



August 29, 2013

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

RE: CMS–1526–P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Proposed Rule

Dear Administrator Tavenner:

Kidney Care Partners (KCP) is pleased to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for the Changes to the End-Stage Renal Disease Prospective Payment System (Proposed Rule). KCP is an alliance¹ of members of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies that support the provision of high quality care for individuals with both chronic kidney disease (CKD) and End-Stage Renal Disease (ESRD).

As we have discussed already with CMS staff, KCP has serious concerns about the proposed payment reduction for the Calendar Year 2014 payment rate, which are discussed in Part 1. In Part 2, we discuss a series of recommendations related to the proposals for the Payment Year 2016 Quality Incentive Program.

Part 1: ESRD Calendar Year 2014 PPS Comments

KCP is deeply concerned about the proposed modifications to ESRD PPS payment rate for CY 2014. As described in detail below, the 2011 cost report data show that the economics of this sector remain extremely fragile. A cut of the magnitude proposed puts beneficiaries at risk and places facilities in an untenable position of having to make difficult choices about reducing staff, services, and even closing facilities. Therefore, we strongly urge the Agency to exercise all of its authority under the statute to protect beneficiary access to care and temper the proposed payment reduction by:

- Accounting for the utilization decrease that was already taken out of the payment rate in 2011 because of the Congressionally mandated cut of 2 percent;

¹ See Appendix A.

- Accounting for the intended shift of dollars from separately billed drugs to the previously underfunded composite rate that took place when the bundle was created, which is reflected in the fact that dialysis facility margins for 2011 remain steady, even as utilization for one component of the bundle changed; and
- Eliminating the inappropriate and continuing loss of dollars from the base rate by revising the standardization factor, eliminating the outlier policy, removing the co-morbidity case-mix adjusters, and resolving the technical problems listed in Appendix C.

In doing so, CMS would be exercising its authority consistent with the requirements that established the ESRD PPS expanded bundle, as well as its long-standing authority to ensure that the payment rate is based upon economic and equitable factors.

Additionally, we urge CMS once again to provide adequate data consistent with the requirements of the Administrative Procedure Act. We also support efforts to remove barriers that could negatively impact the ability of patients to select the modality of their choice in a manner that does not result in additional dollars being taken out of the base rate.

I. CMS should provide adequate data to allow the community to analyze and evaluate the Proposed Rule

Once again, KCP remains concerned that the Agency has not provided sufficient data to analyze and evaluate the Proposed Rule consistent with its obligations under the Administrative Procedures Act (APA). Thus, we unfortunately are limited in our ability to provide comprehensive and meaningful comments on the proposed changes to the ESRD PPS due to the lack of such data. The Agency should provide for greater transparency in the rulemaking process by providing these data, as it does for other Medicare prospective payment systems. The characteristics of such data adequate to evaluate the policies set forth in the current and future rules include:

- Dialysis facility claims for all patients receiving dialysis treatments during the year upon which rates are based linked to an encrypted patient identifier and to the facility providing the services;
- Dates of service so that services can be sequenced;
- The data used by CMS or its contractor to develop and assign case-mix adjusters when any changes are proposed to adjusters or new adjusters are proposed;
- Patient-level data, including a unique flag for each specific case-mix, co-morbidity, low volume, start of dialysis, home dialysis training, or other payment adjusters assigned by CMS as the basis for payment. This flag should be associated with the treatments to which it will apply. This is particularly important for the payment adjusters that are temporary and associated with an acute event in time and will apply for a limited time period;
- The start date for dialysis to calculate the number of adjusted treatments;
- Outlier payments should also be flagged;
- Part D claims for oral drugs in the classifications identified to be incorporated into the bundle in 2016 should be linked by date to the dialysis facility claims by patient; and

- Claims for any other service being added to the bundle.

CMS provides such files to other providers with prospective payment systems, including to hospitals and skilled nursing facilities. The Agency previously provided data with each release of a proposed and final rule that had treatment and service utilization data in it. These data could be released without any compromise to patient data confidentiality consistent with this past practice. CMS even provided such data for dialysis payment rules when the drug spread add-on was created. Thus, we would expect that the Agency would release data that would be sufficient to calculate the 2012 drug utilization for this rule.

We appreciate that the specifications described above would normally be available as a “Limited Data Set.” Such a file could be accessed under Data Use Agreements such as those required for use of the Standard Analytic File. These data would allow the community and interested parties to evaluate the proposed methodology. We urge CMS to release these data prior to the release of the final rule and upon release of future proposed and final rules. Without providing such data, the Agency has not met the requirements of the Administrative Procedure Act because it has issued a proposed rule without sufficient detail to permit meaningful and informed comment by the public.²

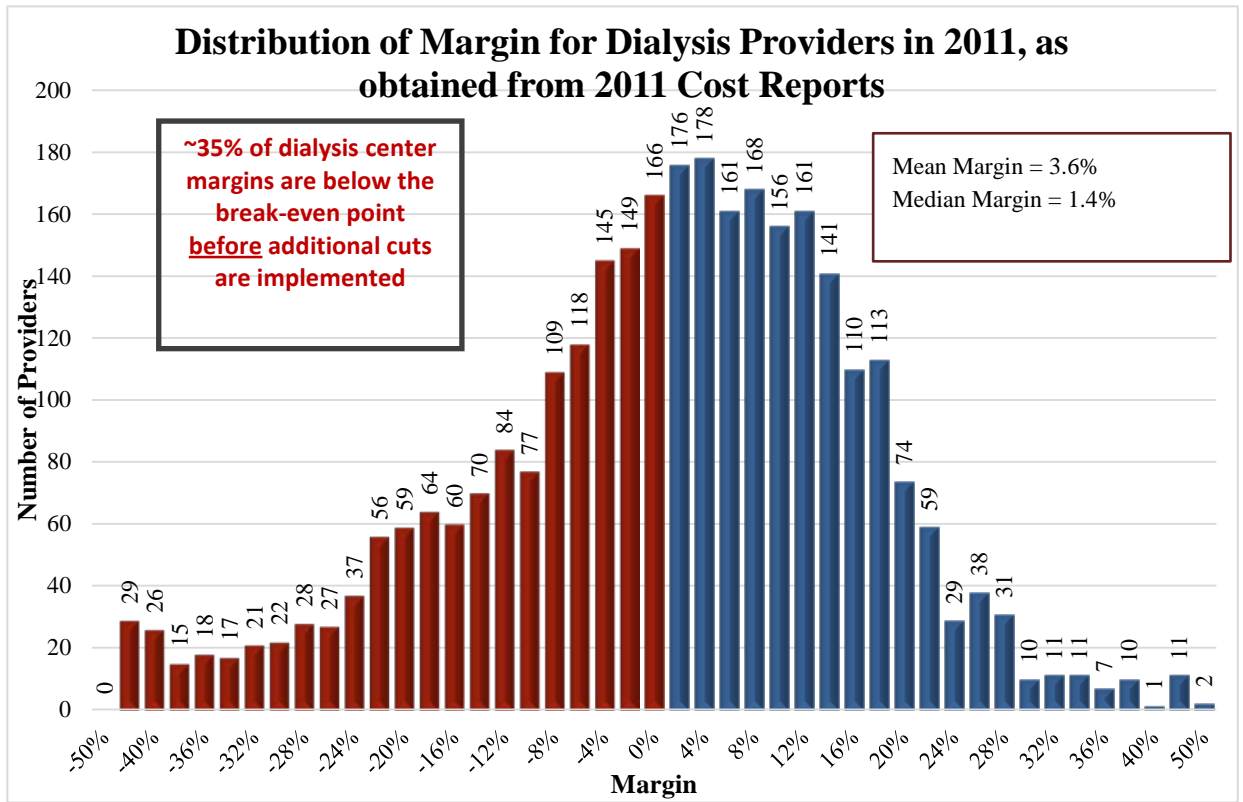
II. KCP opposes the proposal to cut \$30 from the CY 2014 PPS payment rate for providing ESRD services to Medicare beneficiaries

KCP expresses grave concern about the proposed cut. As described in detail below, if it is implemented as proposed, there will be real, negative consequences for beneficiary access to dialysis services and quality outcomes. We strongly encourage CMS to rely upon its existing authority within section 1881 of the Social Security Act to temper the cut. A phase-in alone will not resolve the problem; CMS should get the number right.

A. If CMS were to finalize the proposed cut, beneficiary access to care would be severely compromised because the payment rate would no longer cover the cost of providing care

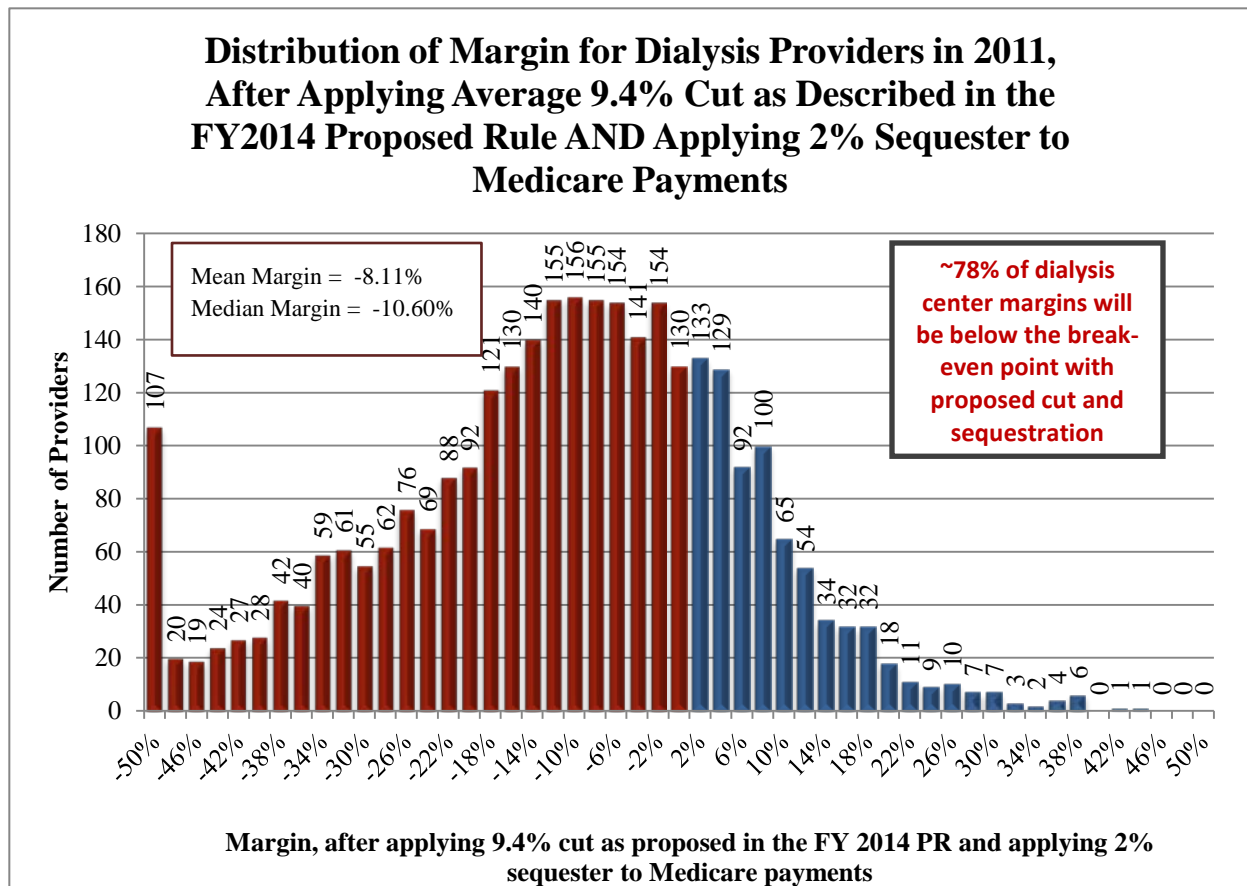
The KCP is extremely concerned that the proposed \$30 cut over what the payment rate would otherwise have been for CY 2014 would disrupt beneficiary access to high quality care and destabilize the fragile economics of the current payment system. The Moran Company analyzed Medicare payments and providers’ costs based upon the 2011 cost report data submitted by freestanding dialysis facilities. The Moran Company found that the mean Medicare margin for outpatient dialysis services was 3.6 percent in 2011.

