KIDNEY CARE PARTNERS

August 29, 2014

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

RE: CMS-1614-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Dear Administrator Tavenner:

Kidney Care Partners (KCP) is pleased to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the "Proposed Rule: End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" (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 ongoing working relationship between CMS and the kidney care community. We believe that KCP and the Agency share the common goal of establishing an adequate payment system that provides sufficient resources not only to allow for the provision of basic treatment, but also to incentivize high quality care and protect access for beneficiaries. Over the years, KCP has focused its efforts on supporting initiatives that recognize facilities for attaining quality benchmarks, as well as those facilities that make improvements toward these goals. We have also promoted efforts to reduce 90-day and first year mortality through the community-lead Performance Excellence and Accountability in Kidney Care (PEAK). Our members have worked with the Agency to reduce morbidities associated with the use of catheters through Fistula First/Catheter Last and been on the front-line of developing coordinated care efforts through the Special Need Plans and other

programs. These efforts, and others, not only lead to better outcomes for patients, but also reduce unnecessary hospitalizations and save Medicare resources.

KCP supports the Agency's interpretation of the provision of the "Protecting Access for Medicare Act of 2014," P.L. 113-93 that sets the base rate for Calendar Year (CY) 2015 at essentially the CY 2014 rate. We also believe that CMS has correctly interpreted PAMA to delay the payment of oral-only drugs through the ESRD bundled payment until 2024. However, KCP has serious concerns about the proposals related to the rebasing of the market basket and ask that CMS adopt a different price proxy for ESRD drugs and biologicals. We also provide recommendations to address: (1) the issue of potentially new drugs that could be essential to the delivery of maintenance dialysis; (2) the confusion surrounding the relationship between Part B and Part D drugs; and (3) the ongoing problems with the comorbid case-mix adjustors, standardization factor, outlier policy, and the low volume adjustor.

I. CMS Should Provide Appropriate Data When Publishing the Proposed and Final Rules

As in years past, the kidney care community remains deeply troubled by the lack of data provided in the Proposed Rule. We appreciate the limited resources that the Agency has, but these data would allow the community and CMS to work together to ensure the adequacy of the payment system so that we can achieve the shared goals of improved patient outcomes and lower hospitalization rates. Thus, we are disappointed by the lack of even a limited rate setting file, which CMS had previously provided with the release of both the proposed and final rules since the creation of the drug add-on policy. This file contained valuable information, including the total billed drugs and other separately paid items, as well the treatment volume. This information allowed facilities to analyze the impact of proposals at their individual level.

We are also concerned that the information that is provided does not document the changes made in each of the seven steps that are listed. For example, in Step 1, it is not clear whether CMS implemented only the changed outlier threshold or included other modifications. It is even more difficult to analyze the other six steps.

In our view, the kidney care community and CMS have always worked in a cooperative manner to ensure fair payment rates. Having adequate data over the years has been at the heart of this relationship. Such data provides transparency and allows the community to have confidence in the payment rates. As CMS proposes major changes in the payment system, such as rebasing the market basket, maintaining this confidence is essential. Therefore, we urge CMS to provide a rate setting file, as we have requested in previous years, or to work with the community

to identify and provide the necessary data elements that will allow for a complete analysis of the Proposed Rule.

II. KCP Supports Rebasing of the ESRD Market Basket, But Urges CMS to Adopt a More Accurate Proxy for Drugs and Biologicals and Ensure that all of the Cost Report Data Have Been Examined for Purposes of Determining the Labor Share

KCP understands that it is appropriate for CMS to rebase market baskets on a regular basis. Overall, we support the revisions to the cost centers and, for the most part, the weights. However, we recommend that CMS review the "Administrative and General" (A&G) and "Wages and Salaries" to ensure that all costs have been included and that there is consistent treatment of salaries associated with the "Capital Related Machinery" cost center. We also note that CMS may want to revisit the allocation of laboratory costs from A&G once some of the providers have re-filed their cost reports. Most importantly, we strongly urge CMS to revise the proposed price proxy for pharmaceuticals and use either a more appropriate single PPI index (PPI for biologicals) or a composite proxy that would better reflect the costs of drugs and biologicals that are included in the ESRD bundle.

