innovation, based on what we understand today and provide an appropriate

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<sup>19</sup>As described below, part of this analysis should include an evaluation of whether the utilization during the TDAPA period supports adding the product to the bundle.

<sup>20</sup>If appropriate to add to a functional category.

<sup>21</sup>Current legislation being considered by the Congress includes criteria such as these. *See* H.R. 5997 “Ensuring Patient Access to Critical Breakthrough Products Act of 2018” introduced by Reps. DelBene (D-WA), Walorksi (R-IN), Sewell (D-AL), Bilirakis (R-FL), and Cardenas (D-CA).

incentive for the evolution of innovative products over time as well. CMS should be able to administer these guardrails because they rely on FDA labeling, which is one of CMS's current criteria, but also recognize that the HCPCS code description may be too narrowly defined to label first-line indications to truly reflect the unique aspects of a novel product.

In addition to these criteria, KCP recommends that CMS clearly state when a drug or biological – even if it were to qualify for a functional category – will not be bundled if it is not provided to the average patient. We appreciate that the preamble to the Proposed Rule states that the bundle is based on the costs incurred by the average patient.<sup>22</sup> This aspect of any analysis is critically important because, if the average patient does not receive a product and it is bundled, then CMS will be creating winners and losers in the system. Those who provide the drug are always doing so at a loss, and those that do not receive a windfall. In the end, if the average patient is not receiving a product and that product is bundled, it is more likely than not that no patient will receive the product.

This concern is not theoretical and has been born out in the hospital outpatient setting, as described above. Bundling of new products after two to three years of pass-through status does not support innovation without adjusting the payment rate for the long-term does not permit sustained diffusion into clinical practice. Most importantly, it means that Medicare patients have lost access to products that could improve their clinical outcomes and quality of life.

Based on anecdotal information from drugs recently packaged in the HOPPS, it appears that, when providers know a drug will be packaged, they will no longer stock and use the products, thereby eliminating access for beneficiaries in their facilities and depressing the overall utilization of the drug in the Medicare program. The problem is especially clear when the packaged/bundled rate is not sufficient to cover the cost of the product. While prescribing is the physician's responsibility, it is difficult for physicians to prescribe drugs that are not stocked by hospital pharmacies and by other providers. This situation results in physicians not being able to use drugs they might otherwise consider of benefit to the patient. This shift in incentives would be devastating in the ESRD program, in which more than half of the dialysis facilities experience negative Medicare margins, making it impossible to cover the cost of new products – regardless of their clinical importance – that are not reimbursed adequately under the bundle.

We appreciate that there may be concerns that there has not been sufficient time for stakeholders to provide comments on these recommendations, so we ask that CMS promulgate the rule as a final rule with comment period. The comment period would also provide CMS with the opportunity to hear from the entire community about potential guardrails and refine the guardrails, based on these comments.

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<sup>22</sup>83 *Fed. Reg.* at 34314.

As noted in previous letters, KCP has raised concerns about the functional categories and recommended further narrowing them. The current categories recognize the primary conditions for which pharmacological treatments are an integral part of the treatment protocol. Given that the disease itself has not changed over the years, the primary potential future innovations in this area would likely come within these functional categories. Any policy that locks the bundled payment amount at current levels – which even MedPAC has recognized falls below the cost of providing treatments -- removes any incentive for developers, manufacturers, and investors to innovate in this area. Restricting the application of the functional categories would alleviate this concern.

The intent of the Congress in establishing the bundle was to define the ESRD PPS to incorporate the historic composite rate services, ESAs, equivalent agents, other drugs and biologicals that would have been paid for separately prior to the PPS being implemented, and other items and services that are for the treatment ESRD. The bundle should be defined, in-line with its original intent, around products that are “associated with the dialytic treatment” to align with this intent. Eliminating the broader scope of the functional categories by further narrowing them and centering the bundle on services and items associated with the dialytic treatment align the ESRD PPS more closely into line with the policies in other Medicare prospective payment systems that do not use functional categories for drugs and biologicals and define the bundle in a manner consistent with the services provided in the dialysis facility under the PPS.