² *Am. Med. Ass’n v. Reno*, 57 F.3d 1129, 1132-33 (D.C. Cir. 1995).



The Moran Company projected the impact of the proposed cut to reduce the mean Medicare margin to negative 6.4 percent. When sequestration is taken into account, the mean Medicare margin is negative 8.11 percent.³

³The Moran Company Analysis of 2011 Cost Report Data (available upon request).



Unlike virtually every other Medicare provider, dialysis facilities are heavily reliant upon Medicare payment rates, as are Americans living with kidney failure. Approximately 84 percent of patients receiving dialysis are Medicare beneficiaries.⁴ Unlike hospitals or other providers, dialysis facilities provide one service – they dialyze patients – for which there is a single payment rate. Thus, they are not able to spread costs over other payment rates that might be higher. While dialysis facilities are also reliant upon higher commercial insurance rates, these payors compose a very small percentage of the payor mix overall. In addition, commercial plans are reducing their payment rates. Thus, negative Medicare margins in this sector are less likely to be successfully offset by relying upon other services or payors.

Beneficiaries are particularly concerned that a negative mean Medicare margin would endanger access to care. While it may be unlikely that there would be a large number of facilities closing on January 1, 2014, facilities would be less likely to renew leases or refurbish or replace those facilities that do not have a significant commercial payor mix or that serve dually eligible beneficiaries. Additionally, facilities would likely reduce hours of operation, which would have a significant impact on patient access. The ability to expand facilities and/or the number of treatments within existing facilities would diminish, just as the number of Americans with kidney

⁴U.S. Renal Data System, 2012 Annual Data Report, Chapter 1, 216.

failure is increasing. Even though it is likely some expansion would continue, the growth would slow and there is a likelihood that the number of treatment stations would be significantly limited in inner city or rural areas.

The narrow margins also reflect that facilities increased spending in allowable cost centers that have accrued to the benefit of patients. For example, some facilities have added care coordination programs. Others have increased the number of dialysis nurses and technicians. These investments improved the quality of care being provided. The margins also reflect the historic reality that the separately billed drugs cross-subsidized a woefully underfunded composite. While the drug add-on may have addressed a portion of the problem, it did not resolve the entire problem.⁵

Both the data from the Medicare Quality Incentive Program (QIP) and the CMS Claims-Based Monitoring Project show that dialysis quality is improving, supporting the view that the ESRD PPS incentivized improvements in care. Under the QIP, 72.6 percent of facilities achieved the top performance tier in 2011, while that percentage rose to 90.6 percent in 2012.⁶ CMS's 2011 data show marked improvements across a variety of quality indicators, including a:

- Decline in hospitalizations;
- Decrease in catheters; increase in fistula placement;
- Decrease in fluid overload events;
- Improved bone mineral metabolism outcomes;
- Decline in cardiac events and heart failure;
- Expansion of home dialysis; and
- Hemoglobin levels maintained consistent with FDA label.⁷

In addition, Kidney Care Partners led the effort to reduce first year patient mortality under the Performance Excellence and Accountability in Kidney Care (PEAK) program. Through the end of 2012, there was a decline of approximately 13.6 percent in first year mortality rates⁸ since the

⁵ See, e.g., MedPAC, *Report to the Congress*, "Outpatient Dialysis Services" 160 (March 2004) ("These changes [MMA] partly reflect concerns previously raised by MedPAC that Medicare's policies do not appropriately pay for outpatient dialysis services. We have shown that injectable drug spending has significantly increased since the mid-1990s and that the profitability of these services is offsetting the decreasing payment margins under the composite rate. These findings led the Commission to make a series of recommendations to modernize how Medicare pays for outpatient dialysis services. These recommendations included broadening the payment bundle to include widely used services currently excluded from it and adjusting for factors affecting providers' costs, including patient case mix, the frequency of dialysis, the dose of dialysis, and the dialysis method (MedPAC 2001).") (emphasis added).

⁶ December 15, 2011 facility performance score data; November 27, 2012 facility performance score data (available upon request).

⁷ <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Spotlight.html>.

⁸ Kidney Care Partners PEAK results as determined by Brown University (available upon request) calculated based on per person years, as does USRDS.

initiation of PEAK in January 2009.

While these results are impressive, we acknowledge that still more can be done to improve patient outcomes. If a cut of the magnitude proposed were implemented even with a phase-in, however, the strides made would be at serious risk. Facilities would be forced to reduce staff, operational hours, and potentially close some facilities. Patient to staff ratios would increase. Programs designed to coordinate and manage patient care to improve outcomes would be cut back or eliminated. Reduced hours of operation could increase patient drive times for receiving treatments and could result in more missed treatments, which leads to poorer outcomes. In sum, the magnitude of the proposed cut places the quality of care achievements of the past several years at significant risk.

Finally, KCP members are concerned that if a cut of this magnitude is finalized, the promise of improving care coordination of the ESRD Seamless Care Organization (ESCO) demonstration program would not be realized. The cut would simply make it impossible for the vast majority of facilities to participate in such a program.

B. CMS has authority to reduce the magnitude of the overall cut

1. CMS should take into account the two percent decrease in utilization Congress removed from the payment system when it was established and the intent to eliminate the cross-subsidization problem

First, CMS can reduce the magnitude of the cut by ensuring that the calculation made under subsection (b)(14)(I) – the ATRA provision – takes into account the decreased utilization Congress already built into the PPS when it established the payment system.⁹ It is fair to say that the reduction was assumed by most to account for the increased efficiencies that could be gained by a reduction in drug utilization rather than other aspects of care because the chronic underfunding of the composite rate would not allow for efficiencies to be realized.

Second, the calculation should also recognize that a central reason for enacting the single payment amount was to eliminate the historic cross-subsidization of the underfunded composite rate by the payments for separately billed drugs. The GAO recognized this fact when it reported that: “facilities relied on payments for separately billable drugs to subsidize the cost of providing dialysis services covered under the composite rate.”¹⁰ In 2004, it reported that for 2001 Medicare’s payment for the composite rate was 11 percent lower on average than facilities’ average costs, while payment for separately billable drugs was 16 percent higher than facilities’ average costs.¹¹ Although

⁹42 U.S.C. § 1881(b)(14)(A)(ii).

¹⁰GAO, “ESRD: Bundling Medicare’s Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility,” 13 (Nov. 2006).

¹¹*Id.*

the drug add-on sought to address the issue, the disparity was not completely resolved at that time. GAO and others continued to recommend a bundled payment system for all ESRD services.¹²

As the cost report data demonstrates, the margins for facilities did not dramatically increase when the utilization for one component decreased. This evidence suggests that the historic cross-subsidization issue was finally resolved when the single payment rate was put into place. By looking at the cost report data, CMS should adjust the calculation of the proposed payment reduction to take this fact into account and not unbundle the bundle. As described in detail below, CMS has sufficient authority to adjust the proposed payment reduction to take these facts into account.

2. CMS should use its full authority under section 1881(b)(14) to address outstanding issues, which would increase the base rate and address bad debt issues

Under section 1881(b)(14) the Agency has the authority to address a set of long-standing issues that, if resolved appropriately, would increase the base rate and offset the size of the proposed cut. First, CMS should address the ongoing problem that the PPS payment amount does not meet the requirement of paragraph (14)(A)(ii) because the amount actually being paid out is significantly less than the amount Congress intended. Second, CMS also has authority within the general authority to establish the payment amount to adjust it and should use such authority to make sure that the payment amount is appropriate.

a. CMS should resolve the ongoing problems with the co-morbidity case-mix adjusters, standardization factor, outlier policy, and low-volume adjuster

For many years, KCP has expressed concerns that the co-morbidity case-mix, standardization factor, outlier policy, and low-volume adjuster have resulted in an inappropriate loss of funding. Problems with these aspects of the payment system remain unresolved. An analysis of the Standard Analytic File (SAF) shows that CMS paid out approximately \$5.31 less per treatment than projected in 2011. This difference shows that the actual payment rate is less than the statutory requirement to set the rate at 98 percent of what would have otherwise been paid if the ESRD PPS had not been implemented. CMS can use the most recently available claims data, which includes the actual prevalence of claimed adjusters, to recalculate the amount of adjuster dollars included in the standardization.¹³

In addition, any reduction to the base rate to capture the decrease in utilization of drugs would result in artificially and unjustifiably high adjuster values for all adjusters that were originally calculated based on the 2007 value of historically separately paid items. The adjuster values would need to be re-calculated taking the lower utilization base into account. This would require a replication of the regression analysis used to set the original adjusters, based on the most recent

¹²*Id.* at 27.

¹³ See Appendix D for suggested methodology.

value of the historically separately billable dialysis services. While CMS may need additional contractor resources to perform this analysis, it could make a proportional adjustment to the adjuster values on a provisional basis to reduce their value relative to the decreased utilization it is removing from the base rate. Continued use of the existing adjuster values at unjustifiably high values would remove dollars from the base rate because those dollars are built into the standardization factor. An interim proportional reduction in adjuster values would estimate the appropriate size of the adjuster dollars that need to be used to reduce the standardization factor. CMS could then reconcile the adjuster values when it has the resources to complete the analytics.

Correct the Standardization Factor. Because of the lack of data, KCP is limited in its ability to evaluate the appropriate reduction to the standardization factor. Based upon our previous work, however, we continue to believe that the standardization is overstated due to a discrepancy between estimated prevalence of adjusters based on the original research used to calculate the 2011 base rate, and actual prevalence with which facilities claimed adjusters. The overstatement of the standardization factor is attributable to problems with the co-morbidity case-mix adjusters and errors in the identification of low-volume facilities (the latter of which the Government Accountability Office (GAO) acknowledged in its recent report).¹⁴ Should CMS implement the statutory payment reduction, the error in standardization will be increased significantly by the overstated size of all adjusters that were originally calculated based upon historically separately paid dialysis services (including the adjusters for body surface area and first 120 days of dialysis).

In its analysis of the CY 2013 Proposed Rule, The Moran Company calculated that by not adjusting the standardization factor, the base rate was reduced by approximately \$3.12 per treatment (or 1.25 percent). In the final rule, we strongly urge CMS to use 2012 data to recalculate the standardization factor based on prevalence of the use of adjusters and to make an interim reduction to the adjuster values proportional to the size of the cut due to decreased drug utilization and to reduce the dollars in the standardization factor due to the overstatement of the value of all adjusters going forward. This would ensure that there is no inappropriate reduction in the base rate.

Correct or Suspend the Co-morbidity Case-Mix Adjusters. Another ongoing problem that inappropriately lowers the base rate and that is inconsistent with the statutory mandate relates to the co-morbidity case-mix adjusters. As KCP and others have noted during the past several years, dialysis facilities simply do not have access to the documentation necessary to support claims of the co-morbidity case-mix adjusters, despite intensive, ongoing efforts to obtain such documentation. This lack of documentation stems from the fact that:

- Dialysis providers have historically not recorded many of the co-morbid case-mix adjuster diagnoses on claims;
- Nephrologists have not recorded most of these diagnoses on claims for patients in a recent time period of one or two years;

¹⁴ GAO, “CMS Should Improve Design and Strengthen Monitoring of Low-Volume Adjustment” (Mar. 2013).

