



August 8, 2016

Andrew M. Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Acting Administrator Slavitt:

Kidney Care Partners (KCP) appreciates the opportunity to provide comments on the “End-Stage Renal Disease Prospective Payment System [ESRD PPS], Coverage and 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 Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model Proposed Rule” (Proposed Rule). This letter addresses the proposals related to the ESRD PPS for Calendar Year (CY) 2017. We have provided our comments on the ESRD Quality Incentive Program in a separate letter.

In sum, KCP:

- Supports the proposed updates to the CY 2017 ESRD PPS, but remains concerned about policies that result in underpayments for the case-mix adjusters and urges CMS to provide more transparency with regard to the ESRD PPS;
- Encourages CMS to provide additional guidance as quickly as possible to allow for the smooth implementation of the calcimimetics policy;
- Recommends that CMS not finalize the payment equivalency proposal and supports continuing the current medical justification policy for more three treatments per week;
- Appreciates that CMS is taking a closer look at home dialysis, supports the home dialysis training add-on, but only if implemented without applying the budget neutrality policy, and supports efforts to improve the data available regarding home dialysis training and retraining; and

- Supports the proposals addressing reimbursement for individuals with Acute Kidney Injury (AKI) and recommends a few clarifications.

## **I. ESRD Program Provisions**

### **A. KCP supports the proposed updates to the CY 2017 ESRD PPS, but remains concerned about policies that result in underpayments for the case-mix adjusters.**

KCP appreciates that CMS has implemented the update to the base rate using the same methodology as in previous years. We also recognize the statutory requirement to apply the productivity adjustment and the cut enacted under the Protecting Access to Medicare Act of 2014. However, we remain deeply concerned about the ongoing problems with the current case-mix adjusters and the lack of transparency in the current data files that are released.

KCP also is pleased that CMS has refined the outlier pool to align the dollars paid out more closely with the estimated amount used to create the outlier pool. However, we note that the alignment has not yet addressed the fact that the outlier pool is consistently paying out less than the amount removed from the base rate. The Moran Company estimates the outlier pool underpaid \$0.68 per treatment in 2015. Other Medicare payment systems at times pay out less than the estimate and at other times pay out more. This fluctuation above and below the estimate indicates that the outlier pool amount is appropriate. We strongly encourage CMS to further refine the outlier policy so that it is more consistent with how outlier policies in other Medicare payment systems work.

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

#### **1. KCP continues to recommend modifications to the case-mix adjusters.**

While we appreciate that CMS undertook the analysis of the case-mix adjusters in last year's rulemaking, KCP remains deeply concerned that many of the recommendations we and others in the kidney care community made regarding the adjusters were not adopted. According to an analysis prepared by The Moran Company, the ongoing problems with the case-mix adjusters resulted in an underpayment of \$5.61 per treatment in 2015. When added to the underpayment from the outlier pool, the total underpayment in 2015 is \$6.29. The underpayment is significantly greater than in previous years.

The Moran Company estimates that the underpayment is due to an inaccurate prediction of the distribution of the adjusters and the overall under-reporting of the adjusters. As we noted in our comments to the CY 2016 Proposed Rule, case-mix adjusters, when appropriately defined, are meant to protect beneficiaries by ensuring that all beneficiaries, regardless of the cost of providing care to them, have access to health care services. CMS has also stated that “[t]he purpose of the co-morbidity adjustments is to provide added payment for those co-morbid diseases that result in higher dialysis costs.”<sup>1</sup> Thus, adjusters counterbalance the incentive inherent in any prospective payment system to treat only the healthiest patients. The chronic underpayment for the adjusters since the inception of the ESRD PPS is strong evidence that the current set of adjusters does not serve the policy purpose of ensuring that beneficiaries have access to the services for which they are eligible.

While we recognize that CMS is unlikely to modify the case-mix adjusters for CY 2017, we continue to urge the Agency to review the analytics and recommendations included in KCP’s comment letter for the CY 2016 ESRD PPS Proposed Rule, as well as the concerns the Medicare Payment Advisory Commission (MedPAC) raised in its comment letter on the CY 2016 ESRD PPS Proposed Rule. In brief, KCP remains concerned that:

- The current age categories and payment modifiers do not align with clinical experience; therefore, we recommend that CMS return to the CY 2015 age categories and payment multipliers while it works with KCP to address the problems in data and the methodology for determining this adjuster.
- The current adjusters cancel each other out and fail to achieve the policy goal; therefore, we recommend that CMS take the dollars for the BMI and BSA adjusters and divide them equally over the low BMI and high BMI adjuster KCP proposed for CY 2016, as well as work with KCP to identify a better approach that would allow the weight of patients to be incorporated into the patient level adjusters.
- The remaining four comorbid case-mix adjusters (pericarditis, Gastrointestinal (GI) Tract Bleeding with Hemorrhage, Hereditary Hemolytic or Sickle Cell Anemia, and Myelodysplastic Syndrome) do not serve a policy purpose; with the decrease in drug utilization and given the experience of nephrologists, the outlier pool, which has otherwise not paid out as predicted, can better address the costs associated with the few patients who have these comorbidities, while limiting the documentation burden on facilities and patients.

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<sup>1</sup>CMS, “End-Stage Renal Disease Prospective Payment System Final Rule” 75 *Fed. Reg.* 49029, 49098 (Aug. 12, 2010).

- The low-volume adjuster and rural adjuster overlap one another; therefore, KCP continues to propose that CMS instead rely upon a two-tiered low-volume adjuster policy, with the CY 2016 low-volume adjuster being the first tier and the second tier applying to facilities with 4,001-6,000 treatments per year.

As noted, we remain deeply concerned that so many dollars are being taken out of the ESRD payment system because of inaccurate case-mix adjusters. We believe the problems stem from the fact that (1) facility cost reports are inappropriate data sources for patient level adjusters; (2) analysis of cost report data shows that control variables are not valid; and (3) payment variables are not independent of each other and, therefore, result in values that are not accurate. This also leads to problems with the standardization factor, which we recommend that CMS update using the most current data available.

KCP would welcome the opportunity to work with CMS and its contractor to solve this perennial problem.