### **C. KCP Recommendations that CMS Obtain Two Full Years of Claims Data Before Folding Any Drug Into the ESRD PPS.**

KCP strongly supported the “at least two years” language that CMS finalized in previous rulemaking. While we understand that it may be viewed as less expensive to affirmatively limit a drug or biological pass-through status to two years, this approach may be pennywise, but is clearly pound foolish.

This problem with only a two-year transition period has been highlighted most recently in the hospital outpatient PPS. The purpose of transitional pass-through payments is to allow for adequate payment of new and innovative technology until there is enough data to incorporate the costs for these items into the base payment group.<sup>23</sup> To make this determination, CMS needs to have sufficient information. Two to three years is not sufficient. First, there is a two-year lag in access to claims data. Although we recognize that CMS can monitor claims in real-time, these raw data points do not capture a complete or an accurate picture of utilization. Second, two years is an insufficient time to account for the rate of diffusion of any new innovative product. Diffusion of new technologies requires determination of the actual benefit to patients and the circumstances for appropriate clinical use. This, in turn, requires the time for clinical experience to be described in

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<sup>23</sup>SSA §1833(t)(6)(A); 42 C.F.R. §419.62.

studies and professional meetings to determine the actual benefit to patients and circumstances for appropriate clinical use. The first year of claims data representing the first year a product is on the market cannot capture the clinical judgements critical to defining how that new technology will actually be used. Initial decisions about placement and treatment in rate setting should be reviewed in light of clinical feedback and actual utilization which is more extensively available after three years of experience. This fact is supported by the experience with calcimimetics in ESRD (see below), as well as data from other Medicare payment systems.

CMS has recognized the need for a longer than two year period in the outpatient setting. While initially focused on a two year pass-through payment, it converted to providing for a three year period in all cases.

The Congress recognized these problems this year when, as part of the Bipartisan Budget Act of 2018 (BBA 2018), it extended the pass-through period for certain outpatient drugs an additional two years beyond the three-year period CMS had implemented. Roughly speaking, to have two full years of claims data available for decision making, the TDAPA period would need to be four calendar years. The BBA's five year period provides CMS with three full calendar years of data.

While KCP is not asking for a five year period, we do believe that CMS should retain the flexibility to extend the TDAPA period beyond two years to ensure that accurate and complete data are available to make determinations about bundling new products and adjustments to the bundled rate. Specifically, CMS should return to the original "at least two years" language for both new drugs and biologicals, which it appears to already retain for calcimimetics. In that way, the Agency would maintain the flexibility to use a two-year period in those instances where there would be sufficient claims to move a drug or biological into the bundle, but also have the ability to extend that period when warranted. This flexibility is especially important when a drug or biological is truly innovative.

A related concern is the proposal "that new renal dialysis injectable or intravenous products [would] no longer required to be assigned an HCPCS code before the TDAPA can apply [and] instead ... would require that an application has been submitted in accordance with the Level II HCPCS coding procedures."<sup>24</sup> This proposal would trigger the start date for a drug or biological under TDAPA prior to the product's actual launch. If this proposal were finalized, it would mean that there is even less data available for evaluating the drug or biological. As KCP has recommended in previous letters, there needs to be a full two years of actual data available to assess these new products. Consistent with the concerns about limiting TDAPA to only two years as described above, we strongly encourage CMS to clarify that while it may acknowledge that a drug or biological will qualify for TDAPA status prior to the assignment of a HCPCS code, the point at which the TDAPA period begins will

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<sup>24</sup>83 *Fed. Reg.* at 34312.

start when the drug or biological is actually available to facilities and reimbursed by Medicare.

**D. KCP Supports the Current Policy for Calcimimetics and Recommends that CMS Obtain at least Two Full Years of Claims Data before Ending the TDAPA Period.**

As noted in our comment letters for CY 2016 and 2017, KCP remains generally supportive of the framework CMS has established for transitioning calcimimetics in to the ESRD PPS. Consistent with the comments above, we support the continued use of ASP+6 percent for the base of the TDAPA amount and reiterate our support for its use for other new drugs and biologicals as well. We also support retaining the “at least two years” language for the TDAPA period, but as described below recommend that CMS indicate in the final rule that this period will extend beyond two calendar years to ensure the Agency has at least two full years of claims data. Finally, we ask that before CMS automatically folds these drugs into the bundle, it consider how their limited utilization will impact the distribution of dollars that will be added. During the TDAPA period, we recommend that CMS work with the community to develop an approach that does not disincentivize their continued utilization once the TDAPA period ends.

