KIDNEY CARE PARTNERS

August 11, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS–1674–P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program

Dear Administrator Verma:

Kidney Care Partners (KCP) appreciates the opportunity to provide comments on the "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program" (Proposed Rule). This letter addresses the proposals related to the ESRD PPS and payments for dialysis services provided to individuals with AKI for Calendar Year (CY) 2018. We have provided our comments on the ESRD Quality Incentive Program and the Request for Information in separate letters.

In sum, KCP:

- Supports the use of Section 1847A pricing for eligible Outlier Drugs and Biologicals;
- Asks CMS to provide guidance to MA and Part D plans, as well as address the inclusion of calcimimetics in MA reimbursement policies;
- Supports the proposed updates to the CY 2018 ESRD PPS, but remains concerned about policies that result in underpayments for the case-mix adjusters;
- Asks that CMS provide data to allow for a complete analysis of the ESRD PPS;
- Requests that CMS explain the monitoring programs for AKI and describe how it will make information from these programs public;

- Asks that CMS include required sharing of dialysis patient information with the treating facility after a hospitalization to promote health information initiatives; and

- Requests that CMS include the Network Fee on the cost reports and resolve implementation problems with the medical director fee cost reporting policy.

I. KCP supports the use of Section 1847A pricing for eligible Outlier Drugs and Biologicals.

KCP supports the proposal to use all of the Social Security Act (SSA) § 1847A pricing methodologies for the ESRD PPS outlier policy.[1] This approach would be consistent with its decision to use the SSA § 1847A pricing policy for the transitional drug add-on payment adjustment as well. However, we urge CMS to rely upon contract pricing, rather than not include a new drug in the outlier calculation, if a drug has neither ASP nor WAC data and cannot otherwise be priced under section 1847A.

We appreciate that CMS recognized in implementing the transitional drug add-on payment adjustment that it is important to implement policies that do not create barriers to accessing new drugs or biologicals. Historically, new drugs and biologicals that come to market in this space can be expensive and not having access to outlier payments may create an unintended barrier. If such a drug or biological does not count toward the outlier calculation, it would make it less likely that physicians would prescribe it. While we believe that it is unlikely a new drug or biological will not have an ASP or WAC, it is important to ensure that payment policies do not disincentivize the use of drugs or biologicals, especially in an area that has experienced very little innovation during the last 25 years. In addition, we ask that CMS provide an analysis of the proposal – both as proposed and as we ask to be finalized – to clarify its impact on the program.

KCP is concerned that CMS in the preamble asserts that ESAs administered in 2016 were roughly 20 percent lower than the value it projected in the ESRD PPS final rule. We do not disagree with the conclusion that there should be no change in the threshold for outlier payments. However, understanding the cost and utilization of drugs generally and ESAs in particular is important to understanding the adequacy of the payment system. We are concerned that the preamble does not describe how it determined this value and it seems inconsistent with trends that some of the KCP members are seeing in their own data.

[1] 82 *Fed. Reg.* 31190, 31195 (July 5, 2017).

II. KCP asks CMS to provide guidance to MA and Part D plans, as well as address the inclusion of calcimimetics in MA reimbursement policies.

In addition, we seek your assistance with making sure that the inclusion of the oral and IV calcimimetics in the bundle does not undermine beneficiary access to Medicare Advantage (MA) plans. In particular, we understand that the rates for MA plans are based on bids and there is no clear mechanism for adjusting these rates if new drugs, biologicals, or technologies are added to the payment system mid-year. Therefore, we ask that you work with the MA team at CMS to ensure the smooth implementation of the policy changes that shift the oral calcimimetic from Part D to Part B and add the oral and IV calcimimetics to the bundle. Specifically, it would be helpful if CMS were to provide clear guidance in advance of 2018 to the MA plans and the Part D pharmacies that as of date the drug is included in the bundle that calcimimetics will be considered Part B services. We also ask that CMS address the reimbursement issues that will arise with moving drugs from Part D to Part C. First, to parallel the TDAPA in the ESRD PPS, CMS should reimburse the oral and IV cacimimetics on a pass through basis under the Part C program. Second, CMS has historically paid 85 percent of the cost of Part D drugs and should take account of this policy as the drug shifts into Part D as well. It is important to understand the impact these changes will have on MA plans and the ability of beneficiaries to access the care prescribed to them by their physicians.