## **2. KCP urges CMS to provide more transparency with regard to the ESRD PPS.**

KCP recognizes and appreciates that CMS has provided more data related to the ESRD PPS during the past two years; yet the Proposed Rule does not contain sufficient information to analyze the proposals completely. For example, it remains impossible to determine the relationship between the standardization factor and the refinement CMS added in last year's rulemaking.

KCP is committed to working with CMS to address the data questions and transparency. If the Agency could provide the specific information outlined below, we believe that the disconnect between the community's analysis of the ESRD PPS methodology and the contractor's conclusions would be clearer and allow us to better address the underpayment of the ESRD PPS. Therefore, we ask that CMS provide:

- A precise description of the information (*e.g.*, sources, years, variables, cells in cost reports) used to develop the variables in the equations.
- Trimming and data cleaning procedures used to exclude data from the analysis, including the number and type of data excluded (*e.g.*, hospital cost reports) for each procedure, and the remainder used.
- Precise description of how each variable is defined. Evidence that variables were tested for independence.
- The regression equations.

- All assumptions used to select and define dependent variables, and criteria used to include in the regression.
- R squared, adjusted R squared, degrees of freedom, explained sum of squares, and residual sum of squares for final regression equation. If other alternative regressions were run, please provide comparable information describing those analyses.
- For each dependent variable, the coefficient, standard error, p value, and R squared.
- Diagnostic testing for multi-collinearity with results, and any other diagnostic testing and results.

We also request that CMS provide the details for the calculation of the refinement budget neutrality adjustment that incorporates the old standardization factor, including:

- The basis for estimating the prevalence of each adjuster (how long a look-back period for each adjuster), and the actual prevalence built into the calculation.
- Whether the data used to calculate the standardization (refinement adjustment) factor is the same as that used in the regressions and whether there are any other data sources used.

Finally, we ask that the rate setting file released with each proposed and final rule, be completed to include specific flags for each payment adjuster that is applied, and all modifiers on claims, particularly the “AY” modifier. The OPSS rate setting file format that is the template for the ESRD rate setting file normally includes all modifiers, and there are a number of ways that adjuster variable flags could be added to that file. These data are necessary to engage in a timely discussion of the impact of the adjusters on accurate estimates of payment and impact analyses.

**B. KCP encourages CMS to provide additional guidance as quickly as possible to allow for the smooth implementation of the calcimimetics policy.**

While the Proposed Rule is silent with regard to the transition of calcimimetics into the ESRD PPS, KCP believes it is important to reiterate our comments and recommendations regarding this implementation. We remain supportive of the framework CMS finalized in 2015, but emphasize that it is important to address the details to ensure a smooth implementation when the new drug is launched. We recognize that many of the issues we raise in the letter we have attached in Appendix B will be addressed in sub-regulatory guidance and encourage CMS to issue such guidance as soon as possible. In addition to the questions outlined in the letter, we would like to understand how CMS will address changes in clinical practice with the advent of new technologies. For example,

additional testing may be required to properly manage patients who receive IV calcimimetics. The transition of calcimimetics will provide the opportunity to develop a process for addressing these issues in the future.

**C. KCP recommends that CMS not finalize the payment equivalency proposal.**

KCP is concerned by the payment equivalency proposal because it is unnecessary and would increase providers' administrative burden. Therefore, KCP urges CMS not to finalize the payment equivalency proposal and to retain the current billing requirements for in-center and home HD, allowing for payments for additional treatments if they are medical justified, as determined by the Medicare Administrative Contractors (MACs).

First, KCP disagrees with the statement in the preamble that facilities "have expressed concern that due to the monthly payment limit of 13 or 14 treatments, they are unable to report all dialysis treatments on their monthly claim, and therefore, they are not appropriately paid for each treatment furnished."<sup>2</sup> This statement is simply not true. The current claims form allows dialysis facilities to record each HD treatment provided, whether in-center or at home. Facilities can report "extra" treatments that are not justified according a MAC LCD by simply reporting them as non-covered and can report those that are justified using a KX modifier (if the MAC so instructs). Rather than adopt a new calculation that creates an administrative burden both on the contractors and the facilities, CMS should issue a clarification to the billing instructions. This clarification would encourage facilities to report all treatments furnished and recognize the number of treatments being provided during a week.

Second, the underlying rationale on which the Agency based the HD equivalency policy for PD remains unchanged and continues to support the current payment policy. When it transitioned from the composite rate to the ESRD PPS, CMS explained the rationale for maintaining the HD equivalency policy for PD in the preamble to that final rule.

The practice of converting PD treatments to HD equivalent treatments arose in the context of developing an appropriate unit of analysis for the PD modalities in which multiple exchanges of dialysate occur during the course of a day. These exchanges are not discrete treatments in the same sense that an HD session represents a treatment.<sup>3</sup>

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<sup>2</sup>Proposed Rule Display Copy 42.

<sup>3</sup>CMS, *supra* note 1, 49064.

Despite the evolving technology, HD requires a distinct treatment session, while PD continues to provide multiple treatments throughout a 24-hour period. There has clearly been no change in the treatment protocols that would warrant different payment policies.

In the rare instances when a PD patient requires an in-center treatment, CMS reimburses a facility on a per-treatment basis. The example in the current Medicare Benefit Policy Manual is illustrative:

Example: Mary is a home CCPD patient. After 21 days on CCPD in a month, Mary's cyclor required repair. Mary received CCPD in-center for 4 consecutive days before returning to home CCPD. The number of HD-equivalent sessions for which payments under the ESRD PPS may be made is 12, determined as follows:

Home CCPD HD-equivalent sessions  $21/7 \times 3 = 9$

In-center PD HD-equivalent sessions (limited to 3) 3

Total HD-equivalent sessions 12

Mary's ESRD facility would receive the case-mix adjusted ESRD PPS base rate for 12 treatments in the month.<sup>4</sup>

Thus, the policy is not to divide the payment rate because there is a potential for additional treatments in a week, but rather because the PD modality provides the equivalent therapy over time to what would otherwise be provided in a treatment session in-center. Because the underpinning of this policy has not changed, it would not be appropriate to try to adopt the payment equivalency policy for both in-center and home HD.