A. KCP Recommends that CMS Clarify How It Calculated the Weights for the A&G and "Wage and Salaries" Cost Centers and Revise the Allocation of Laboratory Costs

KCP supports the revisions to the cost centers and weights with two exceptions. First, when The Moran Company replicated the proposed weights for seven of the nine cost centers, they identified two anomalies in regard to the A&G and "Wages and Salaries" cost centers. First, there are two possible sources for the data used to calculate the ratio of salaries to total costs for A&G: line 18 of worksheet A, or the sum of lines 11, and 13 through 17. Line 18 is supposed to contain the sum of lines 11 and 13 through 17. If the cost reports were completely filled out, they would be identical. While the Proposed Rule indicates that CMS calculated the ratio of non-direct patient salaries contained in A&G, it does not specify whether to use line 18 or to sum the component lines. Unfortunately, line 18 contains data in only 25 percent of the cost reports, whereas if the component lines are summed, then all cost reports have data for the cost center A&G.

If the component lines are summed, then The Moran Company estimates for the weight for cost center "Wages and Salaries" increased from 32.735 percent to 33.585 percent. The estimated weight for "Administrative and General" decreased from 16.476 percent to 15.666 percent. Because the cost center "Wages and Salaries" is a part of the overall labor share percent, this has the effect of increasing the estimated proportion of labor share by .778 percent. KCP encourages CMS to

clarify the source of the percentage of non-direct wages associated with A&G that are obtained from Sheet A of the Medicare Cost reports.

The second concern relates to the assignment of the salaries associated with "Capital Related Machinery." The Proposed Rule states that a ratio of salaries to total costs is calculated for "...the following cost centers: housekeeping and operations, employee benefits for direct patient care, Administrative and General, Supplies, Laboratories and Pharmaceuticals." It also states that salaries for capital are reallocated to the cost center "Wages and Salaries." The Moran Company calculated the weights both ways and obtained a closer estimate by not reallocating salaries from the cost center "Capital Related Machinery" to "Wages and Salaries," which appears to produce a better replication of the reported weights. However, excluding these salaries from the "Wages and Salaries" cost center does not seem to follow the logic of the rest of the Proposed Rule. We suggest that CMS clarify which of the two methods it used in the calculation of the weights when it publishes the final rule.

Finally, we recommend that CMS not allocate A&G to the "Laboratory" cost center and apply the laboratory price proxy only to directly reported laboratory costs. The Proposed Rule allocates cost from A&G to "Laboratory." This approach appears to overstate the proportion of laboratory cost based upon our understanding as to how some providers will allocate these costs once they re-file cost reports. We encourage CMS to review the revised cost reports before finalizing the proposal and to adjust the allocation appropriately.

B. KCP Urges CMS To Adopt More Appropriate Prices Proxies for Pharmaceuticals

For the most part, the KCP supports the modifications to the price proxies in the Proposed Rule. However, while we understand that consistent with the recommendations of the Office of the Inspector General that using the "PPI – Pharmaceuticals for Human Use" for pharmaceuticals in the ESRD PPS may not be appropriate, we do not believe that the proposal to use an over-the-counter proxy for prescription drugs is appropriate either. Therefore, we strongly urge CMS to adopt a more appropriate price proxy for pharmaceuticals in the final rule.

Relying upon the proposed "PPI – Vitamin, Nutrient, and Hematinic Preparations" as the price proxy for pharmaceuticals in the 2015 market basket would undermine the accuracy and integrity of the market basket. The current set of pharmaceuticals in the ESRD PPS are primarily erythropoietin-stimulating agents (ESAs), prescription vitamins and supplements, antibiotics, and a variety of other prescription drugs, including some products historically included in the base rate.

There are two alternative approaches that CMS could adopt to apply a more appropriate price proxy for pharmaceuticals. First, CMS could continue to rely upon a single price proxy, namely "Biological product for human use." Given that ESAs constitute the greatest portion of the pharmaceuticals used in the ESRD bundle, it is appropriate to base the price proxy on this category of drugs.

Another alternative would be to use a composite price proxy. CMS could split the pharmaceuticals into the following categories:

- ESAs;
- Prescription vitamins;
- Antibiotics; and
- Other prescription drugs.

It could then use the following price proxies for each of the categories:

- "Biological products for human use"[1] is the price proxy for ESA. Using the 2012 SAFs, The Moran Company estimated ESAs to constitute 86 percent of ASP+6 percent valuation for drugs in ESRD facilities.

- "Other vitamins and nutrients, prescription"[2] is the price proxy for vitamin D and IV iron. The percentage of ASP+6 percent drug value for these products is 14 percent.