As noted above, it is important that CMS have adequate information about utilization and practice patterns for new products before folding them into the ESRD PPS. The calcimimetics provide a good example of why this statement is true. While oral calcimimetics have been used by approximately one-third of patients since the introduction of Sensipar® (cinacalcet) in 2004, patient compliance with the drug regime has been inconsistent with a high discontinuation rate. With the introduction of Parsabiv® (etelcalcetide) prescribers have been trying to determine which patients will benefit most from the new IV and slowly incorporating it into clinical practice after conducting limited pilots with their patient population. At the same time, others are testing new ways to provide the oral calcimimetic to improve compliance. To complicate matters, unclear policies – particularly as they relate to the Medicare Advantage program and reporting these drugs on the cost reports – have made the data reported to CMS more unstable than it might have been as well.

As the data from the hospital outpatient drugs analysis described above shows, it is extremely difficult to obtain accurate and complete data shortly after a new product is introduced into any area of health care. As CMS recognized in the proposed rule, it takes time for the uptake of a new drug, particularly in ESRD where clinicians are slow and deliberate in their incorporation of new products given the fragile health status of their patients. With the added complications of facilities having to figure out how to dispense oral calcimimetics and continued confusion among MA plans about how to pay for these drugs, the utilization data available to CMS for the first year of TDAPA is highly unlikely to present an accurate picture of clinical practice patterns for this class of medications.

CMS specified in Transmittal 1999 (dated January 9, 2018) that it plans to end the TDAPA period and bundle these drugs into the ESRD PPS for January 1, 2020. KCP has serious concerns that CMS would be making the initial decisions about utilization and pricing based on roughly 8 to 12 months of data (assuming CMS begins working on the proposed rule in November or December). As discussed above, this early data will not show actual ultimate utilization of these products since providers and clinicians are still in the process of incorporating them into their clinical practice. If the portion of patients using these drugs is less than that of the average patient, it may not be appropriate to include them in the bundle because doing so would create significant disincentives to provide the drugs. If the drugs should be included, the limited amount of data will make it difficult to assess what the appropriate amount is that should be added to the base rate. It would also be difficult to assess whether adjusters or other insurance tools should be used to ensure adequate reimbursement. As the outpatient information shows, making a wrong decision in this area can have seriously negative impacts on patient access.

Therefore, we ask that CMS clarify in the final rule that it will use two full years of claims data – meaning that the TDAPA period should be at least three if not four years – before making a decision to include calcimimetics in the bundle and how to do so is made. We recognize that CMS has already stated that it will add these drugs to the bundle after the TDAPA period. However, given the limited number of patients who will be using the drug, we ask CMS to work with stakeholders to develop a mechanism that does not result in facilities that provide the drugs to patients doing so at a significant loss and that does not provide a windfall to those that do not. Similarly, it seems inappropriate to increase the copayment amounts for patients who are not receiving the drug. We recognize that this is a complicated issue, but encourage CMS to allow sufficient time for the development of a policy that can serve as a model for similar drugs in the future. We also ask that CMS outline in the final rule (with a comment period as well) the methodology and data it plans to use to value these drugs when they are added to the bundle.

## **II. KCP recommends that CMS should address the ongoing problems with the case-mix adjusters to promote adequate payment rates.**

While we appreciate that CMS has acknowledged the burden that some of the adjusters have created for providers and patients, the proposals do not address the underlying problem or effectively reduce the continued burdens. Therefore, we ask that CMS follow the recommendations of the kidney care community and MedPAC and also address the long-standing problems with the case-mix adjusters that result in *de facto* cuts to the rates or misappropriate the dollars that are available.