Finally, we are pleased that CMS has released some guidance around the implementation of TDAPA and look forward to further clarifications. Based on that guidance, we ask that CMS ensure that all the information on both calcimimetic products and all payment information, including the Q8 payer value code, be carried forward into the rate setting file released with the 2019 Proposed Rule.

III. Proposed CY 2018 ESRD PPS Update

A. KCP supports the proposed updates to the CY 2018 ESRD PPS, but remains concerned about policies that result in underpayments for the case-mix adjusters.

KCP appreciates that CMS continues to update the ESRD PPS and looks forward to the full market-basket update minus the productivity factor resuming for PY 2019.

We also support CMS's proposal to refine the outlier pool to align the dollars paid out more closely with the estimated amount used to create the outlier pool. Yet, we remain concerned that the Proposed Rule does not yet address 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 $0.46 per

treatment in 2016. Cumulatively since 2011, $4.97 has been removed by the underpayment of the outlier pool. While this may seem like a small amount, it is important to maintain the integrity of the payment system and avoid policies that result in dollars inappropriately coming out of the system, especially when as MedPAC has determined, the average Medicare margin for dialysis facilities is negative, meaning that the rate is below the cost of providing care. We ask that CMS further refine the outlier policy so that it is more consistent with how outlier policies in other Medicare payment systems work.

In addition, KCP generally continues to support the methodology for determining the wage indices and the continued application of the wage index floor. However, we ask that CMS consider how the current policy could be modified to adjust wage index values to take account of laws requiring wage increases. Under the current methodology, there can be a several year lag with the wage index recognizing these changes.

We remain deeply concerned about the underpayment of the PPS rate because of problems with the case-mix adjusters, which we describe in detail in our response to the Request for Information which we have sent as a separate letter. 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.

Finally, while we understand that CMS is required by statute to include a productivity factor adjustment, we are concerned that the proposed rule continues to use a generic productivity factor. Our members have experienced relatively flat patient treatment time hours. There has been no sustained improvement in productivity; in fact, many of our members are seeing a decline in productivity. Therefore, we ask that CMS work with the kidney care community to develop a renal-specific productivity factor that takes into account the mandatory minimum staffing ratio requirements in the Conditions for Coverage and the actual labor hours per treatment.

B. KCP asks that CMS provide data to allow for a complete analysis of the ESRD PPS.

While CMS has provided more data related to the ESRD PPS during the past three years, the files do not yet contain sufficient information to analyze the proposals completely. We cannot, for example, determine the relationship between the standardization factor and the refinement CMS added in previous rulemaking.

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 OPPS 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.

IV. KCP requests that CMS explain the monitoring programs for AKI and describe how it will make information from these programs public.

KCP appreciates that CMS has announced the AKI payment rate as part of the Proposed Rule and provided the kidney care community with the opportunity to provide comments on the recommendations. First, we ask that CMS confirm in the final rule that because the Congress did not mandate that CMS apply a budget neutrality factor when implementing the AKI patients for dialysis facilities that the Agency will ensure that sufficient funds are available to meet the medically necessary utilization of AKI services by Medicare beneficiaries.[2] Second, we are concerned that CMS's estimate of AKI patients is inconsistent with the prevalence of AKI patients who require renal replacement therapy. For example, a 2008 peer-reviewed article in *Critical Care Medicine*, estimated that there are 200-300 such patients per million per the general population per year.[3] The Moran Company recently surveyed members of the Kidney Care Council and found that from January – June 2017 facilities have treated 5,322 individuals with AKI and who are Medicare beneficiaries. We believe that CMS may not be seeing these numbers in the data for a variety of reasons, but most likely because hospitals were not always billing for dialysis for AKI patients. We ask that CMS work with clinicians and researchers and review the literature to ensure that it has correctly estimated the potential number of beneficiaries with AKI who would require renal replacement therapy.

We are pleased that CMS indicated in the Final Rule for CY 2017 that it agreed with comments from the kidney care community that it would "be developing formal monitoring programs for utilization to inform future payment policy."[4] We had hoped that the Agency would provide more details about how these monitoring programs using claims information would work prior to the January 1, 2017, implementation of the new services. As the Renal Physicians

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[2] In the Final Rule for CY 2017, CMS states: "We anticipate an estimated $2 million being redirected from hospital outpatient departments to ESRD facilities in CY 2017 as a result of some AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus continuing to receive those services in the hospital outpatient setting." While this analysis suggests there would be savings as CMS allows beneficiaries with to access dialysis in a lower-cost setting, it does not indicate that the Agency will require the outlay of payments for AKI to be budget neutral to current spending or another type of benchmark. *See* 81 *Fed. Reg.* 77834, 77840 (Nov. 4, 2016).