- "Broad and medium spectrum antibiotics" is the price proxy for antibiotics. The percentage of ASP+6 percent drug value for these products is 0.02 percent.

- "Pharmaceuticals for human use, prescription"[3] is the price proxy associated with miscellaneous prescription drugs used in ESRD centers. The percentage of ASP+6 percent drug value for these products is 0 percent.

In addition to being more accurate, a composite proxy approach is consistent with how Medicare addresses other categories of cost in the market basket.

This alternative supports the principle that the pharmaceutical component of the market basket should reflect the actual drugs that are purchased by the facilities,

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[1] *See* http://data.bls.gov/timeseries/wpu063719.

[2] *See* http://data.bls.gov/timeseries/wpu06380703rx.

[3] *See* http://data.bls.gov/timeseries/wpusi07003.

even when very small amounts of cost are identified. In addition, the use of ASP+6 percent valuation data to construct the proportions by which the pharmaceuticals will be split when the market basket is rebased provides a more accurate method for assessing the portion of each category of pharmaceuticals. Therefore, we strongly urge CMS to adopt either a more accurate single price proxy for pharmaceuticals or the composite proxy approach as described above in the final rule.

C. KCP Supports the Proposed Two-Year Transition To Dampen the Immediate Impact of the Changes to the Labor Share

KCP appreciates that CMS recognizes that the adoption of the revised geographic delineations would harm some facilities and proposes a two-year transition blended wage index for all facilities. KCP supports the proposed transitions and recommends that CMS include it in the final rule.

III. KCP Supports CMS's Efforts to Establish a Clear Policy Related to Addressing New Drugs and Seeks Additional Clarification as to What Drugs Are Currently Included in the ESRD PPS

A. CMS Should Establish a Clear Process for Addressing All New Pharmaceuticals

The KCP appreciates the Agency's request for comments about the process for "(1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the bundled payment under such system." We agree that establishing a transparent process for addressing these issues is important and not an easy task. As a threshold matter, we would like to work with CMS on an ongoing basis to assist in the development of this policy. We believe developing the policy will require more than a single response to a proposed rule. Thus, we seek to provide a set of fundamental principles for the Agency to consider as the basis for the framework of the policy. We will continue to refine our recommendations over time and would welcome the opportunity to continue to share this work with the Agency.

1. The Congress Appears Not To Have Granted CMS Authority to Add New Drugs and Biologicals to the ESRD Bundle

While it would seem likely that CMS has the authority to add new drugs and biologicals to the ESRD bundle, a close review of SSA § 1881(b)(14)(B) raises questions about that assumption. Specifically, paragraph (B) states:

> (B) For purposes of this paragraph, the term "renal dialysis services" includes—
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> (i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;
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> (ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;
>
> (iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this subchapter, and any oral equivalent form of such drug or biological; and
>
> (iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.
>
> Such term does not include vaccines.

Subparagraph (iii) which defines the drugs and biologicals that the Congress required to be within the scope of renal dialysis services limits the type of drugs and biologicals furnished to individuals for the treatment of ESRD to those "for which payment ***was*** (before the application of this paragraph) made separately under this subchapter, and any oral equivalent form of such drug or biological" (emphasis added). This phrase appears to limit the scope of drugs and biologicals to those that existed and were covered and reimbursed by Medicare prior to the implementation of the ERSD PPS. Thus, reading the plain language of the statute, as is required, there is no way to interpret this phrase other than to conclude that the Congress did not intend for new drugs and biologicals to be added to the ESRD bundle.

If Congress had intended for new drugs and biologicals to be added, it would have used a different construction, such as "would otherwise be" rather than the past tense. In terms of erythropoietin stimulating agents (ESAs), it used a different construction that incorporates all current and future ESAs into the ESRD bundle: ESAs that "**are** furnished to individuals for the treatment of end stage renal disease" (emphasis added). It also uses a similar present tense structure with regard to laboratory tests and other items or services not provided for in what had been the composite rate. If the Congress had meant to include future drugs and biologicals, it would have used the same structure it had for the other subparagraphs.

We appreciate that some might argue that the catch-all phase at the end of subparagraph (14) provides sufficient authority for CMS to add new drugs and biologicals to the ESRD bundle. However, reading the subparagraph that broadly

would eliminate the meaning of subparagraph (ii) which speaks specifically to how drugs and biologicals should be treated. More specific phrases control when interpreting statutes.