Third, as CMS points out in the preamble to the Proposed Rule, the current medical justification policy appropriately addresses those patients, who require more than three treatments per week, because of a medical need.

[In center h]emodialysis is typically furnished 3 times per week in sessions of 3 to 5 hours in duration. If the ESRD facility bills for any treatments in excess of this frequency, medical justification is required to be furnished to the A/B MAC (A) and must be based upon an individual patient's need. The A/B MAC (A) reviews the medical justification for each additional treatment and is responsible for making the decision on

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<sup>4</sup>CMS, *Medicare Benefit Policy Manual*, Ch. 11, § 50(4).

the appropriateness of the extra treatment(s) and payments for these additional treatments.<sup>5</sup>

KCP continues to support this policy of billing in excess of three treatments per week and its application and commends CMS's language continuing this long-term policy.

While we appreciate that some MACs have implemented automated systems when facilities report certain diagnoses codes, we also note that reporting such codes is not a requirement for obtaining medical justification and that MACs may accept other documentation to support additional payments so long as that documentation supports medical need.

There is no advantage to adopting the payment equivalency policy for HD, but there are disadvantages to doing so. The current policy limits payments to 3 times a week, unless the additional treatment(s) is medically justified. Yet, the proposed policy would add an additional calculation that could result in underpayments in the system and unnecessarily burdens contractors and dialysis facilities to achieve the same goals that the Agency can and is achieving under the current policy. Therefore, we strongly urge CMS not to finalize the payment equivalency policy for HD.

**D. KCP appreciates that CMS is taking a closer look at home dialysis, but it is neither required nor appropriate to cut the base rate to increase the home dialysis training add-on.**

KCP remains a strong proponent of home dialysis for patients for whom it is the best option. Home dialysis offers patients many advantages, including improved outcomes, more flexible schedules, and improved quality of life. We are pleased that CMS is willing to work with the kidney care community to identify ways to ensure that patients who believe home dialysis is the right option for them are able to access it.

As a threshold matter, it is important to understand that there are many barriers that can make accessing home dialysis difficult for patients; many of which are not related to payment policies. The GAO has characterized the factors that influence whether patients rely upon home dialysis as related to patient preferences, as well as to clinical factors.

Patients often select home dialysis because it provides them with more flexibility than an in-center option allows; yet, "[o]n the other hand, successfully performing home dialysis requires patients to undergo training and assume other

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<sup>5</sup>*Id.*

responsibilities that they would not otherwise have if they dialyzed in a facility.”<sup>6</sup> Additionally, patients need a partner to help them dialyze at home, as well as the appropriate physical location and home resources (such as a grounded electrical outlet, special water systems and drains, etc).<sup>7</sup> There can also be supply shortages that can make it difficult for new patients to access some treatment options.

In terms of clinical factors, the GAO notes that a patient who does not receive care from a nephrologist prior to beginning dialysis may not have the opportunity to receive the necessary training or have a permanent vascular access immediately.<sup>8</sup> Home dialysis may also be more difficult for patients who have physical limitations (such as poor vision or dexterity), as well as those with multiple comorbidities that a nephrologist may also need to manage in an in-center setting.<sup>9</sup>

KCP has consistently prioritized and promoted policies to address barriers to accessing home dialysis. For example, we appreciate that CMS agreed to our recommendations to address problems in the Monthly Capitated Payment (MCP) rates that disadvantaged nephrologists who were providing care to home dialysis patients. We also continue to support efforts to identify and remove barriers to receiving home dialysis.

As CMS continues its review of home dialysis and identifies ways to incentivize access to it, KCP would like to work with CMS to address the barriers the GAO and others have identified. We believe that many of these barriers are best addressed through community efforts, but CMS can assist by ensuring that the base rate for the ESRD PPS bundle is sufficient to cover the cost of providing services for both home and in-center patients.

**1. KCP supports the home dialysis training add-on, but only if implemented without applying the budget neutrality policy.**

The training add-on is an important and necessary component of the ESRD PPS. KCP agrees with the basic methodology CMS has proposed for making an adjustment to the home dialysis training add-on for CY 2017. While we support efforts to monitor and ensure the sufficiency of the home dialysis training add-on payment, we once again object to making the adjustment budget neutral. Put simply, CMS has the authority to increase the training add-on without applying budget

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<sup>6</sup>GAO, “End Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis,” 7 (Nov. 2015).

<sup>7</sup>NIDDK, “Home Hemodialysis” available at <https://www.niddk.nih.gov/health-information/health-topics/kidney-disease/home-hemodialysis/Pages/home-hemodialysis.aspx#think> (last accessed July 18, 2016).

<sup>8</sup>*Supra*, note 6 at 8.

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

neutrality. The statute does not require this budget neutrality calculation. It does not even mention having home dialysis training add-on in the ESRD PPS.<sup>10</sup> As CMS has recognized in the past, the budget neutrality language set forth in 42 U.S.C. § 1395rr(b)(14)(A) applied only to the first year of the ESRD PPS.

KCP recognizes that CMS implements payment adjustments, such as the case-mix adjusters and outlier payments, in a budget neutral way. The training add-on is different, however. For example, case-mix adjusters seek to tailor the more general base rate to ensure that facilities are not penalized for caring for patients who require more resources than those who do not. So, while the rate slightly goes up for the more expensive patients, it is reduced for the less expensive patients. This approach seeks to even out the resources being provided.

As noted by the fact that the training rate is an “add-on” and not an “adjuster,”<sup>11</sup> the training add-on is not redistributing existing resources according to patient need. Rather, it is meant to reimburse facilities for additional costs that otherwise would not be necessary for the typical in-center patient. These costs are outside of the base rate and, as such, there is no rationale for making the adjustment budget neutral.

KCP understands that CMS has historically made modifications to the home dialysis training add-on in a budget neutral manner. However, given the ongoing concerns related to the integrity of the ESRD PPS bundle and underpayment and the growing instability of the economics of the ESRD system overall, there is a solid rationale for changing this policy.