[3] EA Hoste & M Schurgers, "Epidemiology of Acute Kidney Injury: How Big Is the Problem" 36 *Crit. Care Med.*, S146-51, Apr. 2008; *see also* M Schmitz, FP Tillman, *et al.*, "Mortality Risk Factors in Intensive Care Unit Patients with Acute Kidney Injury Requiring Renal Replacement Therapy: A Retrospective Cohort Study," *Clin. Nephr.* Apr. 2017 (DOI 10.5414/CN109078)(indicating that about 6 percent of patients with AKI require renal replacement therapy).

[4] CY 2017 Final Rule, *supra* note 2, at 77871.

Association (RPA) indicated in its consensus White Paper entitled "Acute Kidney Injury Patients Requiring Outpatient Dialysis," individuals with AKI "are not in a steady state."[5] This means that while the services provided to individuals with AKI may be the 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.[6]

KCP is pleased that CMS recognizes the real differences in these patient populations as well, but we know that there is much still to learn about the treatment of patients with AKI who require dialysis, including the utilization of renal dialysis services.

As we learn more about the provision of services to these patients, it may become apparent that an "AKI adjustment" to the payment rate is necessary to address the differences in the services provided to AKI patients. We were pleased that CMS recognize adjustments may be necessary in the future, as well as the need to bill certain services separately in the final rule for CY 2017.

One area that requires special attention is utilization. We believe based upon the experience of KCP members during the first 6 months of 2017 that the estimate of 9170 treatments for 2018 underestimates what the actual utilization will be for 2018. The underestimation is likely because CMS relies upon historical data from hospital treatments increased by the standard increased in the non-ESRD population. Historical data does not represents the actual utilization for several reasons. In other instances, some patients may have qualified for inpatient reimbursement who otherwise could have been dialyzed in an outpatient session. For example, some hospitals have been contracting with dialysis facilities to provide

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[5]RPA, "Acute Kidney Injury Patients Requiring Outpatient Dialysis" 6 (2016).
[6]*Id.*

services to these patients during the past few years and may not have sought reimbursement from Medicare for these services. Therefore, the historic utilization may not be representative of the actual prevalence of AKI patients requiring dialysis.

Thus, we ask that either in the preamble to the Final Rule or in guidance that would be issued as soon as possible and before the end of the year that CMS explain its monitoring programs and how it will provide data from these programs to promote transparency in the program. Using current data and adjusting it upon the experience that will be gained in the coming years will be important to understanding the actual utilization of dialysis for AKI patients.

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 also ask that CMS add an AKI column to Worksheet D to report these costs separately.

V. KCP asks that CMS include required sharing of dialysis patient information with the treating facility after a hospitalization to promote health information initiatives.

KCP appreciates the ongoing focus to promote the use of health information technology (HIT). As we have described in previous comment letters, we believe that HIT can improve the quality of care provided to patients by allowing for a seamless flow of information between providers. As Department of Health and Human Services (HHS) continues to promote interoperable HIT and standards, across the continuum of care, it is important that CMS update the requirements on health care providers to share information with other providers responsible for treating the patients.

Sharing hospital treatment and discharge information is particularly important to ensuring the continuity of care for dialysis patients. While HHS's HIT efforts should have allowed for the improved transfer of such data, it has not. Dialysis patients who have multiple comorbidities, require a substantial number of medications and require dialysis treatments three to four times a week need their providers to coordinate care across the continuum of care. Dialysis facilities and nephrologists must calibrate their treatment protocols to ensure appropriate care. This includes appropriately removing volume to prevent either heart failure or hypotension; administering and dosing medications in such a way to ensure that important medications are not removed with dialysis; ensuring that medication dosing is correct for a person with no kidney function; knowing what medications

need to be administered with dialysis; treating other complications and health issues (including blood pressure and nutrition); addressing important social issues that may have arisen during the hospitalization (including awareness of changes in advance directives); and managing bleeding and clotting issues that can occur with the provision of dialysis. All of these are critical to providing quality care for our patents.

Yet, for the vast majority of patients, their dialysis centers and nephrologists are never told of the care they are provided when hospitalized. This lack of sharing of information creates a black hole that places patients at higher risk of complications, unnecessary treatment, and future hospitalizations.