While we appreciate that some may view this conclusion more like a technical drafting error, it appears that the Congress did not provide CMS with sufficient authority to expand the ESRD bundle to include new drugs and biologicals. Given the current construction of the statute, we believe it is important for CMS and the kidney care community to work with the Congress to develop the appropriate authority for adding new drugs and biologicals into the ESRD bundle.

2. Once New Drugs and Biologicals Can Be Added to the ESRD Bundle, the Policy Should be Guided by a Set of Transparent Principles

Once sufficient authority exists, KCP recommends that CMS work with the kidney care community to develop a policy that is based upon the following principles.

Principle 1: CMS should establish a clear definition of what drugs and biologicals are in the ESRD PPS. It will be important to clarify what drugs and biologicals are eligible for inclusion in the ESRD bundle. Only drugs that are directly related to the provision of renal dialysis services should be considered for inclusion in the ESRD PPS bundle.

Principle 2: CMS should establish criteria related to the frequency with which a drug or biological may be used within the ESRD population. As part of the determination of whether or not a drug or biological is directly related to the provision of renal dialysis services, it will be important to consider the frequency with which a particular product is used within the ESRD population. Drugs that are not frequently used among all dialysis patients should not be deemed essential to providing maintenance dialysis. This approach would be consistent with how CMS originally established the items or services within the ESRD bundle. For example, because blood is rarely provided in facilities, it was excluded from the bundle. The same policy should be applied to drugs and biologicals. While it is not currently clear what such a threshold should be, we are prepared to the work with the Agency to establish appropriate criteria that could be used to evaluate the utilization of drugs and biologicals in this population.

Principle 3: CMS should establish clear criteria for determining when drugs or biologicals are equivalent or interchangeable with existing products that are already in the bundle. It will also be important to develop appropriate criteria for determining what drugs or biologicals may be interchangeable with existing drugs. This determination requires understanding how the Food and Drug

Administration considers such issues, as well as how the drugs and biologicals may be used in the clinical setting.

Principle 4: CMS should rely upon the rulemaking process whenever considering any changes to the bundle. Consistent with our previous comments, we believe that any significant change to the bundle, which by definition includes adding new items or services to it, requires the proposed changes to go through notice and comment rulemaking. By relying upon this process, CMS will provide all interested stakeholders with the opportunity to consider the proposal and offer constructive suggestions.

Principle 5: CMS should establish a clear process to transitioning new drugs and biologicals into the ESRD bundle. This process should describe the period of transition and how the payment will be related to cost. As we have noted in previous comment letters, we believe it would be appropriate to include a transition policy that could be similar to that used in the hospital setting, such as the pass-through payments. This transition would allow CMS to better evaluate the cost and utilization of new drugs and biologicals before adding new dollars to the bundle.

Principle 6: CMS should track the costs of new drugs and biologicals before adding them to the ESRD bundle. It is important for CMS to understand the cost to facilities for providing new drugs and biologicals through the ESRD bundle. Thus, we recommend that in addition to implementing a pass-through policy, CMS should track the cost of these drugs through the ESRD cost reports. This step would require CMS to provide guidance to facilities to ensure that the costs are being reporting the same across all facilities. The approach would provide CMS with an appropriate way to monitor the introduction of new products.

Principle 7: CMS should increase the bundled rate to cover the cost of providing such products. As we have noted previously, when any new item or service is added to the ESRD bundle, CMS should adequately account for the cost of adding a new item or service by increasing the base rate to cover the cost of providing it. This principle should apply to adding new drugs or biologicals to the bundle as well.

We would welcome the opportunity to work close with CMS to translate these principles into policies.

3. These Principles Should Also Apply to Determining When a Drug or Biological Is No Longer an Oral-Only Product

KCP encourages CMS to rely upon the seven principles described above to determine when a drug or biological is no longer an oral-only product. In sum, CMS should determine whether the drug or biological is directly related to the provision

renal dialysis services. If it is, it should be considered for inclusion in the bundle, if the utilization of the drug or biological is not limited to a small number of dialysis patients. As part of this process, it will be important for CMS to establish clear criteria to determine whether or not the oral-only product and the new IV drug or biological are truly interchangeable. Consistent with our recommended principles, CMS should work with the community to determine clear criteria for making this determination.