- Facilities and providers would need access to at least two years of hospital, specialty, and primary care physician claims for their patients;
- Non-nephrologists (and affiliated hospitals) are reluctant to release these data to facilities, citing concerns about the HIPAA Privacy Rule; and
- The significant time lag involved in obtaining these data, if they can be obtained at all, often requires facilities to re-bill their claims.

The documentation requirements demand that facilities have more than a test result or diagnosis. For example, a facility may know that a patient has pneumonia, but does not have a chest X-ray because the treating physician did not require one to make the diagnosis. These impediments to claiming the appropriate adjuster frustrate both dialysis facilities and providers when they submit claims to Medicare.

If CMS does not change the documentation requirements, it should exercise its authority to suspend implementation of the adjusters and return the funds being withheld to the base rate. While the statute requires CMS to implement adjusters generally, it establishes permissive authority for creating adjusters based upon patient co-morbidities.¹⁵ Were the co-morbidity case-mix adjusters to be suspended, then their estimated prevalence should be removed entirely from the standardization factor as well.

Correct the Outlier. Although CMS has evaluated and reset the outlier parameters, this work does not address the ongoing problem that the outlier pool has consistently overstated by a very large amount the actual payments that have been made under the policy. This results in the base rate being inappropriately lower than it should be. The chronic underpayment of the outlier pool suggests that it is not necessary. Last year CMS paid out only 0.2 percent of the pool and only 0.5 percent the year before. While we understand that CMS believed it was obligated under the authorizing statute to implement an outlier pool, it has discretion in subsequent years to determine the appropriate adjusters for the ESRD PPS. Experience demonstrates that the outlier pool serves no purpose at this point. CMS has met its obligation to include such an adjustment by including it in the payment system through CY 2013. However, it would be an absurd result if this provision were interpreted to mean that CMS had to maintain such an adjustment when the data demonstrate it is not necessary. KCP encourages CMS to exercise this authority and substantially reduce the percentage of the outlier pool or eliminate it entirely.

Correct the low-volume adjuster. In addition to the flawed statistical assumptions in calculating the standardization factor, KCP echoes concerns raised by the GAO about the consistent discrepancies in the identification of low-volume facilities. The GAO found that the policy had not been implemented properly.¹⁶ Although limited by lack of data, The Moran Company found a similar pattern.

¹⁵ 42 U.S.C. § 1881(b)(14)(D)(i) (indicating that CMS “may take into account ... comorbidities”).

¹⁶ GAO, *supra* note 13 at 11.

Table 1: Low Volume Adjuster Discrepancies

	Count of Facilities
Low Volume in Impact File Data and Impact File Flag for 2014	239
Low Volume Flag in 2014 but does not meet low volume criteria for last 4 years	136
Meets Low Volume by treatment volume criteria but no flag	341
Not Low Volume by Any Metric	5,055

As Table 1 indicates, The Moran Company has found that more than half of the facilities identified as low volume do not meet low-volume criteria. Additionally, more facilities than are listed appear to meet low-volume criteria but are not being identified as qualifying. On balance, these discrepancies lead to a significant difference between the proposed base rate and what it would be if these problems were resolved. Accordingly, KCP reiterates its call that the Agency address these problems in the final rule.

b. CMS should resolve the technical issues that KCP raised in its comments on the PY 2012 and PY 2013 Proposed Rules to which the Agency has declined to respond.

KCP encourages CMS to address the series of unresolved discrepancies and errors that The Moran Company identified in 2011 with regard to the calculation of payment rates. These errors result in payment reductions of approximately \$1.50 per treatment. Specifically, we request that CMS resolve the following discrepancies identified in previous comment letters.

Using the 2007 Standard Analytic File for 100 percent of Outpatient Hospital Services (SAF) claims with 72x bill types, The Moran Company attempted to replicate the Agency's calculation of the 2011 base rate. It used the 5-percent sample Carrier SAF to simulate paid laboratory tests for ESRD patients in addition to those in the 72x claims. The analysis followed the steps CMS described to generate the 2007 MAP and to inflate that to the unadjusted base rate for 2011, yet resulted in the following discrepancies between the analysis and CMS's published numbers.

- Following the trims described by CMS, The Moran Company identified 331,877 patients, compared to CMS's 328,727 patients, an absolute difference of 3,090 patients or 0.9 percent more patients.¹⁷
- The Moran Company treatment counts are also 200,589 higher than CMS's (0.5 percent). These treatment counts do not include Method II patients (for which there was separate payment at the time). Method II payments are included in the base rate, but we know of no way to count Method II treatments, and neither the proposed nor final rules explained whether or how Method II treatments were counted.

¹⁷ See Appendix B; see also 75 Fed. Reg. at 49068-69.

- The Moran Company's calculations of payments per treatment for components of the 2007 MAP are mostly higher than those reported by CMS.¹⁸
- The Moran Company matched CMS's laboratory payments using the list published with the rule and the carrier claims, but found an additional \$0.44 per treatment in laboratory test payments to facilities in the 72x claims. If these payments are not included in the 2007 MAP and re-priced in 2011 dollars, then the base rate is understated.
- Iron Dextran appears to not have been included in the calculations of the 2007 MAP. Based on the 2007 SAF data, The Moran Company found approximately \$850,000 paid for Iron Dextran in 2007 dollars. If payments for this drug were not included in the 2007 MAP, then the base rate is understated by the 2011 value of these dollars.

Using the inflation values described in Table 12 in the 2011 Final Rule, The Moran Company found:

- For the "other injectable" category in Table 19 in the 2011 Final Rule, it appears that CMS used an inflation factor of 1.905 percent, but Table 12 provides a factor of 1.7 percent. The Moran Company used the 1.905 factor in its replication.
- CMS used a 2007-2009 inflation factor for laboratory tests of 4.47 percent and not 4.5 percent as listed in the 2011 Final Rule. The Moran Company calculated the inflation factor from data in Tables 9 and 19 in the 2011 Final Rule. It is not clear whether the reporting in Table 12 in the 2011 Final Rule rounded numbers and used other values in its calculations or what the correct inflation factors are.
- The Moran Company used CMS values where it could not replicate payments in its SAF data and calculated a MAP of \$245.21 per treatment (using the 1.3 percent increase for composite rate payments) compared to CMS's \$243.65 per treatment, a difference of \$1.56 or 0.6 percent higher than CMS's calculation, using data from 2007 and 2009.

KCP raised these concerns in comment letters in each of the previous two rulemaking cycles. We believe these comments are within the scope of the Proposed Rule, and CMS has never indicated otherwise. We hope the Agency will address these concerns during this critical rulemaking period.

c. CMS should adjust the labor share used to wage adjust payments to reflect changes in the base rate

With the reduction of the base rate by the decreased drug utilization, the labor share used to wage adjust payments will be inaccurate. The labor share calculation was based on 2008 cost reports that were adjusted for estimated spending on separately billable services being added to the bundle. With a decrease in the value of those services, the size of the labor share as a proportion of the

¹⁸ See Appendix B.

bundle would increase, increasing the amount of the payment that is wage adjusted. Cost reports from 2011 and 2012 are now available to re-calculate the labor share based on reduced drug spending. The labor share should be re-calculated for the final rule, and the change in geographically adjusted dollars should be factored into the standardization factor and the budget neutrality of the wage index.

d. CMS should reform the cost report to address the inappropriate restrictions on medical director fees and cost of supporting ESRD Networks

KCP appreciates that CMS has made some changes to the cost reports in recent years, but we continue to be deeply concerned that it has not addressed two long-standing issues, namely, the amount allowed on the cost report for medical director fees and acknowledgement of the 50-cent per treatment statutorily mandated Network fee. Because cost reports provide the foundation for analyses that affect inflationary updates and for ensuring that payment rates are covering costs, not recognizing these amounts undermines the ability of policymakers to evaluate payment rates in terms of the actual cost of providing care. As the pressure on Medicare spending increases, it is critically important that Medicare cost reports reflect the accurate and true cost of providing care to beneficiaries.

One of the core aspects of the cost report that remains deficient relates to the artificial limitation on medical director fees. Put simply, CMS should eliminate this restriction, which is inappropriately based upon the costs associated with internists and does not reflect the true cost of hiring medical directors, who are often nephrologists. The Conditions for Coverage for End-Stage Renal Disease Facilities (CfC)¹⁹ require dialysis facilities to have a medical director who is “a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12-months of experience providing care to patients receiving dialysis.”²⁰ If such a physician is not available, another physician may direct the facility, subject to the approval of the Secretary.²¹ Thus, under CMS’s own regulations, nephrologists are the preferred candidates for serving as dialysis facility medical directors, even if the Agency recognizes they are not always available. Dialysis facilities strive to adhere to this preference and in the vast majority of cases do employ medical directors who are certified nephrologists.

Despite this clear preference, the cost reports establish a strong disincentive for dialysis facilities to seek out and pay for the most qualified medical directors by limiting the allowable costs of medical directors to the reasonable compensation equivalent (RCEs) for internists. This amount is \$165,000 annually or about \$80 per hour. This RCE is not a reasonable proxy for compensation for nephrologists. In addition, the RCE for internists is neither updated to reflect inflation nor geographically adjusted.

¹⁹ 42 C.F.R. pt. 494.

²⁰ *Id.* § 494.140(a)(1).

²¹ *Id.* § 494.140(a)(2).

The limitation suggests the existence of an incentive to overpay medical directors. That is simply not the case. Dialysis facilities engage in arms-length negotiations with nephrologists to establish their compensation levels, consistent with the requirements of the Stark law.²² Given the legal obligations to provide compensation at the fair market value, there is no need for an arbitrary limitation in the cost reports that are designed to approximate cost.

Compensating medical directors is one of the most significant costs facilities incur and one of the most important aspects of the continuum of care that facilities provide to beneficiaries. If the cost report fails to accurately reflect the true cost of hiring medical directors, calculations of payment rates and inflationary updates will artificially underfund the program.

Although KCP has continually raised these concerns in our comments, CMS has yet to address them. Again, we urge the Agency to eliminate the limitation and allow for an exceptions process (similar to that recognized under Part A).

A second core component of facility costs that the cost report ignores is the 50-cent per treatment fee removed from payments to fund the work of the ESRD Networks. Mandated by statute,²³ this fee substantially reduces each payment that facilities receive, yet has not been incorporated into the calculation of margins or payment rates because the cost reports do not capture data on it. Therefore, we urge CMS to add a line-item recognizing this expense in the cost report.

3. CMS should apply the statutory requirement to ensure that the overall payment rate covers the cost of providing care

As the Agency has noted several times when evaluating a proposed or final payment rate, it is appropriate to focus on whether or not the overall rate covers the cost of providing care rather than examining each component of the bundle separately. This evaluation is consistent with section 1881(b)(2)(B), which requires that CMS base the payment amount on “economic and equitable factors,” and section 1862(a)(24), which prohibits the unbundling of items and services. In addition, section 1881(b)(14)(A) provides significant discretion as to how CMS implements the ESRD PPS. Even section 1881(b)(14)(I) (the ATRA provision) indicates that the cut need not be dollar for dollar, but rather only that it “reflect” the change in utilization. Taken together, these provisions of section 1881 provide the Agency with the flexibility to adjust the final payment amount so as to avoid a result that would jeopardize patient access to high quality care.

a. ATRA does not require a dollar for dollar reduction in light of the change in the utilization of certain drugs and biologicals

In ATRA, the Congress required that the Secretary:

²² See generally 69 Fed. Reg. 16092; see also 42 C.F.R. § 411.351.