Despite efforts by KCP members, it has been extremely difficult to obtain discharge information from hospitals. We appreciate that there are many demands on hospital staff. Often, requests from dialysis facilities or nephrologists go unanswered. Thus, we ask that CMS require hospitals, especially those using certified health IT, to send to patient's other health care providers: (1) the discharge instructions and discharge summary within 48 hours; (2) pending test results within 72 hours of their availability; and (3) all other necessary information specified in the "transfer to another facility" requirements. While some patients may tell hospitals about their nephrologists and dialysis facilities, others may forget. Therefore, we encourage CMS to clarify that hospitals must also provide this information upon request by a dialysis facility, as well as when a request is made by a nephrologist. If the hospital knows the dialysis facility and/or nephrologist is treating the patient, the information should be automatically sent; if the hospital does not know, then the hospital should send it upon request. This requirement will promote efficiency and patient safety as patients transition from a hospital to a dialysis facility, as well as promote the goals of HHS' HIT initiative.

VI. KCP requests that CMS include the Network Fee on the cost reports and resolve implementation problems with the medical director fee cost reporting policy.

KCP encourages CMS to allow facilities to include the 50 cents per treatment Network fee on the cost reports. For example, in 2016 there were 38,343,333 dialysis treatments administered. This means that CMS and other policy-makers were not taking into account $19,171,666 of cost incurred by dialysis facilities.

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

> The Secretary shall reduce the amount of each composite rate payment under this paragraph for each treatment by 50 cents (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis) and provide for payment of such amount to the organizations (designated under subsection (c)(1)(A)) for such organizations' necessary and proper administrative costs incurred in carrying out the responsibilities described in subsection (c)(2).[7]

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

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

> Beginning on January 1, 1987, networks would be funded by HCFA taking 50 cents from the payment that would otherwise be made to a dialysis facility for dialysis services under the prospective, composite rate payment method. This would replace the current method of funding from the Medicare trust funds, subject to a specific appropriation.[8]

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

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

Given the reliance of the Congress and its advisory commission, MedPAC, on the cost reports for determining appropriate reimbursement policy, it is important that the cost reports include costs that are related to the care of Medicare beneficiaries. The Network Fee is such a cost. Without including that amount, policy-makers cannot calculate correct margins. It is in the interest of all policymakers that the information provided is as accurate as possible. Therefore, we encourage CMS to add the Network Fee on the facility cost reports beginning in 2017.

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

KCP again thanks CMS for eliminating the medical director fee limitation that had been a policy left over from before dialysis facilities were paid on a prospective payment system basis. We are concerned, however, that some of the contractors overseeing the cost report submissions are requiring facilities to submit detailed physician logs describing the hours worked and tasks performed and still applying the limitation. There may be confusion because the most recent edition of the ESRD Claims Processing Manual (updated 11-10-16) continues to include instructions that do not reflect the policy changes made in previous rulemakings. Specifically, it states:

> Allowable Compensation for Physician Owners and Medical Directors— Compensation, including fringe benefits, paid to a physician owner or medical director may not exceed the reasonable compensation equivalent (RCE) limits currently in effect for a specialty of internal medicine for a metropolitan area of greater than one million people. See §2182 for a description of the RCE limits and §2182.6 for the current salary limit for a specialty of internal medicine. The physician's salary reported as a Medicare allowable cost for administrative services may not exceed the RCE limit. Furthermore, the facility must adjust the RCE limit by the time spent by the physician as owner or medical director performing administrative services for the facility. Based on Medicare program statistics, the median amount of time spent by physicians in ESRD facilities on administrative duties is 25 percent. If a facility reports that a physician spends more than 25 percent of his or her time performing administrative type services, the facility must document its claim. If no documentation is furnished and the facility is reporting physicians' time in excess of 25 percent, the A/B MAC (A) limits the physician's compensation to the lower of the amount claimed or 25 percent of the RCE limit in effect. If the physician as owner or medical director furnishes services to more than one facility, his or her total time may not exceed 25 percent unless the facility has documentation to support its claim. A renal facility may adjust the 25 percent limit to reflect special facts or circumstances, e.g., a medical director may spend more time at a renal facility that furnishes a large number of treatments and other medical services than most renal facilities. If a renal facility claims a higher percentage of time, it must be able to document the medical director's actual time spent performing administrative duties.[9]

[9]Medicare Claims Processing Manual, Ch. 8, "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims" § 40.6.C.2. (2016).