As The Moran Company has identified, the ESRD PPS bundle continues to erode each year; creating further erosion by imposing budget neutrality in the context of the training add-on is inappropriate and unconscionable. While it may be true that a six cents per treatment reduction is small, the problem is that the ongoing systemic reduction of the base rate places in-center patients, as well as those receiving home dialysis, at risk. With an ever-increasing cost of compliance, especially as CMS recognizes in the Regulatory Impact Statement with regard to meeting the ESRD Quality Incentive Program (QIP) requirements in particular, providers will find it more difficult to maintain the high-quality services that patients deserve. CMS should begin to address this problem and restore the integrity of the bundle by eliminating the budget neutrality policy in the context of the home dialysis training add-on.

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<sup>10</sup>See generally, 42 U.S.C. § 1395rr(b)(14).

<sup>11</sup>Proposed Rule Display Copy 51.

## **2. KCP supports efforts to improve the data available regarding home dialysis training and retraining.**

In addition, KCP appreciates that CMS will begin working with the kidney care community as it seeks to better understand retraining, how often it occurs, the amount of nursing time involved, and the most common reasons for it. We continue to support the definition of retraining found in the Medicare Claims Processing Manual that defines retraining as occurring when:

- The patient changes from one mode of dialysis to another, *e.g.*, from hemodialysis to CAPD;
- The patient's home dialysis equipment changes;
- The patient's dialysis setting changes;
- The patient's dialysis partner changes; or
- The patient's medical condition changes, *e.g.*, temporary memory loss due to stroke, physical impairment.<sup>12</sup>

KCP believes that retraining does not occur often, but when it does, each retraining can vary depending on the specific circumstances. In some instances, it would be the same as training, but designated as "retraining" only because the patient had received home dialysis training previously. For example, when a patient changes modalities, there may be consistency in partner support. However, the same amount of RN training time and number of training sessions may be required to ensure that the patient understands how to operate the new device safely. The same could be true if a patient experienced a temporary memory loss. In some instances, it might be possible to reduce the number of training sessions, such as when there is a minor modification to the device, something changes in the patient's home, or the patient's dialysis partner changes. Retraining may also be necessary because there is evidence that a patient needs a refresher in how to properly use the device, as evidenced by infections or other problems.

Therefore, we support CMS's decision to increase monitoring to better understand retraining. We agree that the current cost report data does not provide an accurate view of home dialysis training. We strongly encourage CMS to work with dialysis facilities to provide clear and accurate instructions as to how to report training costs and labor to address this problem. We support efforts to update the cost reports, in all aspects, including addressing the ESRD Network Fee, as we have noted in previous comment letters, to improve the accuracy of the data provided. As noted above, we do not support the payment equivalency policy as part of this effort.

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<sup>12</sup>CMS, *Medicare Claims Processing Manual*, Ch. 8, § 50.8.

**II. KCP supports the proposals addressing reimbursement for individuals with Acute Kidney Injury (AKI) and recommends a few clarifications.**

KCP is pleased that Medicare is expanding treatment options for individuals with AKI by reimbursing treatments provided in freestanding dialysis facilities. We look forward working with CMS on the implementation for the new policy.

**A. KCP supports the proposed payment policy for renal dialysis services furnished to individuals with AKI.**

KCP appreciates that the Congress has established the basic outline of the payment policies related to renal dialysis services furnished to individuals with AKI. While the statute links the payment rate for AKI services, it is clear that the Congress did not intend for these patients to be part of the Medicare ESRD program itself.

We support the adoption of the statutory definition of an individual with AKI as “an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14).”<sup>13</sup> Because there is no consensus on the development of ESRD in an AKI patient<sup>14</sup> or well-validated clinical tools to predict whether an individual is likely to recover renal function,<sup>15</sup> it is important to allow the individual physician to exercise his/her best professional judgment to determine when an individual with AKI has transitioned to an individual with ESRD. This transition should not be subject to arbitrary policies. KCP believes that the statutory definition supports the level of medical flexibility appropriate for treating individuals with AKI. Therefore, we encourage CMS to affirm this interpretation to avoid any potential confusion among contractors.

Because individuals with AKI are not the same as individuals with ESRD, require different treatment protocols, and are not being incorporated into the ESRD program, KCP also supports allowing payment for more than three dialysis sessions a week. We also support the decision not to apply the ESRD case-mix adjusters to individuals with AKI. We remain deeply concerned that the co-morbid case-mix adjusters in particular are not predictive of the cost of providing care to individuals with ESRD and no work has been undertaken to evaluate any of the ESRD case-mix adjusters in the AKI population. Therefore, we recommend that CMS finalize both of these proposals with regard to the payment for dialysis services provided to individuals with AKI.

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<sup>13</sup>Proposed Rule Display Copy 78.

<sup>14</sup>Ishani *et al*, “Acute Kidney Injury Increases Risk of ESRD among Elderly 20 JASN 223-28 (2009).

<sup>15</sup>Bellomo, R, Ronco C, Kellum JA, Mehta RL, Palevsky P. ADQI Workgroup: Acute renal failure—definition, outcome measures, animal models, fluid therapy, and informational technology needs: The Second International Consensus Conference of the ADQI Group. *Crit Care* 2004; 8: R204-R212.

In terms of payment recommendations, KCP supports the proposal to pay separately for items and services furnished to beneficiaries with AKI that are not considered to be renal dialysis services. As CMS correctly recognizes, there may be items or services that should be provided in a dialysis facility and that are not part of the ESRD PPS bundle.

**B. Applicability of ESRD PPS Policies to AKI Dialysis.**

KCP appreciates that CMS has included certain proposals that currently apply to ESRD and they may also be relevant to the separate AKI services. For the same reasons outlined in the preamble, KCP supports applying the policy that if a dialysis treatment is started, but the treatment is not completed for some unforeseen, but valid reason, both the ESRD facility and the hospital would be paid. We also support the proposal to allow ESRD facilities to furnish vaccines to beneficiaries with AKI and bill Medicare.