KCP greatly appreciates that CMS has “determined that the documentation requirements associated with the conditions that are eligible for the comorbidity payment



adjustment should be revisited.”<sup>25</sup> We thank CMS for hearing our concerns, but unfortunately the use of ICD Official Guidelines will not sufficiently address this problem. First, the preamble is silent on what documentation will be required to support the ICD-10 codes that seem to be what the Proposed Rule would ask the dialysis facilities to use to support a claim with one of the four comorbid adjusters. Dialysis facilities do not diagnose patients with these conditions, which means that they will continue to have to rely upon documentation from other providers to support the claim. This documentation is rarely, if ever, available because CMS does not require the other providers to disclose the information to dialysis facilities. This problem is so acute even at the most basic level that we continue to ask CMS to require hospitals to provide discharge information to facilities. If hospitals will not provide facilities with the most basic information – such as whether anemia management drugs were administered and whether a patient was adequately dialyzed during a hospital stay – it seems highly unlikely that any provider will provide documentation to support one of the comorbid adjusters.

Without documentation, the money set aside to pay these adjusters is cut from the system. The Moran Company estimates that, if the actual rates at which the comorbidity adjusters would be claimed had been used, the base rate for 2011 would have been at least \$0.95 higher. This loss persists every year, so the loss for the comorbid adjusters is now at least \$7 per treatment. As we have stated in the past – and MedPAC has recommended – the better course is for CMS to eliminate the case-mix adjusters and rely upon the outlier pool to appropriately adjust for higher acuity patients.

MedPAC’s comments support this recommendation. In its comment letters on the CY 2016 and CY 2017 Proposed Rules, MedPAC stated, respectively:

- “CMS should consider removing all comorbidity adjustment factors.”<sup>26</sup>
- “The inclusion of adjustment factors for comorbid conditions that are poorly identified on dialysis facility claims may cause undue burden on patients undergoing additional diagnostic procedures in order to meet documentation requirements, and reflect differences only in the cost of formerly separately billable services.”<sup>27</sup>

The second step CMS could take to help stabilize the payment system is to make sure that the other patient-characteristic case-mix adjusters are targeting high-cost patients. In previous letters, KCP has explained how the current case-mix adjusters for age and weight do not accurately capture the patients that require more costly care. Appendix A includes a memo from The Moran Company that we shared with CMS earlier this year. It

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<sup>25</sup>*Id.* at 34391.

<sup>26</sup>MedPAC, Comment Letter on the ESRD PPS CY 2016 (2015).

<sup>27</sup>MedPAC, Comment Letter on the ESRD PPS CY 2017 (2016).

details the problems with the current adjusters. MedPAC has called on CMS to replace the two-equation regression model. The current model inappropriately relies upon related/correlated patient characteristics which leads to the inaccurate adjusters being used today. The age adjuster also does not reflect the costs centers that drive the overall cost of treatment, such as labor (which is linked to time on dialysis) and fix costs (that are spread over all patients). The variability of costs sits in the pharmaceuticals, which are addressed through the outlier payment. For facilities, the current system means that they are paid less for the more expensive patients and more for patients who require fewer services. Unless the problems are fixed, facilities will not be appropriately paid for high cost patients.

To address this problem, KCP asks that CMS work with its contractor and engage the community to identify variables that are independent and can be accurately measured in existing data. Adjusters should not be proxies for high cost patients, but capture the actual sources of high-cost care. Specifically, KCP recommends that CMS suspend the use of the age and weight patient-characteristic adjusters until it can build a single equation model, as MedPAC has recommended. This model is favorable because it removes using facility-level data for determining patient-level adjusters.<sup>28</sup> As CMS undertakes this model, it should identify specific cost-drivers to use, such as drug-cost data for determining the weight adjuster.

Third, the rural and low volume adjusters also overlap, resulting in dollars being inappropriately targeted. The Facility-Level Impact file shows that of the 330 low-volume facilities 168 are rural, so more than 50 percent of facilities that claimed the low volume adjuster are also claiming the rural adjuster.<sup>29</sup> During previous rulemaking cycles, KCP has proposed eliminating the rural adjuster – which is not mandated by statute – and modifying the low volume adjuster – which is required by statute. Based on The Moran Company's analysis, facilities with 6,000 or fewer treatments have significant negative margins. The low volume adjuster could be modified therefore, KCP continues to propose that CMS instead rely upon a two-tiered low-volume adjuster policy, with the current low-volume adjuster being the first tier and the second tier applying to facilities with 4,001-6,000 treatments per year. This modification can be made without having to create a new model.

We also ask that any change to the adjusters be accompanied by a recalculation of the standardization factor so that the dollars represented by the adjuster can be returned to the base rate.