Therefore, we ask CMS to revise the instructions in the Medicare Claims Processing Manual to align with the policy finalized in previous rulemaking that eliminates the limitation on medical director fees. We also ask that it clarify that detailed physician logs not be required, consistent with the elimination of the limitation and the requirements (such as providing an invoice) applied to other health care providers and suppliers with regard to establishing medical director fees.

VII. 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. Please do not hesitate to contact Kathy Lester at (202) 534-1773 or klester@lesterhealthlaw.com if you have any questions in the meantime.

Sincerely,

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
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
Keryx Biopharmaceuticals, Inc.
Kidney Care Council
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Nephrology Nursing Certification Commission
NxStage Medical, Inc.
Renal Physicians Association
Renal Support Network
Rogosin Institute
Sanofi
Satellite Health Care
U.S. Renal Care

Appendix B: Technical Appendix by The Moran Company

Historical Trend of Underpayment CMS Projected ESRD Budget Neutral Payments
KCP has provided extensive commentary based on analytic work performed by The Moran Company (TMC) using both rate setting files released with proposed and final ESRD rules, and Medicare Standard Analytic Files (SAFs) that contain complete claims for ESRD services for each calendar year 2011 through 2015. Using 2018 rates setting files released with the proposed rule includes an incomplete set of 2016 claims: comparisons are made to 2017 proposed rule rate setting files with a comparable incomplete set of 2015 claims, and to 100% 2015 claims in the SAFs.

In each year, TMC compares projected payments reported in CMS's impact files at the facility level released with each proposed and final rule, to actual payments for the same set of facilities for the same year for which the impact file projected payments. The CMS projected payments are supposed to represent budget neutrality at the 98% of historical payment level in 2011, updated for ESRD updates and other budget neutrality adjustments.

CMS has never answered many questions submitted during comment periods and following final rules by KCP, seeking clarification of methods. In particular, CMS has not addressed a repeated request by the industry to update the "standardization factor", used each year to align the ESRD base rate with a budget neutral level that is adjusted for the impact of all the payment adjusters in the program. The industry has asked that standardization be corrected each year to account for the actual frequency with which each payment adjuster is claimed. The original standardization factor was based on a research project used to develop the payment system, relying on historic claims data not accessible to the dialysis industry, and designed to estimate what the frequencies would be for each assumption. These data were derived from claims from 2009 and earlier. Rules released after the initial year of the new payment system in 2011 do not explain any re-calibration of the standardization factor based on the actual frequency with which ESRD facilities have claimed each adjuster. KCP and others have provided CMS with extensive evidence to demonstrate that facilities have not been claiming adjusters at the level projected and assumed by the standardization factor. With the revision of adjusters in 2016, CMS does not clearly assert that it has corrected standardization for the actual frequencies of all adjusters. It indicates modification of the standardization factor to account for the changed value of the age and rural adjusters, and accounts for the proportion of standardization accounted for by each adjuster.

The standardization factor reduces the base rate from the total estimated payment level that forms the single base rate per treatment originally calculated as the base payment meeting the statutory budget neutrality to 98% of historical spending in 2007, the year the system was being re-based to in the original authorizing legislation. This reduction has been historically over-stated due to a lack of similarity in the original projection of frequency of adjuster characteristics compared to the actual frequency of adjuster

characteristics. CMS has consistently over-estimated adjuster frequencies since the new payment system was implemented in 2011, and has refused to acknowledge that this mis-match between its estimate and actual affects the foundation for the payment system. The result of this failure to adjust the standardization factor to actual practice, is underpayment.

The Moran Company reviewed the 2018 proposed rule impact file, and compared projected payments by facility to the same set of facilities showing actual payments in the rate setting file. In this process, TMC identified a further lack of transparency in both regulatory documentation and in all of the data documentation. TMC and CMS use approximately the same data in all rate setting analytics, and a recent review found that there is no documentation for how sequestration is accounted for in payment rates reported in claims data. After intensive investigation and numerous calls to CMS's data contractor attempting to get answers to related questions without receiving any clear answers, TMC went into the SAF and rate setting file claims data before and after sequestration went into effect in 2013, and found evidence that suggests that all the payment data in the claims files have been differentially reduced for sequestration: co-pays show no change, but total Medicare payments (inclusive of co-pays) are reduced by approximately 1.6% (the impact of sequestration is 2% on the Medicare portion of the payment). Understanding this is important because CMS made no statement regarding its recognition of sequestration in 2014 when it revised the adjusters and recalibrated the standardization factor.