We also ask that the final rule also articulate that while collecting data on individuals with AKI who are receiving dialysis is important, the same quality metrics that are used for the ESRD population are not necessarily appropriate to use to evaluate the quality of care provided to individuals with AKI who require dialysis. As the RPA in its consensus White Paper notes, “[t]here is also no evidence that existing ESRD clinical practice guidelines for anemia management, metabolic bone disease, vascular access management, dialysis adequacy, and nutrition are applicable to AKI-D patients.”<sup>16</sup> Given that more work is needed to better understand the progression of AKI, it would not be appropriate to apply the ESRD measures to this group of patients. Therefore, we ask that in the final rule CMS acknowledge this difference and clarify that individuals with AKI who receive dialysis will not be included in the quality programs within the Center for Medicare, as well as those under the jurisdiction of the Center for Clinical Standards and Quality, the Centers for Disease Control and Prevention, and other entities involved in collecting ESRD data for federal quality programs.

**C. Monitoring of beneficiaries with AKI receiving dialysis in ESRD facilities.**

KCP strongly supports the Agency’s proposal to closely monitor this patient population, including the utilization of dialysis treatments and the drugs, labs and services provided to these beneficiaries. In its consensus White Paper entitled “Acute Kidney Injury Patients Requiring Outpatient Dialysis,” the Renal Physicians Association (RPA) indicates that individuals with AKI “are not in a steady state.”<sup>17</sup> This means that while the services provided to individuals with AKI may be the

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<sup>16</sup>Renal Physicians Association, “Acute Kidney Injury Patients Requiring Outpatient Dialysis” 7 (2016).

<sup>17</sup>*Id.* at 6.

same, the frequency with which they are provided and the labor required to provide them may differ from that required for individuals with ESRD.

None of these care needs is beyond the capability of most dialysis facilities, but the cumulative degree of care and attention required for the [acute kidney injury requiring dialysis] AKI-D patient typically exceeds that for a patient with ESRD. Additional staff time per patient and specialized staff training may be needed to address the increased needs of these patients.

AKI-D patients may require more frequent lab testing to review kidney function, and assess drug levels, nutritional status, infection, and other organ function. They may require antibiotic administration and monitoring for infections unrelated to the dialysis procedure. Intercurrent illness, hospital based treatments and debility may increase the frequency of missed treatments.<sup>18</sup>

Throughout the Proposed Rule, CMS recognizes the real differences in these patient populations as well.<sup>19</sup>

There is much still to learn about the treatment of patients with AKI who require dialysis, including the utilization of renal dialysis services. Because the ESRD base rate includes not only the cost of items and services, but also the frequency of their use, it is important to understand how individuals with AKI who require dialysis utilize these items and services. As we learn more about the provision of services to these patients, it may become apparent that an “AKI adjustment” is necessary to address the differences in the services provided to AKI patients. We encourage CMS to work closely with the kidney care community as well to determine if the utilization of certain items or services should result in a modification to the payment amount in the future.

As CMS monitors AKI patients, we also ask that the Agency keep in mind that hospitals have been contracting with dialysis facilities to provide services to these patients during the past few years. It is not always clear whether the hospitals ultimately sought reimbursement for every treatment. Therefore, the historic utilization may not be representative of the actual prevalence of AKI patients requiring dialysis.

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<sup>18</sup>*Id.*

<sup>19</sup>“[W]e recognize that the utilization of items and services for beneficiaries with AKI receiving dialysis may differ from the utilization of these same services by ESRD beneficiaries.” *Id.* at 81.

#### **D. AKI and the ESRD Conditions for Coverage.**

KCP agrees that the Conditions for Coverage (CfCs) provide important health and safety standards that all Medicare-participating dialysis facilities should meet. We also agree that for the most part the current CfCs do not require modifications to address the needs of individuals with AKI who require dialysis. Requirements related to infection control, water purity, governance, personnel, and other similar standards do not need to be modified at this time.

However, there are two exceptions to these general statements that we recommend CMS consider. First, with regard to the assessment of patients, § 494.70(a)(7) requires facilities to inform patients of all treatment modalities and settings. Similarly, § 494.80 requires the care team to evaluate patients for the suitability of home dialysis and transplant. Given the unique nature of AKI patients, as CMS recognizes in the preamble, these provisions do not seem appropriate to apply to those individuals with AKI receiving dialysis. If these patients were to transition to ESRD patients, such provision would be applicable and should be followed.

Second, § 494.90 relates to the development of a patient's plan of care. The current regulations highlight targeted Kt/V levels developed for ESRD patients that may or may not be appropriate for patients with AKI who are receiving dialysis. Similarly, the plan of care is required to include explanations related to home dialysis, transplant status, and transplantation tracking. As with the patient assessment and evaluation provisions, these requirements are not aligned with the treatment of AKI patients who require dialysis and should not apply.

Therefore, we recommend that CMS incorporate language in the CfCs that clarifies that patient's plan assessment/evaluation and the plan of care are appropriately tailored to meet the needs of individuals with AKI who require dialysis, notwithstanding the provisions of the CfCs related to home dialysis and transplant.

#### **E. ESRD facility billing for AKI dialysis.**

KCP supports the proposal to identify AKI patients through a specific code. We encourage CMS to work with the kidney care community to ensure that billing guidance is provided in a timely, clear, and transparent manner to allow for a smooth transition. More specifically, KCP supports The Moran Company recommendation that CMS issue the following billing guidance:

- Treatments should be reported on the claim using the hemodialysis revenue code or the appropriate peritoneal dialysis code.

- The AKI patient claim will need a newly defined condition code that will identify the claim as an AKI claim.
- The condition code should be linked to logic in the pricer that blocks any action on claims based upon presence of:
  - Any ESRD condition code.
  - Any ESRD specific modifiers, as these are inappropriate (*e.g.*, GS, ED, EE).
  - Any ESRD specific value claim codes with the exception of height and weight.
- No ESRD condition codes, value claim codes, or modifiers should be required for AKI claims processing.
- No ESRD edits should be applied to AKI claims:
  - No checks for 2728 form.
  - No constraint on number of treatments per month.
  - No constraints on ESA dosage or diagnosis codes for ESRD.
- An AKI ICD-10 diagnosis should appear in the primary diagnosis position on AKI claims. A list of approved diagnosis codes should be published.
- A new AKI modifier should be identified for all laboratory tests and for drugs used by AKI patients that are required strictly for AKI and would not be routine for ESRD patients. This modifier should allow for separate payment. Guidance would define when this modifier may be used (*e.g.*, when lab test are repeated more frequently than would occur for an ESRD patient). The “AY” modifier should not be used on AKI claims.