If after this evaluation, CMS determines that the new product and its oral equivalent should be added to the bundle, the Agency should propose to do so through notice and comment rulemaking. CMS should also evaluate the cost of providing the new product. For the initial 2-3 years, we believe that the new IV drug and its oral equivalent should be paid for on a pass-through basis to allow for CMS to assess the cost associated with adding these products to the bundle. After that period, CMS through notice and comment rulemaking should increase the base rate to cover the cost of providing the products through the bundled payment.

Finally, we encourage CMS to establish a more detailed set of criteria based upon the principles we have recommended for making such determinations. We encourage CMS to describe its evaluation process and criteria in rulemaking before making a determination that a product is no longer an oral-only drug.

B. CMS Should Clarify the Reimbursement of Current Pharmaceuticals

KCP appreciates the Agency's efforts to clarify what drugs and biologicals are included in the ESRD prospective payment. Consistent with our earlier letter on the Part D Proposed Rule, we remain concerned that current guidance has resulted in Part D plan sponsors inappropriately refusing to cover oral drugs that are not for the provision of renal dialysis nor essential to the delivery of such services.

Specifically, beneficiaries have had difficulties obtaining necessary medications and, in some instances, physicians have had to hospitalize their patients so they can receive antibiotics for conditions unrelated to maintenance dialysis. The fact that beneficiaries are being told that any oral medications, such as oral antibiotics, are part of the ESRD bundled payment, solely because a nephrologist wrote the prescription, inappropriately expands the bundle to beyond the score of the authorizing statute.

There are several examples of this problem. In some instances, Part D plans either have refused to cover or have required a prior authorization for <u>all</u> antibiotics, even when the oral antibiotic is being used to treat conditions not related to maintenance dialysis, such as pneumonia. The problem has also occurred with regard to prescription pain medication. For example, some Part D plans are

refusing to cover oral medicines used in combination with an opioid to prevent overdoses. Even if the underlying opioid is being prescribed for back pain, and not pain related to a vascular access graft, the Part D plan asserts that the drug should be paid for under the bundle. Given the problems facing beneficiaries, we strongly urge CMS to provide clarity in the final rule, the Policy Benefits Manual, and to Part D plan sponsors.

As a first step, the guidance should clearly articulate the scope of the bundle. Recent guidance has unfortunately used different terms to identify the group of drugs and biologicals that under certain circumstances may come within the scope of the bundle. Congress defined the scope of the bundle as renal dialysis services.[4] The statute defines renal dialysis services to include ESAs, certain laboratory services, and "other drugs and biologicals that are furnished to individuals for the treatment of ESRD."[5] While these is little specific legislative history, discussions about this provision at the time clearly indicated that the Congress wanted to avoid providers shifting patients from IV Vitamin D to oral Vitamin D, which would have been reimbursed outside of the bundle.

Through regulation, CMS has also indicated that "[r]enal dialysis services do not include those services that are not essential for the delivery of maintenance dialysis."[6] Thus, only drugs or biologicals that are directly related to the provision of renal dialysis services, meaning essential for the delivery of maintenance dialysis, should be paid for under the ESRD prospective payment rate. All other drugs are outside the scope of the bundle.

Prior to January 1, 2014, there appeared to be a clear understanding as to what drugs and biologicals should be reimbursed through the ESRD prospective payment. Guidance issued in 2011 by CMS correctly recognized that "drugs used as substitutes for any of [the drugs list in Table C of the final ESRD PPS rule published August 12, 2010], or used to accomplish the same effect, would also be covered under the ESRD bundled payment and, therefore, ineligible for separate payment."[7] However, drugs that were not substitutes would remain outside of the bundled payment.

The Guidance also included an example related to two antibiotics – vancomycin and daptomycin. It noted that when these drugs are "furnished to an

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[4] 42 U.S.C. § 1395rr(b)(14)(B).

[5] *Id.* at § 1395rr(b)(14)(B)(iii).

[6] 45 C.F.R. § 413.171.

[7] CMS, "Memorandum to All Part D Plans: Clarification of Exclusion of Part D Payment for Drugs Included in the End-Stage Renal Disease Prospective Payment" (February 17, 2011).

ESRD patient receiving dialysis services **and used to treat access site infections** [they are] considered always covered….when furnished to an ESRD dialysis patient for other uses, however, [they] may be covered under Part D." (emphasis in original). The preamble to the 2010 final rule also noted that any anti-infective that is used as a substitute for an injectible anti-infective to treat a vascular access infection or peritonitis would be included under the bundle payment rate. It follows, then, that any drug used to treat another type of infection should not be included under the bundled payment rate. Maintaining a healthy vascular access is clearly essential for the delivery of maintenance dialysis, but treating pneumonia is not.