Therefore, we do not know what assumptions were made at that time that have been carried forward into rate setting for subsequent years, including for 2018. CMS reports simply taking the base rate each year and applying the update factors. But it is using claims and payment levels in its impact analyses and other re-calibrations, making it impossible to know what had actually been done.

That said, using the best approximation of its methods, and testing different approaches, TMC revised its analysis of underpayment ("leakage") to incorporate both Medicare savings due to the QIP penalties, and the impact of sequestration on payment levels believed to not be reflected in the impact analysis projected payment levels which appear not to include sequestration. The analysis relies on CMS's calculation of the outlier payout rate.

A review of the data show that sequestration had a huge impact on estimated underpayment after its implementation for the first full year in 2014. Note that ATRA and then PAMA cuts to payment were also implemented after sequestration hit in 2013. Also note that the underpayment attributable to other factors, which we hypothesize are a mismatch between adjusters frequencies assumed by the standardization factor compared to actual payment are continuing to increase from 2014 (when they dropped relative to

prior years) and 2016, though they are lower than they were without sequestration taken into account. This analysis is based on facilities in both year's data (impact analysis and either rate setting or SAF claims data), so it does not account for the full value of underpayment, though that should be accurately reflected in the amount per treatment. There is underpayment in every year, and actual payment never exceeds predicted payment, so this analysis suggests consistent underpayment in the program since the inception of the ESRD Bundled PPS.

The distribution of underpayment by number of facilities is shown in Tables 1-3.

Table 1.

THE MORAN COMPANY

Analysis of "Leakage" in 2016 & Facility Distribution By Impact Level
Client: KCC &KCP
Source: CMS ESRD Rate Setting File 2016
Date: July 2017

Average leakage per treatment without sequestration (QIP penalty+Outlier+Net after sequestration= $2.56

Difference between Predicted and Actual Payments per Tx for 2016*	Number of Facilities	% of Total
TOTAL	*6,006*	*100%*
Actual Payment per Tx was greater than Predicted Payment per Tx	*1,818*	*37%*
$10 or more	313	6%
$5 to $10	333	6%
$5 to $0	1,172	25%
Leakage (Predicted greater than Actual Payment)	*4,188*	*63%*
$0 to $5	2,175	38%
$5 to $10	1,361	17%
$10 or more	652	8%

**All ranges include the value of the upper bound and not the lower bound*
***Leakage as reported here includes all but leakage due to sequestration.*

Table 2.

THE MORAN COMPANY

Distribution of Facilities by the Outlier $/tx that were Underpaid in 2016

Prepared for KCC
Date: July 2017
Source: Final 2017 Impact File

Average underpaid outlier $/tx = $0.46

Underpaid Outlier $/tx*	Number of Facilities	% of Total
TOTAL	*6,001*	*100%*
≤ $0	10	4%
$0 - $0.28	2,037	52%
$0.28 - $0.5	1,761	32%
$0.5 - $0.75	1,225	9%
$0.75 - $1.00	587	2%
> $1.00	381	1%

**All ranges include the value of the upper bound and not the lower bound*

Table 3.

THE MORAN C(

Underpayment of ESRD PPS 2016 reported by Facility Characteristic

Client: KCC &KCP

Source: CMS ESRD Rate Setting File 2016; CMS ESRD Impact File 2016

Date: July 2017

Facility Characteristic	Count of Facilities	Underpayment per Tx (PPS, Outlier, and QIP Leakage)	Underpayment Per Tx of PPS net of Outlier, Sequestration	Underpayment of Outlier Pool per Tx*
Location				
Rural	1,246	$ 0.28	$ (0.16)	0.44
Urban	4,760	$ 3.16	$ 2.70	0.46
Ownership				
LDO	4,387	$ 2.98	$ 2.53	0.45
Regional	912	$ 0.56	$ 0.09	0.47
Independent	573	$ 4.25	$ 3.86	0.39
Hospital	134	$ (4.56)	$ (5.17)	0.61
Low-Volume				
Yes	298	$ 24.07	$ 23.64	$ 0.43
No	5,704	$ 1.44	$ 0.99	$ 0.45

*Outlier Leakage numbers accurate to two decimals due to rounding error.