We support The Moran Company recommendation that CMS modify the cost report to account for AKI patients. A new row should be added to Worksheet D, to be defined for AKI hemodialysis treatments. Instructions should explain that AKI treatments are to be reported separately from all other ESRD dialysis treatments. Payment rates should be reported net of a reduction for the network fee, this is because the current statutory requirement to reduce the base rate for the Network Fee applies only to the ESRD PPS rate and is not referenced in the statutory authority establishing the AKI rate.

#### **F. Announcement of AKI payment rates in future years.**

While we appreciate that the process for announcing the AKI payment rate in future years may require less explanation, we encourage CMS to allow for notice and comment rulemaking for these rates, as it currently does with the ESRD PPS rates. As we have seen with the ESRD PPS rate over the years, it is important to be able to

Acting Administrator Andrew M. Slavitt

August 8, 2016

Page 17 of 17

provide the kidney care community with the opportunity to review the calculations and policies each year, even if CMS does not propose a significant change. We appreciate that the ESRD PPS rate will be subject to notice and comment each year, so it is equally important that the AKI payment rate, which is inextricably linked to the ESRD PPS rate, also be subject to the same process.

### **III. Conclusion**

KCP appreciates having the opportunity to provide comments on the Proposed Rule. We look forward to working with CMS to address the recommendations we have made in this letter. While we have a meeting scheduled already, please do not hesitate to contact Kathy Lester at (202) 534-1773 or [klester@lesterhealthlaw.com](mailto:klester@lesterhealthlaw.com) if you have any questions in the meantime.

Sincerely,

A handwritten signature in cursive script that reads "Frank Maddux M.D." with a stylized flourish at the end.

Frank Maddux, M.D.  
Chairman  
Kidney Care Partners

**Appendix A: KCP Members**

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



May 6, 2016

Sean Cavanaugh  
Director  
Center for Medicare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Laurence Wilson  
Director  
Chronic Care Management Group  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Sean and Laurence:

As you prepare for the market introduction of an IV calcimimetic, Kidney Care Partners (KCP) would like to work closely with you and your teams to ensure that appropriate policies are adopted to maintain the integrity of the ESRD prospective payment system (PPS) bundle through adequate payment amounts, while also ensuring that patients have access to this new drug. We reiterate our support for the payment framework to pay for the IV calcimimetic, as well as the oral calcimimetic, based on the Wholesale Acquisition Cost (WAC) and then the Average Sales Price (ASP) plus six percent for two to three years while we learn more about the appropriate dosing and utilization of the drugs before they are added to the ESRD payment system.

With the framework in place, it is important to address the details to ensure a smooth implementation when the new drug is launched. This correspondence outlines an initial set of recommendations that KCP has developed as the community also prepares for the introduction of the IV calcimimetic, and we would like to discuss the issues with you in the coming weeks as well.

## **I. Confirming the Process**

We applaud the Agency for setting forth in the preamble of the Calendar Year (CY) 2016 End Stage Renal Disease (ESRD) PPS Final Rule (Final Rule) the steps it plans to take with regard to the approval of a new IV calcimimetic. Based on the final rule, we understand that process to include the following steps:

- The FDA approves the IV calcimimetic.
- CMS creates a HCPCS code for the approved IV calcimimetic.
- CMS issues a change request to provide notice that the IV calcimimetic is available.
- CMS pays for both the oral and IV calcimimetic using a transitional drug add-on payment adjustment for oral and IV forms, using methodologies in section 1847A.

- After 2 to 3 years, CMS engages in notice and comment rulemaking to include oral and IV drugs in the ESRD payment system.

## **II. Shifting the Oral Calcimimetic to Part B and Mitigating Negative Impact on Beneficiaries**

We are pleased that CMS has agreed to issue a Change Notice to indicate when the IV calcimimetic is available for purposes of reimbursement. It is important that the change request is clear and explicit regarding the reimbursement of the oral calcimimetic under Part B and whether it will no longer be reimbursable under Part D.

The following statement in the Final Rule preamble suggests that CMS will pay the oral calcimimetic under Part B upon the availability of the IV calcimimetic: “both the injectable and oral form will be paid under the ESRD PPS bundled payment using that adjustment.”<sup>1</sup> We encourage CMS to confirm the timing of the Change Notice relative to FDA approval of the IV calcimimetic as soon as possible, as well as to include a clarifying statement in the Change Notice when it is published to avoid any potential confusion of the payment pathway for the oral calcimimetic. We recommend that CMS implement the Change Notice only after the IV calcimimetic has been launched and is being used. It is important that the transition period does not begin tolling until the drug is in use to ensure that there are no months included in the transition period when the drug is not being used. This step will allow CMS to collect as much data as possible about utilization and price. Also, given the historical problems dialysis patients have faced in getting their Part D drugs from some Prescription Drug Plans (PDPs), we suggest that CMS also clarify with the PDPs that the oral calcimimetic remains reimbursable under Part D for ESRD patients until the date CMS specifies in the Change Notice.

KCP supports moving the oral calcimimetic to Part B reimbursement during the transition period because it will be important to have data that can only be obtained through the Part B program when CMS ultimately adds the oral drug into the ESRD bundle. Part D data on the oral calcimimetic may not adequately reflect the utilization of the drug once it is part of the Part B program. In addition, pricing in Part D, which is based on negotiations with PDPs, is different than the ASP calculation under Part B. While CMS has been using Plan Finder price data to impute value to orals as outlier services, this source is not sufficient for higher cost products. Thus, Part D information alone would not provide an accurate picture of utilization or cost.