²³ 42 U.S.C. § 1395rr(b)(7).

compar[e] per patient utilization data from 2007 with such data from 2012 [and] make reductions to the single payment that would otherwise apply under this paragraph for renal dialysis services to reflect the Secretary’s estimate of the change in the utilization of drugs and biologicals...²⁴

It is significant that the Congress used the term “reflect.” In another part of section 1881, subsection (b)(14)(A)(ii), the Congress used “equal” when it meant that the payment amount must reflect a dollar for dollar match.²⁵ Because the Congress did not use the term “equal” when enacting ATRA, CMS has the authority to adjust the reduction consistent with other provisions of section 1881 as a whole. Additionally, the reduction applies to “this paragraph” (which establishes the PPS bundle) and, thus, does not change other provisions of this section, including section 1881(b)(2)(B).

b. Section 1881(b)(14) authorizes the Agency to adjust the payment system over time to ensure appropriate implementation

In evaluating the final payment amount, CMS should also take into account the inherent authority provided in section 1881(b)(14), which requires the Secretary to implement the ESRD PPS. Paragraph (14)(A) provides the specific authority to implement the single payment amount for providing renal dialysis services. Paragraph (14)(D) provides specific authority to establish adjusters, including the authority to establish “other payment adjustments as the Secretary determines appropriate.” It would be an absurd result to conclude that this authority does not allow the Secretary to make adjustments to the payment rate over time because of changes in the costs associated with providing care.²⁶ For example, if the Agency were to determine that the payment amount as calculated was not sufficient in its view to cover the cost of providing care, it could exercise its authority to establish new adjusters or modify the base rate under this authority to resolve the problem. It would not have to wait for Congress to act because it has the authority to implement the PPS. It was only in 2011 that the Agency was bound by a Congressional mandate as to how the payment rate would be calculated.²⁷

²⁴*Id.* at § 1395rr(b)(14)(I).

²⁵ “[W]here Congress includes particular language in one section of a statute but omits it in another . . . , it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.” *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)).

²⁶ *See, e.g., United States v. Granderson*, 511 U.S. 39, 47 n.5 (1994) (dismissing an interpretation said to lead to an absurd result); *Densnup v. Timm*, 502 U.S. 410, 427 (1992) (Justice Scalia, dissenting) (“[i]f possible, we should avoid construing the statute in a way that produces such absurd results”); *Public Citizen v. Department of Justice*, 491 U.S. 440, 454 (1989) (“[w]here the literal reading of a statutory term would compel ‘an odd result,’ . . . we must search for other evidence of congressional intent to lend the term its proper scope”).

²⁷ Subparagraph (b)(14)(A)(ii) requires that for 2011 the payment amount be set at 98 percent of what would otherwise have been paid out if the PPS had not been implemented.

c. Section 1881(b)(2)(B) provides sufficient authority to adjust the final payment amount to reflect economic and equitable factors

The Secretary not only has the authority, but also the obligation, to ensure that the aggregate payment amount for services provided to beneficiaries with kidney failure satisfies the long-standing statutory requirement that payment amounts for dialysis services be determined on a “cost-related basis or other economical and equitable basis.”²⁸ As described in detail below, Congress has not repealed this statutory requirement. If payment rates do not reflect the cost of providing care then they are not economical or equitable. Thus, when the Agency considers the payment rate as determined by its implementation of the ATRA provision, as well as modifications required to address the unresolved issues described above, it should also consider whether or not the payment amount would lead to an average Medicare margin that is negative.

Subsection (b)(2)(B) requires the Secretary to “determine, on a cost-related basis or other economical and equitable basis . . . the amounts of payments to be made for part B services furnished by such providers and facilities to such individuals [Medicare ESRD beneficiaries].”²⁹ This provision is unique to the dialysis payment setting, and complying with it would not establish potentially problematic precedent for other payment systems. This section, as described below, has not been repealed. Subsection (b)(14)(I) does not repeal this section, nor as described above, are the two provisions in conflict with one another. All provisions of a statute that do not conflict irreconcilably must be given effect.³⁰ Repeals by implication are disfavored in the law;³¹ they should not be entertained where the different provisions can be reconciled.³²

While subsection (b)(2)(B) was made a part of the Medicare statute nearly 35 years ago,³³ it remains in effect, even though subsequent amendments have modified the structure of the payment models over the years.³⁴ In 1981, Congress enacted subsection (b)(7), which established the composite rate methodology for determining payment rates for home and in-center dialysis.³⁵ This provision was enacted three years after the enactment of subsection (b)(2) and did not eliminate the requirement that the Agency base payments on the expressly stated factors. Congress inserted an

²⁸ See 42 U.S.C. § 1395rr(b)(2)(B)(2013).

²⁹ *Id.* § 1395rr(b)(2)(B)(ii).

³⁰ *Watt v. Alaska*, 451 U.S. 259, 267-68 (1981).

³¹ *Rodriguez v. United States*, 480 U.S. 522, 524 (1987) (“intent to repeal [must be] clear and manifest.”).

³² When interpreting a statute, the reader must give effect to all provisions of the statute unless the provisions conflict irreconcilably. *Watt*, 451 U.S. at 267-68 (1981).

³³ Pub. L. No. 95-292 § 2, 92 Stat. 307, 309 (June 13, 1978).

³⁴ See, e.g., 42 U.S.C. § 1395rr(b)(7) (establishing the composite rate and separately billed drugs payment structure); see also *id.* § 1395rr(b)(14) (establishing the prospective payment system).

³⁵ Pub. L. No. 97-35 § 2145(a)(7), 95 Stat. 800 (1981) (added par. (7)).

“and” between the (b)(2)(B) requirements and the (b)(7) calculation. This conjunction suggests that the Secretary must take a two-step approach in determining the payment amount for renal dialysis services.

The 1981 amendment removed the payment model language from paragraph (2) and shifted the payment model description to paragraph (7).³⁶ The amendment also added language to specify that the application of the methodology in paragraph (2) must be “consistent with any regulations promulgated under paragraph (7).”³⁷ Thus, the (b)(2) principles must be accorded meaning independent of paragraph (7) and the payment model in order for this statutory construction to retain meaning.³⁸

In 2003, Congress reformed the payment methodology again, replacing the model described in paragraph (7) with a new paragraph (12). Paragraph (12) repeals paragraph (7) explicitly by stating that payments under this model are “in lieu of paragraph (7).”³⁹ The phrase “in lieu of paragraph (7)” require CMS to look at paragraph (12) to calculate the initial payment amount (instead of – or in lieu of – at paragraph (7)). If Congress had wanted to eliminate the requirements of paragraph (2), it would have used a phrase such as “notwithstanding,” but it did not.⁴⁰ Therefore, paragraph (2) remained in effect. Congress knew how to repeal the application of paragraph (2) and chose not to do so.

In 2008, Congress enacted an amendment that subjected paragraph (12) to paragraph (14), which establishes the bundled prospective payment system (PPS).⁴¹ Again, Congress chose to use the phrase “in lieu of any other payment.”⁴² The “in lieu of any other payment” clause of paragraph (14) requires CMS to determine the initial payment amount using the paragraph (14) model, but does not repeal the requirements of paragraph (2). The purpose of the new language in paragraph (14) is to abolish payment for separately billed drugs set forth in paragraphs (11) and (13).⁴³ If Congress had wanted to eliminate the applicability of subsection (b)(2)(B) for purposes of establishing the ESRD PPS single payment amount, it would have used language such as “notwithstanding any other provision in this section,” but it did not.

³⁶ *Id.* Provisions should be interpreted to avoid rendering other provisions of a statute as superfluous or unnecessary. *See Ratzlaf v. United States*, 510 U.S. 135, 141 (1994).

³⁷ Pub. L. No. 97-35 § 2145(a)(7), 95 Stat. 800 (1981) (added par. (7)) (codified at 42 U.S.C. § 1395rr(b)(2)(B)(ii)).

³⁸ *See Watt*, 451 U.S. at 267-68.

³⁹ Pub. L. No. 108-173 § 623(d)(1), 117 Stat. 2312 (2003) (added par. (12)).

⁴⁰ *See, e.g., Central Bank of Denver v. First Interstate Bank*, 511 U.S. 164, 176-77 (1994).

⁴¹ Pub. L. No. 110-275, §153(b)(1), 122 Stat. 2556 (2008) (added par. (14)).

⁴² 42 U.S.C. § 1395rr(b)(14).

⁴³ *See id.* §§ 1395rr(b)(11), (13).

The “and” in subsection (b)(2)(B) suggests that the Secretary must determine the initial payment amount using the appropriate model, which currently is subsection (b)(14), and then evaluate whether or not subsection (b)(2)(B) should trigger additional consideration.

The Secretary has acknowledged the Agency’s authority and obligations under subsection (b)(2)(B) in regulations, as well as through arguments submitted to the courts.⁴⁴ Most interestingly, the Secretary focused on setting rates on an “economic and equitable” basis when setting the initial composite rate.⁴⁵ The Agency described how this provision should be applied as well. The method of establishing payment rates on a “cost-related basis” does not mean that each facility should be paid based upon their own costs, presumably as reported through the cost reports. “If a facility’s costs per treatment were less than its payment rate, it would be allowed to retain the difference; if its costs were greater, it would not be able to recover them, unless it had requested and received a higher payment rate under the exception process.”⁴⁶

While the Secretary has clearly rejected the idea that cost-related principles mandate that rates be determined on an individual facility level, she has remained silent as to how this basis would apply if the payment amount did not cover the cost of providing services as determined by the cost reports in the aggregate, divorcing it from economic and equitable factors.

Given this acknowledgment, CMS must give meaning to both subsection (b)(14)(I) and subsection (b)(2)(B) of the authorizing statute. The plain reading of the provisions together authorize CMS to temper any payment reduction so the final amount remains based either upon the cost of providing services or economic and equitable factors. A payment amount that does not cover the cost of providing care would result in it failing to be cost-related or equitable.

⁴⁴ In *Kidney Center of Hollywood v. Shalala*, 133 F.3d 78, 87 (D.C. Cir. 1998), the Secretary argued that she “based the [ESRD] prospective rate upon reasonable cost principles” and, therefore, chose to cap bad debt at cost to comply with the prohibition on cross-subsidization. While the court rejected this argument, it did so based upon the use of the cross-subsidization principle. It did not invalidate subsection (b)(2)(B) or eliminate the requirement to comply with it.

⁴⁵ 47 Fed. Reg. 6556, 6563 (Feb. 12, 1982)(These new provisions on the methods of establishing prospective rates supplement the basic standard in [section 1395rr], which requires that payments be determined on a ‘cost-related basis or other economic and equitable basis’ Accordingly, a fundamental standard is that the rates must be economic and equitable, as well as promote the increased use of home dialysis. Reading the statute as a whole, we conclude that Congress intended for us to set rates that are economic and that at the same time differentiate between hospital-based facilities and independent facilities based on justifiable differences in costs incurred by each type of facility”).

⁴⁶ *Id.* at 6561. *See also* 48 Fed. Reg. 21,254, 21,257-58 (May 11, 1983) (“When section [1395rr] was enacted in 1978, it authorized the Secretary to determine the costs incurred by facilities and to determine, ‘on a cost-related basis or other economical or equitable basis,’ the amounts of payments to be made to facilities. Under this provision, the cost report filed by a facility could have had substantial significance if the Secretary had chosen to set the amounts of payments on a cost-related basis in which reimbursement depended on the costs of a particular facility, rather than by using the alternative “other economical or equitable basis.” . . . Under this prospective rate system which is authorized under the statute that was enacted in 1981 [subsection (b)(7)], the cost report of an individual facility has little or no bearing on its reimbursement.”)

4. CMS has clear parameters for applying the statute as a whole and ensuring that the final payment amount covers the average cost of providing care to beneficiaries with kidney failure

CMS should undertake a three-step approach to determining the payment rate for CY 2014. First, the Agency should address the long-standing underfunding of the single payment amount, as described in section B.2. of this letter. Second, we agree that it must calculate the payment reduction referenced in subsection (b)(14)(I), as well as the market basket update required by subsection (b)(14)(F), as well as make any other annual adjustments that are required or appropriate. Finally, it should examine the 2011 cost report data and determine if the proposed payment amount would result in a negative average Medicare margin. If this were the case, which as noted in section A of this letter, we believe it is, then CMS should adjust the payment amount to avoid this outcome and protect patient access to care. For example, CMS could evaluate various payment amounts and select the amount that would provide adequate access to appropriate care.⁴⁷ We believe this guideline would allow the Agency to set the payment amount so that the average Medicare margin is zero plus some small amount to account for errors in calculation, two year lag in data, etc. We would propose this adjustment be set conservatively at 2 percent.