We appreciate the continued review of these issues and look forward to addressing these problems to work toward a viable payment system. More specifically, we ask that

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<sup>28</sup> Facility data represent variation in organizational costs for chain facilities, not variation in the cost for individual patients.

<sup>29</sup>See ESRD PPS CY 2019 Proposed Rule Facility Level Impact File.

The Honorable Alex M. Azar  
The Honorable Seema Verma  
August 10, 2018  
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CMS indicate in the preamble to the final rule that it will make the interim changes suggested here and engage with the contract and stakeholders prior to the CY 2020 proposed rule being published to consider the methodological changes recommended by KCP, other stakeholders, and MedPAC.

### **III. Conclusion**

We are grateful for the commitment to innovation in the kidney space made by HHS through KidneyX, and we look forward to working with HHS on policies that can optimize the likelihood of changing the kidney failure treatment paradigm for the better. As noted, we will provide comments on the other provisions in the Proposed Rule separately. If you have questions or comments, please contact Kathy Lester at [klester@lesterhealthlaw.com](mailto:klester@lesterhealthlaw.com) or (202) 534-1773. Thank you again for considering our recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "Allen Nissenson".

Allen Nissenson  
Chairman  
Kidney Care Partners

cc: Demetrios Kouzoukas, Principal Deputy Administrator for Medicare and Director  
Laurence Wilson, Director Chronic Care Policy Group  
Jeanette Kranacs, Deputy Director Chronic Care Policy Group  
Jana Lindquist, Director Division of Chronic Care Management  
Abby Ryan, Deputy Director Division of Chronic Care Management

**Appendix A: KCP Members**

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  
Atlantic Dialysis  
Baxter Healthcare Corporation  
Board of Nephrology Examiners and Technology  
Cara Therapeutics  
Centers for Dialysis Care  
Corvidia  
DaVita Healthcare Partners, Inc.  
Dialysis Patient Citizens  
Dialysis Clinic, Inc.  
Fresenius Medical Care North America  
Fresenius Medical Care Renal Therapies Group  
Greenfield Health Systems  
Keryx Biopharmaceuticals, Inc.  
Kidney Care Council  
Medtronic  
National Kidney Foundation  
National Renal Administrators Association  
Nephrology Nursing Certification Commission  
Northwest Kidney Centers  
NxStage Medical  
Otsuka  
Renal Physicians Association  
Renal Support Network  
Rogosin Institute  
Satellite Healthcare  
U.S. Renal Care

## **Appendix B: The Moran Company Memo**

### **Memorandum (May 2, 2018)**

**To: Kidney Care Partners**  
**From: Mark Desmarais, The Moran Company**  
**Subject: Follow-up from April 18 Meeting with KCP**

As a follow up to our April 18<sup>th</sup> meeting, KCP asked me to provide you with a memo highlighting the key points we discussed as well as a more detailed discussion of some of the technical slides we presented on behalf of KCP. This memorandum expands the technical discussion around several topics discussed during that meeting.

#### **Key Discussion Items**

- Age adjuster appears unreliable due to frequent swings in reference group
- Cost reports are inappropriate for setting patient level adjusters such as the age adjustment
- Rural and low volume adjusters overlap substantially and are not independent
- Co-morbidity adjusters continue to be burdensome to capture in claims data, rate with which they are claimed dramatically lags original projections and causes leakage

#### **Age Adjuster**

The age adjuster reference group has changed in each of the published runs of the ESRD-PPS model. In the 2011 Proposed Rule the reference (least costly) group was age 45-59. In this run of the model patients age 70-79 were 7% more expensive for the delivery of composite rate services than patients aged 45-59. In the second run of the ESRD-PPS model in the 2011 Final Rule the reference group switched to patients aged 60-69. In this run, patients aged 45-59 and 70-79 had virtually identical adjusters, indicating that they were now considered to be approximately the same expense to treat. In the 2016 Proposed Rule, the ESRD-PPS now found patients aged 70-79 to be the least costly group. In this run, patients aged 45-59 were now 6.8% more expensive than patients aged 70-79. Taken together, this means that between the 2011

and 2016 runs of the model, patients aged 45-59 had shifted nearly 15% relative to patients aged 70-79. Neither industry experts or MedPAC believe there is a clinical explanation for this substantial change in relative cost. It appears that the age adjuster is picking up statistical noise from some other source, since clinical practice has not changed for these two age groups.