While we support moving the oral calcimimetic to Part B, we encourage CMS to consider the impact that the shift could have on beneficiaries’ financial obligations under Part D and new obligations they could incur under Part B. Shifting from Part D to Part B would result in changes in beneficiary co-payment amounts. Under the Part D standard prescription drug benefit, covered drugs are subject to an annual deductible, 25 percent

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<sup>1</sup>CMS, ESRD Prospective Payment System (PPS) Final Rule for Calendar Year (CY) 2016, Display Copy 217.

coinsurance up to an initial coverage limit, and catastrophic coverage after an individual incurs out-of-pocket expenses above a certain annual threshold. For 2016, the annual deductible is \$360, the initial coverage limit is \$3,310, and the annual out-of-pocket threshold is \$4,850. In 2016, once the PDP enrollee reaches the annual out-of-pocket threshold, his or her nominal cost-sharing is equal to the greater of 5 percent coinsurance or copayment of \$2.95 for a generic drug or a preferred multiple source drug and \$67.40 for any other drug.<sup>2</sup>

Once the oral calcimimetic is moved to Part B, beneficiaries could be responsible for 20 percent of the transitional add-on amount, but CMS has not specified whether it plans to apply a co-payment amount to these add-on payments. Given the unique nature of the introduction of the IV calcimimetic, which CMS recognizes in the Final Rule, we encourage CMS to use its discretionary authority and not require beneficiaries to have a co-payment on the transition amount.

There is precedent for this approach in the hospital outpatient prospective payment system.

[P]ass-through payment amounts, by law, are not subject to coinsurance. CMS considers the amount of the pass-through drug payment rate that exceeds the otherwise applicable OPPS payment rate to be the pass-through payment amount. Thus, in situations where the pass-through payment rate exceeds the otherwise applicable OPPS payment rate, the coinsurance is based on a portion of the total drug payment rate, not the full payment rate.<sup>3</sup>

Once the drug is shifted to Part B, beneficiaries will no longer be able to count their cost-sharing and other out-of-pocket amounts for purposes of Part D. This could impact their annual out-of-pocket threshold. We understand that it is not possible to insulate beneficiaries from the entire impact of the shift, but CMS could mitigate some of the effect by reducing and/or eliminating cost-sharing on the transitional add-on amounts.

### **III. Establishing Payment Rates During the Transition Period**

In the Final Rule CMS indicates that the “transitional drug add-on payment adjustment [will be] calculated based on the payment methodologies in section 1847A of the Act.”<sup>4</sup> Because the relationship between the oral and IV calcimimetics is unknown at this time, we recommend that CMS set the transition rate for the IV calcimimetic using its own WAC and ASP, while CMS use a separate price for the oral calcimimetic.

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<sup>2</sup>Announcement of Calendar Year 2016 MA Capitation Rates and MA and Part D Payment Policies and Final Call Letter, April 6, 2015.

<sup>3</sup>Medicare Claims Processing Manual, Ch. 17, § 10.

<sup>4</sup>Display Copy at 217.

Section 1847A of the Social Security Act (SSA) establishes separate methodologies for calculating WAC and ASP for single source and multisource drugs. For drugs to be considered multisource, the FDA must rate the new drug as therapeutically equivalent and pharmaceutically equivalent to an existing drug(s). The drugs must also be sold in the United States in the same quarter.<sup>5</sup>

We appreciate that CMS may not want to make a decision about whether the drugs are single or multisource until after the FDA has issued the label; however, we encourage CMS as quickly as possible after the FDA does issue the label to clarify the methodology it will use to calculate the transitional drug add-on adjustment and provide the kidney care community with the opportunity to comment on it.

Additionally, KCP would welcome the opportunity to work with CMS during the transition period to collect information about how the drugs are being prescribed, how they are being administered, and which patients may benefit from their use. We anticipate that this information would be relied upon to determine the appropriate amount of dollars that would be added to the ESRD bundled payment amount if the drugs are added to the bundle after the transition period.

#### **IV. Billing Requirements for Oral Calcimimetics**

As an initial matter, we have identified the following set of issues and recommendations that we hope can be addressed. We anticipate that additional issues and recommendations may arise as we learn more about the new drug and consider the transition of the oral calcimimetic into Part B.

##### **A. State Pharmacy Laws**

Dialysis facilities are rarely licensed as pharmacies and, therefore, will likely have to contract with pharmacies to be able to supply the oral calcimimetics to beneficiaries. There are many questions surrounding whether dialysis facilities will be permitted under these state laws to provide the oral calcimimetic to patients when they are in a facility. We may need the Agency's assistance in addressing some of these issues as they arise and encourage CMS to provide appropriate guidance to encourage states to avoid using pharmacy laws to create unnecessary barriers to access for patients receiving the oral calcimimetic through a dialysis facility.

##### **B. Submitting Amount Dispensed on Claims**

KCP requests that CMS provide more details about how it plans to require dialysis facilities to include information on the oral calcimimetic after the IV calcimimetic becomes available and the oral drug is incorporated into Part B. While we do not know

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<sup>5</sup>SSA § 1847A(c)(6)(C).

the pricing information yet, the historical price of the oral calcimimetic has been significant compared to oral equivalent drugs that are currently included in the ESRD PPS.

These facts create a novel situation for dialysis facilities, but appear similar to the situation many skilled nursing facilities (SNFs) and hospital outpatient departments face when it comes to providing certain drugs to beneficiaries. When a SNF dispenses an immunosuppressive drug (generally through a contract arrangement with a pharmacy), CMS requires the SNF to include the amount dispensed on the claim.<sup>6</sup> CMS also requires hospitals to report the amount of drugs dispensed when a beneficiary comes to a hospital outpatient department to receive a drug (such as an anti-cancer drug, either oral or infused) and is sent home with more than a single day's supply of the drug so that it can be taken at home.<sup>7</sup>

We understand that currently, CMS requires dialysis facilities to report the amount a patient has used on the claim. While this policy may have seemed appropriate for lower cost drugs, it is not appropriate for more expensive drugs like oral calcimimetics. In addition, it is inconsistent with the requirements CMS places on similarly situated providers, SNFs and hospitals, as described above. Therefore, we ask CMS to clarify that when billing for the oral calcimimetic, dialysis facilities should report the amount that has been dispensed. Just as it is impossible for hospital outpatient departments to monitor what patients do with drugs that are dispensed post hospital stay or outpatient/ER visit, a dialysis facility cannot accurately or with the certainty needed for purposes of attesting to the accuracy of the information submitted on a claim determine the amount of an oral drug a patient has actually used. Even SNFs, which are arguably in a better position to know what medications a patient actually takes, are required to report the amount dispensed, not the amount used. Therefore, we ask that CMS align the billing requirements with those it already uses in other similar situations and require that the amount of the oral calcimimetic dispensed be recorded on the claim.