Relying upon the average/mean margin is the appropriate benchmark for the Agency's evaluation because many of the costs facilities incur today are not influenced by "efficiencies." For example, providing access in rural communities results in small facility sizes and higher costs that the low volume adjuster has not addressed. Facilities with high dually eligible populations face the significant problem of not being reimbursed for the 20 percent copayment in 24 States. Patient need drives the duration of dialysis and pharmaceuticals, not the size of the facility. There are also regional factors that the geographic wage index does not adequately address. These realities coupled with the facts that the historic underfunding of the program drove facilities to institute efficiencies prior to the implementation of the PPS and that there has been little innovation in this sector because of chronic underfunding suggest that it would be inappropriate to develop and use an "efficient provider" benchmark at this time.

CMS's request for comment on a potential phase-in of the payment reduction required by section 1881(b)(14)(I) signals the Agency's understanding that the proposed cut is simply too large for dialysis facilities to absorb without harming patient access and quality of care. While the kidney care community appreciates the willingness to consider a phase-in, we believe that the Agency must first address the many as-yet unresolved problems within the PPS that have resulted in the payment amount being less than what Congress required it to be by statute.

As the 2011 cost report data show, the current Medicare payment rate is insufficient to cover the cost of care for one-third of all dialysis providers. If CMS were to further reduce payments by \$30 per treatment, then more than three out of every four dialysis facilities would be operating with a negative margin. A cut of this magnitude – or a cut that reduces overall Medicare payments – will have significant and lasting negative consequences for patient access to care, as providers reduce

⁴⁷ This standard is one that MedPAC has adopted when making its recommendations to the Congress. *See, e.g.,* MedPAC, *Executive Summary in REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY*, xi (Mar. 2013).

staff and services, consolidate operations, or even close facilities.

A phase-in cannot and should not be viewed as a substitute for making necessary corrections to the current payment system. Therefore, the Agency's priority should address the following crucial issues simultaneous with any proposed payment reduction. Specifically, CMS should:

- Account for the utilization decrease that was already taken out of the payment rate in 2011 because of the Congressionally mandated cut of 2 percent.
- Account for the intended shift of dollars from separately billed drugs to the previously underfunded composite rate that took place when the bundle was created, which is reflected in the fact that dialysis facility margins for 2011 remain steady, even as utilization for one component of the bundle changed.
- Eliminate the inappropriate and continuing loss of dollars from the base rate by revising the standardization factor, eliminating the outlier policy, removing the co-morbidity case-mix adjusters, and resolving the technical problems listed in Appendix C. Resolving or not resolving these long-standing problems will have a dramatic impact on the base rate and would influence how a phase-in would be structured.

Without knowing how the Agency plans to address these issues, it is impossible to understand the magnitude of the cut and provide meaningful recommendations about how a phase-in should be structured.

Nonetheless, as the cost data presented in this letter demonstrate, the economics of this sector are extremely fragile. Even the smallest of cuts would require a phase-in over multiple years to protect access and quality. However, we underscore the fact that a phase-in does not substitute for addressing the major problem identified in this letter — namely, that dialysis facilities will be unable to adapt to a cut the magnitude of which is proposed, even if that cut is phased-in over time. A phase-in would serve only as a safety mechanism to allow CMS the opportunity to monitor the impact of any payment adjustment and reverse it in coming years to try to limit the negative impact on patients.

Therefore, the KCP strongly urges CMS first to address the problems with the payment amount identified in this letter and revise the payment reduction. Once the amount of the overall payment rate is known, the community stands ready to work with the Agency to determine the appropriate structure of a phase-in. The Agency could achieve this pathway by publishing an interim final rule with comment.

III. KCP supports removing barriers to all modalities of home dialysis

KCP supports efforts to ensure patient choice and informed decision-making as patients seek treatment for kidney disease and kidney failure. One important decision is which dialysis modality they select to use for their treatment. KCP supports efforts to ensure that patients have access to their preferred treatment modality and to remove barriers that might discourage

patients from pursuing certain modalities, including home dialysis. To accomplish this goal, federal policies must be aligned with the following principles.

First, these policies should be consistent with, and respectful of, the patient-physician relationship, as well as the relationship between patients, providers, facilities, and other health care professionals. They must also recognize the role of providers outside the kidney care community, such as primary care physicians and internists; acknowledge that multiple health care professionals influence patients' decisions even before patients develop kidney failure; and encourage early referral to nephrologists. Second, they should provide for and/or support the clinical and educational needs of patients. Third, policies should improve health care professional training programs to include more information about all treatment modalities, including home dialysis and transplantation. Fourth, efforts should be made to align quality and educational initiatives to ensure that there are no inappropriate barriers that reduce or impede access to any treatment option. Fifth, policies should balance the needs of patients with the administrative or clinical requirements placed on providers in a way that is operationally feasible. Sixth, policies should account for variations in individual patient care regimes, promote patient choice, and support patient decision-making. Finally, policies should maintain the integrity of the ESRD bundled payment such that the base payment rate for dialysis is protected and not reduced in an effort to expand coverage for new services or products by shifting existing funding amounts.

The proposal to "holdback" a portion of a facility's home dialysis training payments does not adhere to these principles. Accepting the responsibility to receive home dialysis is a very personal decision for patients and their families. It is also one that depends upon a variety of clinical factors that may change over time. Implementing a policy that imposes a financial penalty when a patient decides no longer to pursue home dialysis but to instead receive treatment in a center would create an inappropriate disincentive for both facilities and patients. Patients who want to receive home dialysis and meet the clinical criteria, as well as the other factors necessary to make home dialysis feasible, should be allowed to seek such care. They should also be permitted to stop such treatments when they or their physicians decide it is no longer right for them. Financial penalties would inappropriately interfere with this decision-making process.

KCP appreciates and supports the efforts to increase the number of patients receiving dialysis at home. As the 2011 CMS Claims Monitoring Data show, the implementation of the ESRD PPS has resulted in an increase of beneficiaries receiving home dialysis. As noted in Section II, a draconian cut to the PPS payment rate would jeopardize this important gain in patient care, along with improvements in other quality indicators. Thus, we also urge the Agency once again not to disrupt the progress made in home dialysis by inappropriately cutting the payment rate for treatments overall. In addition, the Agency should update the home dialysis training adjuster, as KCP has recommended in previous comment letters. The update applied to the base rate should also be applied to the training adjuster so that it keeps pace with the cost of providing care. In terms of payment policy, taking these two steps would be more effective in continuing to expand the use of home dialysis than a holdback policy.

KCP also appreciates that CMS requested comments on the cost of providing home hemodialysis (HDD) services. On behalf of one of the KCP member companies, The Moran Company reviewed 2010 CMS cost reports and found that the average cost of a HHD training

session for all centers providing HHD services was \$438.17 (including treatment and training, exclusive of IV pharmaceuticals), representing \$251.75 in additional costs when compared to an average HD treatment without training at these centers (\$186.42, again, exclusive of IV pharmaceuticals)⁴⁸. This added \$251.75 in cost exceeds the current add-on training payment of \$33.44. The discrepancy between the cost and the payment amount appears to be due to an incorrect assumption that HDD training requires only one hour of nursing time. This is another example of how the payments for the system are underfunded.

As CMS reviews payments for home dialysis training generally, we ask that the Agency establish training rates that are more closely related to the actual cost of providing the service. KCP supports increasing the payment amount for the training add-on, but only if it is done by adding new money to the system. The increase cannot be made in a way that removes funds from the current bundled payment amount.

IV. Conclusion

In sum, KCP strongly urges CMS to protect beneficiary access to high quality dialysis services by ensuring that the payment rate for CY 2014 covers the average cost of providing such care. As the 2011 cost report data show, the proposed CY 2014 payment rate would fall far short of doing so. While the Agency is required to calculate the change in utilization of certain drugs and biologicals taking into account the price of these items, the Agency is not required to make a dollar-for-dollar cut based upon that calculation. In making this calculation, it should take into account changes in utilization that were already built into the payment system and acknowledge the bundled payment sought to end the cross-subsidization of an underfunded composite rate. Additionally, the Agency should exercise its authority and address the historical problems with the calculation of the payment rate before applying any payment reduction. While even the smallest of cuts would require a phase-in over multiple years to protect access and quality, a phase-in should not be viewed as a substitute for providing an adequate payment rate that covers the cost of providing life-sustaining care to beneficiaries. As always, we appreciate the Agency's willingness to work with KCP on these important issues.

Part 2: KCP Comments on the QIP PY 2014 and PY 2015 Proposed Rule

KCP appreciates the opportunity to offer comments on the QIP provisions of the Proposed Rule. At the outset, we wish to reiterate our strong support for linking payment to the quality of care provided. As noted in Part 1, the ESRD PPS has provided facilities with the flexibility to improve patient quality of care, which the QIP and other claims-based data monitoring programs have shown. Even though we continue to urge the Agency to find a way to incentivize quality attainment and improvement rather than solely focusing on penalizing facilities, we are pleased that the Agency continues to work with us to refine the program. We remain committed to improving care for all individuals with kidney disease in a way that will reduce overall Medicare costs.

⁴⁸ The Moran Company, "Analysis of Home Hemodialysis Maintenance and Training Costs Compared to Other Dialysis Modalities in the Medicare Program", August 2013. These findings are consistent with a 2010 Moran Company Study of 2006 cost reports previously provided to the Agency, which found a per HHD training session cost of \$430.29 versus a per session HD cost of 208.82, representing \$221.47 in additional costs.

However, as noted in Part 1, facilities can continue to improve only if the payment rate for their services covers the cost of providing care.

Although KCP continues to support the QIP generally, we remain concerned about certain aspects of the program that remain unresolved, despite our ongoing discussions with the Agency about them. In this regard, we suggest that CMS adopt the following recommendations in the final rule for PY 2016:

- For the QIP overall, CMS should:
 - Establish a consistent minimum set of exclusions that apply to all measures;
 - Refrain from relying upon CROWNWeb until the problems that continue to plague the system are resolved; and
 - Adopt a more transparent approach by providing the data and assumptions used to calculate the rate of improvement and performance benchmarks for all measures at the time of publication of the proposed rule to allow stakeholders the opportunity to assess the impact on facilities.

- For PY 2016, CMS should:
 - Maintain the anemia management hemoglobin >12 d/gL, the adequacy of dialysis, and vascular access measures;
 - Provide clarification on proposed modifications to the specifications for the mineral metabolism and anemia management reporting measures;
 - Adopt additional modifications to the proposed mineral metabolism and anemia management reporting measures, as well as the ICH CAHPS measure;
 - Not adopt the patient informed consent for anemia treatment, the use of iron therapy for pediatric patients, and co-morbidity data measures;
 - Not adopt the hypercalcemia measure as a clinical measure, but rather include it as a structural reporting measure;
 - Not move the NHSN bloodstream infection measure from a structural reporting measure to a clinical measure;
 - Adopt a minimum sample size of 26 patients for reporting and exclude the small numbers adjustment;
 - Revise the weighting of the PY 2016 measures; and
 - Use a different scoring model for measures with highly compressed performance ranges.

- For future rulemakings, CMS should work closely with the kidney care community to develop a comprehensive strategic plan for measure development, adoption, and retirement/removal.