These problems arose with use of less precise language in changes to the Policy Benefits Manual and the implementation of the CY 2014 Part D Call Letter. These documents rely on more general terms, such as "ESRD-related" and "for the treatment of ESRD" and do not attempt to define them. These terms, when used in isolation, are broader that the statutory and regulatory provisions that limit the inclusion of drugs and biologicals to those that are essential for the delivery of maintenance dialysis. Neither of these documents provides the clarifying examples that were part of the 2011 Guidance.

Given the lack of specificity in the guidance, it is understandable that significant confusion has arisen. For example, the table indicates that anti-infectives are "drugs used to treat infections. These may include antibacterial and antifungal drugs." The 2014 Call Letter does not include the specific example or reference to the 2010 final rule that describe that these drugs are only paid for under the ESRD bundled payment when there they are used to treated vascular access infections or peritonitis, the treatment of which are essential to the delivery of maintenance dialysis. Whether CMS intended to expand the scope of the bundle or not, the language used in the 2014 Call Letter and the Benefits Policy Manual inappropriately does so.

CMS also recognizes that through the use of the AY modifier that some IV drugs provided in a facility are not within the scope of the bundled payment. The Agency did not include dollars in its calculation of the base rate for the oral versions of such drugs when the AY modifier would be applied either. For example, if a patient receives an IV drug or biological that is provided in a dialysis facility but is not essential for the delivery of maintenance, the facility will code that with the AY modifier. If a physician, even a nephrologist, writes a prescription for the oral form of that IV drug or biological, the oral form also remains not essential for the delivery of maintenance dialysis.

There is no question that separately billable IV drugs or biologicals that were related to the treatment of ESRD and essential to the delivery of maintenance dialysis were incorporated into the base rate of the ESRD bundled payment. Those

drugs were included in the 2010 Final Rule. Certain other medications that were administered intravenously during dialysis and billed separately prior to the PPS were identified as drugs that "may be related to ESRD" in the 2010 Final Rule as well. When CMS calculated the inclusion of such separately billable IV medications, it included them at $0.06 - $0.08 cents per treatment in the payment rate. CMS recognizes that some of those IV drugs that "may be related to ESRD" may be administered for a non-ESRD-related purpose, in which case they can be billed through the use of the AY modifier. There is no question about that with regard to drugs administered intravenously. The problem arises if the beneficiary is also given a prescription for an oral version of the IV drug when it is being administered for a non-ESRD-related purpose.

Prior to the PPS, most of the drugs that were listed as "may be related" to the treatment of ESRD in the 2010 Final Rule, were also prescribed for patients to take at home, because they are medications that are needed on a daily basis for varying lengths of time. The Agency did not include dollars in its calculation of the base rate for the oral versions of such drugs. Today, prescriptions for those oral medications are not substitutions for the previously separately billable IV versions of those drugs. They are simply a continuation of care that existed prior to the PPS, that remains today outside the PPS, and should, therefore, be covered by Part D or other pharmacy benefit plans.

Such drugs are often needed for ongoing treatment of various conditions. For example, many people, including dialysis patients, need anxiety medication, a long running course of antibiotic therapy, anti-nausea treatment, anti-pruritics, pain medication, and fluid management, that they take on a daily basis. In the case of dialysis patients, the cost of these routinely prescribed oral medications prior to the PPS were not included in the PPS. They were covered by the Part D program and other pharmacy benefit plans. The treatment of these drugs remained the same until January 1, 2014, subject to a change in guidance in the 2014 Part D Call Letter. These drugs should not be considered to be included in the ESRD bundled payment. To address this problem, KCP recommends that CMS provide additional clarity in the final rule, revise the language in the Benefits Policy Manual, and provide revised guidance to the Part D plan sponsors.

In addition, we encourage CMS to revise the terminology used to describe these drugs by building off of the current regulatory text. The reference should be: "Prescription drugs and biologicals that may be within the bundle are covered under the Part B bundle when they are directly related to the provision of renal dialysis services."

We would welcome the opportunity to discuss these concerns in greater detail, but also urge the Agency to act quickly to resolve this problem, which has been occurring for almost nine months.