### **C. Removing Potential Barrier to Access**

Some physicians have expressed concern that the Stark Law could create an access barrier for physicians. Under the Stark Law, a physician may not refer a Medicare beneficiary for "designated health services" to an entity with which the physician has a financial relationship, unless one of a set of enumerated exceptions applies.<sup>8</sup> Currently, outpatient prescription drugs are defined as designated health services. Through regulation, CMS has excluded items and services reimbursed by the ESRD composite rate.<sup>9</sup> CMS has maintained a list of CPT and HCPCS codes to clarify what items and services are eligible for this exclusion.<sup>10</sup> We anticipate that once there is a HCPCS code for

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<sup>6</sup>Medicare Claims Processing Manual, Ch. 17 § 80.3.

<sup>7</sup> *Id.* at § 90.4

<sup>8</sup>SSA § 1877.

<sup>9</sup>42 C.F.R. § 411.351.

<sup>10</sup>*Id.* at § 411.355(g).

the IV calcimimetic, CMS will shift the oral calcimimetic into the bundle through the Change Notice and the HCPCS codes for both drugs will be added to the list of items and services eligible for the exclusion. It would be extremely helpful if CMS could clarify in writing how it will address this issue so there is no confusion about the drug being excluded from the restriction.

#### **D. Coding Requirements**

KCP recommends that CMS establish the HCPCS code rather than the NDC for purposes of reporting the IV and oral calcimimetic drugs. The HCPCS code will simplify the billing and establish consistency in reporting. HCPCS codes are tailored to the dosing levels, while NDC focus on the way drugs are packaged. Given all of the other complexities surrounding the introduction of the oral calcimimetic and a new IV calcimimetic to the ESRD bundle, it would be beneficial to rely on the HCPCS code.

#### **E. Billing Questions Related to Discarding Oral Drugs**

We agree that it will be important to try to limit discarding oral medications as much as possible. However, there are situations in which the best option, because of safety concerns, will be to discard the medication. We ask that CMS review the scenarios below and provide clear instructions as to the steps dialysis facilities should take.

##### ***1. Does CMS plan to establish a minimum and/or maximum number of days of medication that can be supplied?***

We understand that providing beneficiaries with multiple month supplies of oral drugs can create unnecessary waste. To that end, CMS currently limits the amount of EPO that a home dialysis patient may have on hand to a two-month supply.<sup>11</sup> CMS also limits the supply of immunosuppressive drugs a SNF may provide to a beneficiary to 30 days.<sup>12</sup> Because we have limited experience and understanding of the utilization of oral calcimimetics in the Part B setting, we recommend that CMS not establish a minimum or maximum number of days of medication that can be supplied, at least during the transition period. We would like to work with the Agency to determine the appropriate supply policy as we learn more about the needs of beneficiaries and utilization of the oral calcimimetic through the transition period.

##### ***2. Who bears the risk if a patient receives a multi-day supply of the oral calcimimetic and the patient dies?***

Under the current Medicare Claims Processing Manual, CMS requires facilities to report any amount of EPO supplied to certain home dialysis patients and that a facility

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<sup>11</sup> Medicare Claims Processing Manual, Ch. 17 § 40.1.

<sup>12</sup> Medicare Claims Processing Manual, Ch. 7, § 70.

discards because the patient has died.<sup>13</sup> Because these medications have not remained in the control of the facility or a pharmacy, they should not be considered for reuse under any circumstances. There is no guarantee that they have been maintained properly and safely. In addition, there is no way to operationally require beneficiaries or their families to return any unused drugs to dialysis facilities. Therefore, we recommend that CMS clarify that when a beneficiary dies without having used the complete prescription, it will not require reverse billing.

**3. *How should changes in physician dosing requirements be implemented if a patient has a 30-day or greater supply of the drug?***

Changes in dosing requirements may occur from time to time. In some instances, there may not be a need to order a new prescription, such as if the change in dose relates to the number of pills a patient is supposed to take (*e.g.*, shifting from one pill to two pills). However, if the dose change requires a change in the number of pills the patient has, then it will be necessary to dispense more drugs. To that end, we recommend that CMS allow the facility to submit a claim and receive payment for the newly dispensed drug even if the previously dispensed drugs have not been consumed completely. Because it will be impossible to ensure the integrity of the drugs once they are in the possession of the patient, we again believe it would not be safe or appropriate to require the return and reverse billing of these drugs.

**4. *How should dialysis facilities bill if medication is sent to a beneficiary's home, the beneficiary indicates he/she never received it, and a new supply is sent? Can the facility bill for the second supply?***

We agree that it is the responsibility of the dialysis facility working in coordination with the pharmacy, to ensure that beneficiary delivery information is correct. However, mistakes can occur and third party carriers may not always deliver packages correctly. In these latter instances, we request that CMS allow the facility to submit a claim and be reimbursed for the second supply by including a modifier on the claim indicating a problem with delivery. If a facility repeatedly uses the modifier, CMS will be able to identify the problem quickly and investigate.

**V. Conclusion**

We appreciate CMS's continued efforts to work with the kidney care community as a new IV calcimimetic comes to market. To that end, we hope that this letter and these recommendations will help the Agency as it develops more detailed policies related not only to the IV drug, but also the existing oral calcimimetic. Creating a comprehensive data set of prescribing behaviors will be particularly important given the high variability in calcimimetic usage seen to date. CMS and the community will need to work closely to

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<sup>13</sup> Medicare Claims Processing Manual, Ch. 17 § 40.1.

Sean Cavanaugh and Laurence Wilson

May 6, 2016

Page 8 of 8

determine if a single dollar amount can appropriately be added to the bundled rate. However, we also note that these questions are likely only a beginning. We would welcome the opportunity to discuss these issues with you in more detail and to maintain an ongoing dialogue as the Agency and the community identify additional issues. Also, please do not hesitate to contact Kathy Lester at (202) 534-1773 or [klester@lesterhealthlaw.com](mailto:klester@lesterhealthlaw.com) if you have any questions as well.

Sincerely,

A handwritten signature in black ink that reads "Frank Maddux M.D." with a stylized flourish at the end.

Frank Maddux, M.D.

Chairman

Kidney Care Partners