We also call on CMS to provide the underlying data necessary to evaluate the Proposed Rule. We understand that Healthcare Management Solutions (HMS) has submitted to CMS its report on the validity and reliability of CROWNWeb data. While we requested that such data be publicly released before the QIP was finalized, it has not been. The validity and reliability of the data source is central to the ability to fairly judge performance on individual measures, as well as the structure

and scoring. Without such providing such data, the Agency has not met its obligations under the Administrative Procedures Act.

I. CMS should address three overarching issues to bring consistency and transparency to the QIP

As we have stated in previous comment letters, KCP strongly encourages the Agency to address three overarching issues that would significantly improve the QIP. First, the Agency should develop and apply a consistent minimum set of exclusions for all measures. Second, it should address ongoing problems with CROWNWeb and not rely upon that data until the problems are resolved. Third, it should improve transparency and allow for the opportunity for meaningful comment by providing the data and assumptions used to calculate the rate of improvement and performance benchmarks for all measures, as well as other aspects of calculating the total performance score. This should occur at the time of publication of any proposed rule to allow stakeholders the opportunity to assess the impact on facilities.

A. The Agency should establish a consistent set of minimum exclusions that apply to all measures

As we have noted historically, the issue of including or excluding patients from a particular measure is a critical one. While KCP's direct experience as measure developers teaches us that many of these decisions should be made on an individual measure level, it is also true that there should be a global set of exclusions that would apply consistently to all measures related to the treatment of ESRD patients. Thus, we again urge CMS to adopt a set of minimum global exclusions that would be automatically applied to all measures, unless there is a specific clinical or operational reason they should not be. There may be instances when some measures may require additional exclusions, such as those related to the number of days a patient has been receiving treatment (either as a new patient or when returning to dialysis after transplant). KCP believes such a tailored approach is necessary when clinically appropriate.

To this end, KCP recommends that CMS adopt the following global exclusions and apply them to all (meaning both clinical and reporting) measures in PY 2016:

- Beneficiaries who are regularly treated by the facility and who fit into any of these categories:
 - Beneficiaries who die within the applicable month;
 - Beneficiaries who receive fewer than 7 treatments in a month;⁴⁹
 - Beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented good faith effort to have them participate in such a visit during the applicable month;
- Transient dialysis patients;⁵⁰

⁴⁹See CMS, Transmittal 2311, "Implementation of the MIPPA 153c End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and Other Requirements for ESRD Claims" 50.9 (Sept. 23, 2011).

- Pediatric patients (unless the measure is specific to pediatric patients); and
- Kidney transplant recipients with a functioning graft.

These recommended exclusions seek to target the measures to those beneficiaries who regularly receive care from a facility. They are consistent with exclusions included in CMS's own measures that the National Quality Forum (NQF) endorsed in 2007, CROWNWeb, and the urea reduction ratio (URR) reporting specifications.⁵¹

We also reiterate our concerns about the minimum number of treatments a beneficiary must receive to be included in the measure. CMS has recognized previously that there are instances during which a facility may not be able to draw a beneficiary's blood because the beneficiary is not present for other treatments during the month.⁵² As health professionals know, consistent interaction is required to monitor patient conditions, modify treatment protocols, and evaluate the impact of such changes. Just as CMS recognized that transient patients—i.e., beneficiaries who receive fewer than 7 treatments in a month—should be excluded from the reporting measures, so should this exclusion be applied to clinical measures.

Another concern is that beneficiaries who receive only two treatments in a particular month will likely miss the scheduled blood draw. This is particularly a concern for the Kt/V measure. In some instances, a facility might be able to make it up, but if the draw is scheduled for the middle or end of the month and the patient comes to the facility only during the first week, the facility will not have the opportunity to reschedule the draw and will be inappropriately penalized under the QIP. This is particularly true if the laboratory results were recently drawn from the prior month and no clinical indication existed for repeating the blood sample. Furthermore, absence from the facility resulting from hospitalization is not easily predictable within the first two treatments of each month when an expectation exists that the patient would have their blood sampled later during the month. As we have noted in the past, it is neither possible nor appropriate to assume that facilities can or should obtain such data from hospitals or other providers. Our experience with trying to obtain documentation required to claim the co-morbidity case mix adjusters has demonstrated that other providers do not share such data readily and there is as of yet no seamless electronic medical record that would promote such coordination.

Another exclusion that we urge the Agency to apply to all measures is one for transient patients. NQF-endorsed measures expressly exclude transient patients,⁵³ as have other CMS

⁵⁰See, e.g., NQF #0261 Measurement of Serum Calcium Concentration (denominator exclusions include transient dialysis patients, pediatric patients, and kidney transplant recipients with a functioning graft).

⁵¹See *id.*

⁵²See 77 Fed. Reg. 40952, 40968 (July 11, 2012).

⁵³See NQF #0261 Measurement of Serum Calcium Concentration & NQF # 0255 Measurement of Serum Phosphorous Concentration.

measures, such as the urea reduction ratio (URR).⁵⁴ The claims form also distinguishes reporting URR values for patients who receive dialysis six days or less in a facility in a month.⁵⁵

We offer an additional exclusion to address the concern that home dialysis patients, who are often independent, may not always believe they need to visit an in-center facility each month to be monitored. While we agree that dialysis facilities should do everything in their power to encourage these patients to actively participate in such visits, the reality is that some patients may not always believe such a visit is medically necessary. Furthermore, the patients treated at home historically present with better outcomes, and there is little evidence to indicate that their prognosis will further improve if they make sure to come in for a medical visit during the month as opposed to a few days after the calendar month has ended. In these instances, we suggest a balanced approach that would allow facilities to exclude home dialysis patients who miss a visit but only when the facility has made a good faith effort to have the patient come into the facility and has documented it. There is precedent in both federal privacy and fraud and abuse law for using a documented good faith effort to acknowledge that providers may not always be able to control the behavior of others.⁵⁶ Thus, we believe this compromise would address CMS's desire to make sure that facilities work with home dialysis patients to receive medically necessary monitoring, while not penalizing the facilities if a patient refuses to come in.

In addition, we encourage the adoption of an exclusion for kidney transplant recipients with a functioning graft, which the NQF-endorsed measures also contained.

Establishing appropriate exclusions is consistent with the measure harmonization promoted by NQF through its voluntary consensus-based process. It is also the right approach to incentivize high quality care while addressing the problem of accounting for patients who may receive treatment at a facility, but who are not consistently present to allow facilities to provide the level of care anticipated by the measures. Therefore, we strongly recommend that CMS adopt these global exclusions for all measures to ensure that these beneficiaries are not included in the denominator.

B. The Agency should avoid relying upon CROWNWeb data as a source for the QIP until the problems with CROWNWeb are fully resolved

KCP remains concerned that CROWNWeb will not provide an adequate reporting system for the measures. It is also inappropriate to rely upon CROWNWeb data to establish performance benchmarks for attainment and improvement, in particular when the results from the reliability and

⁵⁴See Quality Measure Specifications for PY 2013 and PY 2014 ESRD QIP Final Rule, 76 Fed. Reg. 70228 (Nov. 10, 2011).

⁵⁵See CMS, Transmittal 2311, "Implementation of the MIPPA 153c End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and Other Requirements for ESRD Claims" §50.9 (Sept. 23, 2011).

⁵⁶For example, the HIPAA Privacy Rule requires that covered entities obtain an acknowledgment of receipt of the Notice of Privacy Protection from their patients/enrollees, but accepts a documented good faith effort if a patient/enrollee does not sign the acknowledgment form. See 45 C.F.R. § 164.520. Federal fraud and abuse laws similarly allow some providers to use a good faith effort to obtain a physician certification statement (PCS) in some instances. See 42 C.F.R. § 410.40.

validity study that CMS has contracted for through HMS has not been completed and made publicly available. These inconsistencies make it inappropriate to rely on the CROWNWeb data to establish performance standards. Even though our members continue to work closely with CMS to try to address the problems with the system, these problems have not yet been resolved. Because of these problems, the data collected through CROWNWeb must be demonstrated as reliable and valid through public release of the HMS study.

There are three specific CROWNWeb problems that lead to the overall concerns expressed by KCP historically. First, since CROWNWeb was launched, there have been a myriad of change requests that modify how data are submitted. The almost constant changing of these business rules means that there has not been a consistent set of rules under which data are collected, making the data collected unreliable for setting performance standards and benchmarks. Second, the CROWNWeb team reports that they have approximately 90 percent of facility data – not 100 percent. Not having all of the data when measure performance standards are set at 93 percent or higher means that if the CROWNWeb system “kicks out” a particular patient and/or data for a particular patient, the facility could be found not to meet the QIP standard not because of a clinical performance issue but because of a problem with CROWNWeb. Furthermore, it opens the possibility of “gaming the system” by manually and preferentially excluding the data for patients who fail to meet a particular goal, while keeping within the range of “missing data” for dialysis facilities – particularly for measures that have a narrow performance gap where a few patients or patient-months can determine whether a facility has a perfect score or no points. Finally, there is still a problem with accurate reconciliation with dialysis census data and the patient counts in CROWNWeb. If the attribution of patients to a facility is wrong, again a facility may be penalized under the QIP because of a process, rather than a quality, problem. These problems demonstrate that CMS should not rely upon CROWNWeb for setting performance standards and benchmarks or to collect individual patient-level data to evaluate facility performance in the QIP. These problems do not affect the use of CROWNWeb for collecting facility level attestations.

Thus, KCP urges the Agency not to rely upon CROWNWeb until the data collected are demonstrated, through release of the HMS report, as reliable and valid for patient-level measures in the QIP. We urge the Agency to undertake the following steps that would address the primary concerns raised by the community:

- 1) Reconcile the patient attribution so that facility and CROWNWeb lists are identical;
- 2) Ensure that less than 1 percent of the data are “kicked out” before using the CROWNWeb data for the QIP; and
- 3) Establish clear business rules that will remain in place for at least 1 year to allow for the consistent collection data before the data are used for the QIP.

C. The Agency should provide the data and assumptions used to calculate the rate of improvement and performance benchmarks for all measures to allow stakeholders to have the opportunity to assess the impact on facilities

As we have discussed previously with the CMS staff overseeing the QIP, the proposed and final rules for the QIP have not provided sufficient data and explanation to allow the kidney care community to understand the methodology underlying the models used to estimate QIP payment

adjustments and the calculation of the total performance score. Our consultants have not been able to replicate the results set forth in the rules because key data elements are missing or there are gaps in the explanation of the methodology that require making assumptions to get to the results set forth in the rules. Therefore, our ability to offer meaningful comment on the Proposed Rule is limited. Simply put, there is a lack of publicly available data and a series of gaps in the explanation of the methodology.

In order to provide meaningful comments under the Administrative Procedure Act requirements, the community needs to have the data and know the assumptions CMS uses in its modeling. Thus, we again ask that CMS make public the data upon which it relies to develop the performance standards (both the performance benchmarks and rate of improvement) and estimate the distribution of penalties. We also urge CMS to release at least the range of, if not the actual, standard error values used in the small sample size adjustment calculations. Not having this information makes it impossible to evaluate the performance standards and benchmarks, as well as the impact of individual measures on facilities with small numbers of patients. CMS should make available the CROWNWeb data set that the contractor relies upon for measure development, which would be consistent with how the Agency historically provided Dialysis Facility Compare data and other provider claims files.

II. KCP supports the continued use of the anemia management hemoglobin >12 d/gL, the adequacy of dialysis, and vascular access measures for PY 2016

KCP supports CMS's proposal to maintain three current QIP measures for PY 2016; however, as described below in the section addressing the weighting of measures we continue to urge the Agency to place more weight on the catheter reduction metric because of its significant impact on patient morbidity and mortality.

KCP continues to support inclusion of the hemoglobin greater than 12 g/dL measure in the QIP.⁵⁷ In light of FDA guidance this measure remains important to patient care.