IV. The Ongoing Problems with the Co-morbid Case-Mix Adjustors, Standardization Factor, and Outlier Policy Continue to Erode the Base Payment Amount and Should Be Addressed, as Should the Problems with the Low Volume Adjustor

We appreciate that CMS has indicated in the Proposed Rule that it plans to "reevaluate all of the patient- and facility-level adjustments together in a regression analysis" for CY 2016. We interpret this statement to mean that CMS will re-evaluate the need for each of the adjustors and, as recommended in previous comment letters, eliminate those that no longer serve any purpose. It is important to take this step to protect the integrity of the base rate payment amount.

As noted in previous comment letters, the inclusion of adjustors that are not paid out resulted in the base rate being approximately $5.30 per treatment less than the finalized amount in 2011. Without more precise rate setting data, we have been unable to calculate this amount for the CY 2015 Proposed Rule, but anticipate it would be the higher in CY 2015. Therefore, we strongly encourage CMS to work with the community as it undertakes its analysis of the patient- and facility-level adjustors. We also would like to work with the Agency to address the specific issues related to the co-morbid case-mix adjustors, standardization factor, and outlier policy that we believe can be addressed for CY 2015 with existing data.

A. The Standardization Factor Is Overstated Because of Differences between the Estimated and Actual Prevalence of Adjustors

The lack of data prevents KCP from providing precise dollar amounts as to the effect of the overstatement of the standardization factor because of the differences between the estimated and actual prevalence of adjustors for CY 2015. However, there is no question that the actual prevalence of the adjustors is significantly different than that predicted by the Agency prior to CY 2011. Another factor that contributes to this problem is the implementation of the low-volume adjustor. The discrepancy in the standardization factor has also increased because of the recent reductions in the base payment rate.

We believe that CMS could address the standardization problem for CY 2015 with the current data available. The correction of this problem is not dependent upon the analysis that CMS plans to undertake for CY 2016. Specifically, CMS could use 2013 data to recalculate the standardization factor based on prevalence of the use of adjustors. CMS could also make an interim reduction to the adjustor values that would take into account the decrease in drug utilization. This step is important because the adjustor values are based largely upon drug utilization in many instances. With these values, CMS could reduce the dollars in the standardization factor for CY 2015.

The standardization factor discrepancy accounts for a loss of between one to two percent in the base rate. With many dialysis facilities' Medicare margins below the break-even point, returning this amount to the payment would make an important difference. Thus, KCP encourages CMS to address this problem in the CY 2015 Final Rule.

B. Eliminate the Co-morbid Case-Mix Adjustors for CY 2015

As we have noted in previous letters, the continued reliance upon the co-morbid case-mix adjustors remains inappropriate because these adjustors do not reflect the reality of providing care in dialysis facilities today. While CMS has the necessary data to identify these patients, dialysis facilities do not. If a facility suspects that a patient has pneumonia, for example, it will administer the care ordered by the patient's physician. That action does not mean, however, that the patient has been subject to an X-ray or other test required by CMS to document the co-morbidity. Even if the patient has undergone the test, it would not be performed at the facility and, even when exercising best efforts, the facility would not have access to the data. The documentation requirements are problematic for all of the co-morbid case-mix adjustors. Because facilities cannot document the co-morbid conditions, they cannot claim the adjustors. Because the system is budget neutral, this means that the dollars set aside for these adjustors are lost.

We believe that CMS has the discretionary authority to eliminate the co-morbid case-mix adjustors. While the Congress indicated that the Agency must establish "payment adjustments based on case mix," the Congress also stated that these adjustments "<u>may</u> take into account…comorbidities."[8] Similarly, the Congress included the potential for an adjustment based on race or ethnicity.[9] The Agency appears to agree with this interpretation in as much as it has not implemented adjustors based upon these patient characteristics.

The community agrees that case-mix adjustors are an important component of any prospective payment system. However, their primary purpose of adjustors is to increase the payment amounts to providers who are caring for more complex and higher cost patients. As designed, the co-morbid case-mix adjustors do not accomplish this goal. Therefore, we ask that CMS eliminate the co-morbid case-mix adjustors for CY 2015 to stop the erosion of the base rate. We would welcome the opportunity to work closely with the Agency as it undertakes its evaluation of the adjustors in the coming year to determine what, if any, co-morbid case-mix adjustors would be appropriate for this sector.

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[8] 42 U.S.C. § 1395rr(b)(14)(D)(i) (emphasis added).