### **Cost Report Data Used to Measure Patient Level Characteristics**

The currently used two-equation model uses cost report data to attempt to measure variation in clinical practice. At the facility level, for the determination of differences in cost among low volume providers or similar adjustments, this data can appropriately measure facility-to-facility cost differences. It cannot, however, accurately measure patient level variation in costs. Machine and supply costs reflect facility negotiations and discounts, labor costs reflect specific market conditions and the utilization rate of available staff, and rent is allocated across all patients uniformly. None of these variations are attributable to patient characteristics.

A cost report-based patient metric offers too much opportunity for noise rather than actual cost difference to be measured. It is a large leap to go from modest correlation (as measured by published  $R^2$ ) to the causation needed to justify adjusting payments. For the age adjuster specifically, the 2016 run of the ESRD-PPS model showed no variation in separately billable cost among the three major age groupings, which means that the cost report data is entirely responsible for the resulting adjuster.

### **Rural and Low Volume Adjusters**

The rural and low volume adjusters, as presently designed are clearly not independent variables. This is problematic as it is unclear exactly how appropriate it is for facilities to claim both adjusters at the same time. Intuition suggests that it is unlikely that the appropriate adjuster is the product of the two adjusters themselves. According to the 2018 Final Rule, 183 of the 1,243 facilities (14.7%) claiming the rural adjuster also claimed the low volume adjuster. More alarmingly, only 348 total facilities claimed the low volume adjuster, thus 53% of facilities claiming the low volume adjuster were also rural facilities. With such a high degree of overlap, it is unclear how the model could arrive at appropriate adjusters when it assumes correlation. A model measuring a single adjuster for rural, low volume, and 'both rural and low volume' would be much more accurate than the current double adjuster model.

Of particular concern – margins at low volume facilities remain low, despite the presence of the adjuster. Of the 1,830 facilities with fewer than 6000 total dialysis treatments in 2016 cost reports, we find that 1,440 (79%) had negative margins. Of the 1,125 rural facilities, 595 (53%)

had negative margins. As MedPAC and others have noted, it does not appear that the low volume and rural adjusters are presently properly accounting for the cost structure at these facilities. If the low volume and rural adjusters were appropriately scaled and sized, these facilities should have a similar distribution of positive and negative margins as the rest of the industry.

### **Co-Morbidity Adjusters**

As MedPAC has commented, the co-morbidity adjusters appear to be poor predictors of more costly patients. In addition, many patients would be eligible clinically for the payment adjustment but facilities cannot claim the adjustment because of their inability to document sufficiently the clinical condition. In some cases, facilities would need to subject patients to unnecessary diagnostic procedures in order to document the condition. The original ESRD-PPS model was flawed in that it tested 44 clinical conditions for potential adjustment, often without a strong theory of why patients with these conditions would be costlier. The initial run of the model in the 2011 proposed rule found the majority of conditions tested did not merit inclusion for adjustment. Subsequent runs of the model have continued to find more and more conditions are not appropriate choices for payment adjustment due to low correlation with cost of care. The testing of such a large number of clinical conditions increased the possibility that statistical noise would cause adjustments to be made where none were clinically needed.

In addition to the substantial burden on facilities and patients and the inappropriateness of testing such a large number of conditions, there already exists a mechanism by which the costliest patients could receive increased payments from Medicare – the outlier pool. Given the very low volume of co-morbid adjuster cases, it may be more appropriate to let the outlier pool pick up these patients. This would decrease the reporting burden on facilities and patients while still providing for these patients when their costs greatly exceed a typical dialysis patient. It would also cease the current program's differential payment treatment of patients for whom medical documentation of co-morbid conditions is easy to obtain (and receive adjuster payments) or for whom such documentation is impossible under the current system (who receive only outlier payments).

### **Continued Dialogue**

The Moran Company is willing to participate in continued dialogue with both CMS and its contractor to facilitate discussion of technical challenges and potential solutions throughout the year. We look forward to working with KCP and CMS to strength the ESRD PPS so that it allows providers to deliver high quality care to ESRD patients.