We continue to support the use of Kt/V as the measure for adequacy of dialysis for both adult and pediatric patients. As we have previously commented, the clinical literature demonstrates that Kt/V is the outcome metric upon which practitioners primarily rely when making treatment decisions related to adequacy.

KCP also strongly supports the inclusion of vascular access measures.⁵⁸ Reducing catheters in favor of a permanent access (ideally, an AV fistula, but in some instances a clinically appropriate graft) is arguably the most important factor in improving patient outcomes. Yet, we remain concerned that the Agency has not addressed previous comments regarding the negative clinical impact created by having fistula and catheter measures without a graft measure. By not including a graft measure, the vascular access type composite measure creates a disincentive for using this clinically appropriate access even when it is in the best interest of a patient. We have previously, and

⁵⁷See 78 Fed. Reg. at 40857.

⁵⁸See *id.*

repeat again this letter, encouraged the Agency to adjust the weighting of the catheter measure as an interim way to address the concern. Thus, KCP encourages the Agency to work with the kidney care community to develop a graft measure over the long-term and in the meantime adjust the weighting within the vascular access type composite measure to more heavily weight the catheter minimization measure (two-thirds compared to one-third for the maximizing of AV fistulas).

III. Even though the preamble does not provide sufficient clarification to comment fully, KCP urges CMS to clarify the specifications to allow for full comment

We appreciate the Agency's clarification as to one of our questions regarding the proposed modifications, but two of our questions remain unanswered. Thus, we reiterate them in this letter and urge the Agency to provide additional time to comment on these measures after such clarifications have been provided by issuing an interim final rule with comment. Specifically, KCP seeks clarification on the following technical issues related to the measures proposed to PY 2016:

- 1. Exclusion Discrepancy in the Reporting Measures.** The anemia management reporting measure excludes patients not on chronic dialysis as defined by a completed 2728 form or a SIMS/CROWNWeb record. However, while all other exclusions are consistent between the two measures, the mineral metabolism reporting measure does not exclude patients not on chronic dialysis. We can discern no clinical reason as to why this exclusion would not be present in the mineral metabolism measure. Is this an oversight?
- 2. Small Numbers for Reporting Measures.** We note that for the anemia management reporting and mineral metabolism reporting measures, language within the Proposed Rule states: "if a facility only has 1 qualifying case during the entire performance period, a facility will have to attest to that fact in CROWNWeb by January 31 of the year following the performance period in order to avoid being scored on the measure." However, the technical specifications for these measures note that facilities treating:

"fewer than 1 patient during the performance period who are (i) in-center Medicare patients who have been treated at least 7 times by the facility during the reporting month; or (ii) home dialysis Medicare patients for whom the facility submits a claim during the reporting month" are excluded.

We request that CMS clarify this discrepancy. Under a reasonable interpretation of the technical specifications, a facility with only 1 qualifying case would be required to report and would be scored on the measure. Conversely, the Proposed Rule indicates that such facilities would be required to attest to having only one patient, but would not be scored on the measure. We further note that the same language is applied within the Proposed Rule to the pediatric iron therapy reporting measure, but no corresponding exclusion is contained in the technical specifications for this measure.

IV. KCP recommends important modifications to the proposed mineral metabolism reporting, anemia management reporting, and ICH CAHPS measures before they are added to the PY 2016 QIP

KCP continues to support the use of a mineral metabolism reporting measure, as well as the anemia management reporting measure. However, important modifications need to be made before CMS publishes them as final. Additionally, the community continues to have serious concerns about the ICH CAHPS measure and urges the Agency to modify it.

A. KCP urges CMS to make several clarifications to the proposed mineral metabolism and anemia management reporting measures before incorporating them into the PY 2016 QIP

Generally speaking, KCP supports both the mineral metabolism and anemia management reporting measures. We agree that it is important to continue monitoring Medicare ESRD patients' mineral metabolism and hemoglobin levels. We are pleased that the measures now include home PD patients. However, there are several issues that the Agency should resolve before incorporating these measures into the PY 2016 QIP.

First, CMS should standardize the exclusions for both reporting measures. In addition to the global exclusions described in section I.A. of this letter, the Agency should also exclude patients not on chronic dialysis as defined by a completed 2728 form or a SIMS/CROWNWeb record from the mineral metabolism reporting measure. While all other exclusions are consistent between the anemia management reporting and mineral metabolism reporting measures, only the anemia management reporting measure has this exclusion. We ask that the exclusions for reporting measures be standardized.

Second, KCP has significant concerns about the reporting thresholds and small numbers that we describe in section VI of this letter. These concerns are exacerbated with the reporting measures, which now apply to $n=2$ to 10 patients (with room for only one missing value), whereas previously the threshold was that used across the QIP was <11 . Despite the significant concerns we have expressed about the <11 threshold in the past and new evidence that we present in this comment letter on how it can unfairly penalize facilities that may legitimately miss a few patients' values, CMS has unreasonably lowered the threshold for PY 2016. We urge CMS to address the small numbers problem as described below and apply a consistent minimum number of cases (26) to all QIP measures, including these reporting measures.

Third, as we have just noted, there appears to be a conflict between the Proposed Rule and the specifications for both the mineral metabolism and anemia management reporting measures. The Proposed Rule states that a facility with 1 patient must still report an attestation, but need not report monthly. The exclusion specifications that have been posted refer to fewer than 1 patients—*i.e.*, the specifications in effect say reporting must occur unless you have 0 patients. We recommend the posted specifications provide more clarity about the requirements.

Finally, regarding the specifications for both these reporting measures, we note the measure specifications refer to SIMS records as a source of data. Our understanding is that SIMS has been

decommissioned and is no longer in use. If so, the specifications should be changed to reflect this. If not, we would appreciate understanding how these records are still used.

Additionally, KCP recommends that the mineral metabolism reporting measure specifications be modified to indicate that plasma is an acceptable substrate in addition to serum. At least one renal laboratory has been using plasma testing since 2006 and others are considering it because it is more patient-centered. It is more stable and requires less manipulation should additional testing be required. Serum and plasma testing have been validated for most clinical chemistry analyzers, with both deemed acceptable and equivalent by analyzer manufacturers. Unpublished data from Spectra Laboratories provided to a KCP member found there was virtually no difference between phosphorus measured in serum vs. plasma: a difference of 0.01 mg/dL; phosphorus values are reported to the nearest 0.1 mg/dL. And although some reported differences in serum phosphorus vs. plasma measurement occur, i) such differences are within the College of American Pathologists total allowable error; and ii) such differences could not be replicated by two large experiments conducted by Spectra Laboratories.

In sum, we urge CMS to clarify the points described above and make these corrections to the modified measures before incorporating them into the PY 2016 QIP.

B. KCP urges CMS to modify the ICH CAHPS measure before incorporating it into the PY 2016 QIP

KCP recognizes the importance of evaluating patients' experiences when receiving dialysis. However, we continue to be concerned about the burden of ICH CAHPS on patients and providers. We also have several concerns about the new administrative specifications that depart from AHRQ's tested approach.

First, CMS requires that patients answer 29 of the CAHPS Survey's 58 core items to be considered complete. As previously noted, we maintain that patients will find it difficult to complete such a lengthy survey. Many KCP members have developed their own patient satisfaction tools and understand the difficulty patients have in completing them. Often patients require assistance from caregivers or family members to complete these forms. While monitoring patients' experiences is important, it should not be done in a way that burdens patients and is likely to result in incomplete surveys that benefit no one. To address this issue of "survey fatigue," we again propose that CMS allow the vendor to divide the survey into AHRQ's three independently verified domains when administering it. Under this option, one-third of a facility's patient population would receive one of the three domains plus the core demographic questions. In this manner, a facility would be assessed for all three domains to provide a complete picture of patient experience, but the burden on patients of a lengthy survey would be significantly reduced, thereby resulting in higher completion rates and a valid assessment of performance on this measure.

Second, CMS further proposes that the ICH CAHPS survey be administered twice yearly. In addition to creating significant and additional risk for survey fatigue with patients, the cost associated with fielding the survey twice is not trivial. We note that this proposal comes at a time when CMS is also proposing an unsustainable reduction in reimbursement rates to dialysis facilities. To implement what is, in effect, a pricey and unfunded mandate on a twice-yearly basis at a time of

reimbursement cuts is neither a prudent nor logical action and is not a sustainable proposition for dialysis facilities. KCP strongly urges CMS to reduce the fielding requirement to once yearly, as in PY 2015, utilizing the single-domain administration approach discussed above. Doing so would allow for more meaningful and reliable information to be collected from patients who are not overwhelmed with frequent and lengthy surveys. This approach would strike the appropriate balance between gathering important information and not overwhelming patients and caregivers. KCP also notes that an annual survey would permit facilities to develop a more thoughtful approach to improve patient experience with care in light of the American Institutes for Research/RAND et al. study's conclusions about the difficulties in translating the results from ICH CAHPS into interventions resulting in meaningful improvement.⁵⁹

Third, CMS's proposed revised administrative specifications for ICH CAHPS include homeless persons as eligible for surveying. This population is excluded from the AHRQ administrative specifications. There are intrinsic hardships that homeless persons may face in accessing the survey and that facilities and vendors may face in fielding it to this patient population. A facility should not be penalized for an incomplete survey given these substantial challenges. We recommend that, consistent with the AHRQ administrative specifications, individuals who are homeless should be removed from the list of eligible patients.

Fourth, because CMS will identify the patients who will complete the survey and a third-party vendor will administer the survey, there is no apparent mechanism for facilities to ensure that patients' contact information is as accurate and up-to-date as possible. As response rates necessarily depend on accurate contact information, we object to CMS's proposal that facilities be held accountable for low response rates from such populations for which CMS's contact information may be inaccurate and/or out of date. There will undoubtedly be instances where the contact information is out of date due to the time lag in drawing the sample, providing the information to vendors, and administering the survey. We believe it is important for the CMS administrative specifications to provide an opportunity for facilities to ensure that the primary survey and/or any follow-up is delivered to the most current contact (phone or mail) given the penalty that applies for non-responsiveness.

Fifth, regarding the specification related to "sharing survey responses," the CMS specifications state "survey responses will not be shared with individual facilities, even if the respondent were to provide permission to do so." KCP assumes that aggregate responses will be shared with facilities, but believes the administrative specifications are ambiguous and subject to misinterpretation. The specifications for this topic should clearly state that aggregate responses will be provided, but individual survey responses will not be.

Finally, KCP is concerned that the CAHPS survey is designed to monitor the experience of patients who receive dialysis in-center and does not account for experience of care for patients on

⁵⁹ American Institutes for Research, RAND, Harvard Medical School, Westat, Network 15. *Using the CAHPS® In-center Hemodialysis Survey to Improve Quality: Lessons Learned from a Demonstration Project*. Rockville, MD: Agency for Healthcare Research and Quality. December 2006.

other modalities. CMS should assess the experience of all patients, not just those whose treatments are in-center.

In sum, KCP strongly urges CMS to address these concerns before incorporating the measure into the PY 2016 QIP.

V. KCP has serious concerns about the proposed new measures for PY 2016 and the areas highlighted for future measure development and inclusion in the QIP

In sum, KCP opposes the adoption of the patient informed consent for anemia treatment measure. We support the adoption of the hypercalcemia measure, but only as a structural reporting measure and not as a clinical measure. Similarly, we support the NHSN bloodstream infection measure as a structural reporting measure, but not as a clinical measure. We also oppose the proposals to adopt the iron therapy measure for pediatric patients because of feasibility issues and the use of the QIP to collect data on patient co-morbidities. Finally, we remain deeply concerned about the process CMS is using to consider future areas for measure development.