[9] *Id.*

C. Correct the Outlier Pool

While we continue to appreciate the Agency's update to the fixed dollar loss amounts that are added to the predicted MAP amounts per treatment to determine the outlier thresholds for CY 2015, this adjustment does not address the underlying problem with the outlier pool. The problem is that since its inception, the outlier pool has not been paid out in its entirety. While one percent is withheld from the base rate to fund the pool, only 0.5 percent of that amount was paid out to facilities in CY 2013.[10] Even less has been paid out in previous years.

We believe that the Agency can address this problem prior to undertaking its review of the adjustors. Congress did not mandate a specific amount for the outlier pool. As with the drug add-on adjustment, CMS could set the pool at less than one percent or even at zero to address the fact that the one percent withhold is more than is needed to fund the outlier payments in any given year. We would welcome the opportunity to work with CMS and the data analysts to resolve this problem for CY 2015.

D. CMS Should Address the Problems with the Low-Volume Adjustor

We appreciate that the Agency recognizes the need to address problems with the low-volume adjustor. KCP supports the extension of the filing deadline to December 31 and recognizes that allowing the submission of additional data for all types of facilities, not only those that are hospital-based, could help the contractors more effectively identify facilities that qualify for the low-volume adjustor. However, we also believe that more can and should be done to make sure that the contractors are appropriately evaluating facilities to ensure accurate determinations.

The purpose of the low-volume adjustor is to ensure that facilities that have smaller patient populations receive sufficient reimbursement to protect access to care for beneficiaries in these areas. Yet, according to the work of The Moran Company, a significantly number of facilities that should be receiving the adjustment are not.

[10] 79 Fed. Reg. 40208, 40233 (July 11, 2014).

	Number of Facilities	% of total
Total number of dialysis facilities in NPRM 2015 Impact File	5,996	100%
Facilities identified as having >4,000 treatments, but labeled as low-volume facilities	20	0.3%
Facilities with treatment counts <3,200 that were not labeled as low-volume facilities	1,016	16.9%

More than 1,000 facilities that appear to meet the criteria to receive the low-volume adjustment are not determined to be eligible by the contractors, while 20 facilities that do not meet the criteria continue to receive it.

We strongly encourage CMS to clarify the process for meeting the definition of a low-volume facility and to work with the contractors and dialysis facilities to make sure that the current process results in the correct assessment. We all recognize that receiving regular treatments in dialysis facilities will reduce more costly hospitalizations and allow beneficiaries to maintain a higher quality of life than they otherwise would have in light of the disease. Both CMS and the community have a strong interest in protecting access to dialysis services in low-volume areas.

V. KCP Supports the Flexibility to Provide Beneficiaries with More Than Three Treatments Per Week Policy when Medically Necessary

KCP supports the Agency's clarification of its policy regarding payments for more than three dialysis treatments per week. We agree with the Agency that it is important to provide an exception for an extra treatment when it is medically necessary for the patient. As the preamble indicates, some beneficiaries may require more than three treatments per week.[11] We agree that the payment policy should be sufficiently flexible to adjust to the individual needs of patients.

VI. KCP Supports Efforts To Remove Barriers to Home Dialysis, but Only if the Policies Do Not Take Resources Away from In-Center Patients

KCP supports efforts to ensure patient choice and informed decision-making as patients seek treatment for kidney disease and kidney failure. One important decision is which dialysis modality they select to use for their treatment. KCP

[11] *Id.*

supports efforts to ensure that patients have access to their preferred treatment modality and to remove barriers that might discourage patients from pursuing certain modalities, including home dialysis.

We continue to believe that training rates should be more closely related to the actual cost of providing the service. However, we were extremely disappointed with the decision last year to take dollars from the base rate that applies to all dialysis patients to increase payments for only a limited number of patients. While removing barriers to home dialysis is important, it cannot come at the expense of in-center patients. KCP does not support increasing the payment amount for the training add-on, unless CMS adds new money to the system. Any increases should not be made in a way that removes funds from the current bundled payment amount.

VII. Conclusion

In conclusion, KCP strongly urges CMS to establish a different price proxy for pharmaceuticals in the ESRD market basket. We also encourage the Agency to engage in both a formal and informal dialogue regarding how CMS plans to address new drugs and biologicals, as well as when drugs are no longer oral-only products. Finally, we encourage to address the long standing issues that have inappropriate reduced the base rate since the initial implementation of the ESRD bundle.

KCP appreciates the opportunity to provide comments on the ERSD QIP Proposed Rule. We look forward to working with CMS to resolve our concerns. 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

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