A. KCP opposes including the patient informed consent for anemia treatment in the PY 2016 QIP

KCP strongly objects to the proposal to include the patient informed consent for anemia treatment in the QIP, as we described in May during the ESRD Technical Expert Panel (TEP) process. This measure is not appropriate as a facility-level measure. The risk-benefit discussion should occur between the physician and the patient. The Food and Drug Administration already has in place a Risk Evaluation and Mitigation Strategies (REMS) requirement that mandates that the physician and patient discuss the use of erythropoietin stimulating agents (ESAs). Moreover, informed consent is a very specific term-of-art with legal implications that vary by state. An “informed consent” process by facilities would not be consistent with the current REMS process and could lead to significant confusion among patients. We also question the advisability of singling out this one issue among the many topics for which informed consent could be required. Finally, it is KCP’s understanding that this measure was not discussed nor proposed at the in-person TEP meeting. As we discuss later in this letter, we have grave concerns about the measure development process; this particular measure is a prime illustration of why it is problematic.

B. KCP opposes the proposal to include the hypercalcemia measure as a clinical measure, but supports its inclusion as a structural measure

KCP continues to support the mineral metabolism structural reporting measure, as noted already in this letter. We also support the inclusion of a clinical mineral metabolism metric, when appropriate. While we understand that the only available clinical mineral metabolism measure that has been endorsed by the NQF is #1454: *Proportion of patients with hypercalcemia*, KCP remains concerned that this metric is not the best measure in this domain to impact patient outcomes, in the absence of clinical metrics for other related mineral disturbances, such as phosphorous and PTH,⁶⁰

⁶⁰KCP has supported both a phosphorous and PTH measure for endorsement by the NQF.

to encourage proper bone mineral metabolism management in a meaningful way. Instead of moving forward with a single suboptimal measure, CMS should commit to working with the kidney care community to develop clinically meaningful measures for this area.

We are also concerned that CMS has not collected a full year of data that would support the performance standards, achievement thresholds, and benchmarks for the hypercalcemia measure. Consistent with our previous comments, we believe it is important for CMS to have a systematic approach for adopting measures. Having at least one year of reporting data is a core criterion for moving structural reporting measures to clinical measures, as we have noted previously. CMS has only seven months of data for the proposed hypercalcemia measure, collected under a setting of multiple change requests for CROWNWeb, which is not sufficient for baseline data.

Given these serious concerns, we urge CMS to adopt the hypercalcemia measure as a structural reporting measure for PY 2016, rather than as a clinical measure. This approach would allow the Agency to collect a full year's worth of data to develop valid performance standards, achievement and improvement thresholds, and benchmarks. As noted in section IV.A., we also further note that plasma should be an acceptable substrate in addition to serum. Additionally, CMS should make every effort to work with the kidney care community to develop a more robust measure(s) that could replace hypercalcemia in the near future.

C. KCP opposes inclusion of the iron therapy measure for pediatric patients because it fails to meet one of the basic criteria for measure adoption

KCP recognizes the importance of iron therapy for pediatric patients, but believes the measure specifications should be limited to IV iron. Facilities do not routinely track oral over-the-counter iron medication, thereby making attestation to this measure as currently specified not feasible. One of the basic requirements for a measure is that those reporting can operationalize it. Because there is no way to operationalize this measure, it should not be included in the QIP.

D. KCP opposes the proposal to move the NHSN bloodstream infection measure from a reporting to a clinical measure at this time

KCP recognizes the vital importance of reducing infections and strongly supports efforts to do so. However, we strongly oppose moving the NHSN measure from reporting to clinical status. CMS notes that it lacks the data to establish a baseline to set a standard and to provide an improvement score and so arbitrarily proposes a 50th percentile approach. It further proposes to require facilities to report 12 months of infection data; failure to do so results in 0 points for the measure. To recommend that facilities achieve or improve quality with such an opaque and all-or-nothing environment is ill-advised.

As we have noted in previous comment letters and reiterate now, KCP believes it is imperative that CMS adopt a systematic method for onboarding new measures into the QIP and for moving measures from structural reporting measures to clinical measures, except in evidentiary exigency or legislative mandate. We believe the current ad hoc approach is suboptimal. A more systematic approach would provide a much-needed regularity to the QIP and permit all parties to efficiently and strategically approach quality improvement and accountability.

E. KCP opposes the proposal to include a co-morbidity data collection requirement in the QIP

KCP applauds CMS for recognizing that before it can adopt standardized mortality ratio (SMR) and standardized hospitalization ratio (SHR) measures, it must risk adjust them to account for dialysis patient characteristics. However, we strongly oppose using the QIP as a mechanism for undertaking a data collection effort as outlined in the Proposed Rule. It is inconsistent with the statutory mandate and would establish an inappropriate precedent that anytime the Agency sought data it could impose an unfunded mandate on facilities to provide data under the guise of value-based purchasing programs.

First, the proposed co-morbidity “measure” is not a quality measure, which is one reason such a metric has never been developed nor endorsed by a consensus-based organization. The NQF defines a measure as “A standard: a basis for comparison; a reference point against which other things can be evaluated; “they set the measure for all subsequent work... v. To bring into comparison against a standard.”⁶¹ It further states that “[p]erformance measures give us a way to assess healthcare against recognized standards.”⁶² In addition, the NQF has established a clear set of criteria that it applies when evaluating measures. Four of the fundamental components are:

- Having a high impact on an aspect of dialysis care, address a demonstrated performance gap and present an opportunity for improvement in dialysis care, and be grounded in evidence supporting the relationship of the outcome to a process or structure of care **(Impact, Opportunity and Evidence)**;
- Containing data elements that produce the same results a high proportion of the time when assessed in the same population in the same time period; having specifications that are consistent with the evidence to support the focus of the measure; having been the subject of testing validating that the data elements and measure scoring are correct; containing necessary exclusions supported by clinical evidence or sufficient observation; for outcomes-based measures, including a specified evidence-based risk-adjustment strategy; demonstrating that methods for scoring and analysis are statistically significant; and allowing for identification of disparities if identified through stratification of results **(Reliability and Validity)**;
- Demonstrating that the intended audience (beneficiaries, purchasers, providers, and policymakers) can understand the results and find them useful for decision-making **(Usability)**;
- Having data that are readily available or could be captured without undue burden **(Feasibility)**; and

⁶¹NQF, “ABCs of Measurement” available at http://www.qualityforum.org/Measuring_Performance/ABCs_of_Measurement.aspx.

⁶²*Id.*

- Being harmonized with related measures or justifying the differences in the specifications **(Comparison to Related or Competing Measures)**.⁶³

The proposed co-morbidity measure does not meet the definition of a measure because it is not establishing a true standard. Instead, it is subjecting facilities to a penalty if they do not supply the required data elements. Second, it does not meet the criteria for measure adoption/endorsement. It is not grounded in evidence supporting the relationship of the outcome to a process or structure of care. It has not been subject to testing or evaluation to ensure reliability or validity. It will not inform decision making by caregivers or policy-makers in and of itself. The burden of providing these data points is substantial on facilities because they rarely have complete information on patient co-morbidities, as the experience with the PPS co-morbidity case-mix adjusters has demonstrated since 2011. It is also unnecessarily burdensome because CMS already has the most up-to-date co-morbidity patient-level data available in its own Common Working File.

The Social Security Act authorizes CMS to establish measures against which to judge facility performance; it does not authorize data collection.⁶⁴ Because the proposed co-morbidity “measure” is not actually a measure, KCP opposes its adoption within the QIP.

Even so, we agree with the Agency that the data it seeks are important to allow for the development or refinement of actual measures that would be meaningful. In that regard, we first encourage the Agency to use its own data to develop the necessary risk adjusters and allow those in the kidney care community to have access to a public version of such information so that the Agency and community in concert can help refine the SMR and SHR measures. If the Agency insists on collecting the data from facilities, it should compensate them for providing such data and seek it through a mechanism other than the QIP.

F. KCP reiterates our strong recommendation that CMS work with the kidney care community to develop future measures and a strategic vision for the QIP

As we have noted in previous comment letters, the Agency should develop a more transparent and inclusive approach to measure development that relies not upon an outside contractor to drive the decisions, but rather builds meaningful consensus among stakeholders of all types to establish a strategic vision for the future of the ESRD QIP. It will not be a surprise that KCP remains extremely concerned about the current process for selecting domains and developing measures. In addition to discussing the proposed domains outlined in the comment letter, we reiterate our concerns with the current process. Specifically, we urge CMS to suspend its current track, solicit comments from the community as to how the process should be structured, and work closely with all members of the community to implement an improved, consensus-based process.

⁶³For a complete description of the NQF measure evaluation criteria, *see* http://www.qualityforum.org/docs/measures_evaluation_criteria.aspx.

⁶⁴ 42 U.S.C. § 1395rr(h).

1. The current process is neither transparent nor consensus based and should be stopped until it can be restructured

Our experiences with the TEPs in May and most recently in August re-affirm our view that the process is being driven in a manner that disregards not only the views of the broader community, but also of the TEP members themselves. For example, in May of last year, the KCP and many other organizations raised serious concerns about the patient informed consent measure for anemia management. Even so, CMS proposes it again in this rulemaking without acknowledging those comments or trying to address the concerns. There is no question that the process is irrevocably broken and must be replaced with a meaningful, transparent, and consensus-based process.

The problems with the TEPs are numerous, so we only highlight our previous comments in this letter. First, concerns remain as to the constitution of the individual TEPs. Many members of KCP continue to express concerns that the day-to-day operations of dialysis facilities are not being discussed or considered in a meaningful manner during these discussions. Second, the process seemed pre-determined to endorse proposed measures, as opposed to an open process for responding to comments and recommendations of TEP members. Third, the process results did not always correspond with the discussions many of the TEP members understood to have occurred, leading to measures that were inconsistent with the direction the TEP suggested. For example, members on the readmissions TEP did not view the discussion as final, but rather very preliminary. Despite the need for additional discussions and refinement of the measure, the TEP was never reconvened. The process was rushed and did not allow for adequate evaluation, questioning, and refinement of the proposal. It was a suboptimal process that led to a suboptimal result.

In the past, we have made the following recommendations to improve the process, but have never been contacted or received a response to solicit further information. While we reiterate them again, we also urge CMS to engage directly with KCP and others to establish a more appropriate process going forward. Our past recommendations have urged CMS and the contractor to:

- Share the agenda and other materials with interested stakeholders broadly through the CMS website prior to the TEP meeting;
- Provide for a more open process by allowing non-TEP members to listen in on the TEP work group calls and provide comments at the end of these calls and in writing via email to the CMS staff member coordinating the particular group that are also shared with TEP members;
- Increase transparency in the TEP grading criteria by having overt grading by each panel member and identification of the aggregate results.
- Provide TEP members all measure comments received through this process for discussion on work group calls and permit non-TEP members to participate through a public comment period in such calls;
- Create a transparent framework for how population measures should be created and ensure that participants consider measures at the population level;

- Require TEPs to review data from the dialysis unit level in addition to data from large randomized controlled trials/national aggregated data so that measures that are to be used at the facility level will be developed with such data;
- Instruct TEP members to evaluate measures not solely on their clinical significance, but also on the ability to implement them in the dialysis setting, their impact on morbidity and mortality (including improved quality of life for patients), and their appropriateness for being reported and and/or incorporated into the ESRD Quality Incentive Program (QIP);
- Include patients and their advocates in the process, as well as nurses and other non-physicians, to ensure that any measures developed represent consensus from the entire community;
- Reinstitute the Data TEP into each TEP process, which will allow for a second level of review and consideration of all relevant aspects of the data requirements for a particular measure; and
- Publicly post all comments each TEP receives along with the response to each in a fashion similar to that deployed by CMS during rulemaking and NQF during its review of measures.

Given the overarching concerns that the community has expressed with regard to the TEP process for the past several years, we also encourage CMS to open the bidding process for selecting the contractor that oversees it going forward.

Additionally, KCP is in the process of finalizing its community, consensus-based quality blueprint that evaluates how quality can be maintained and/or improved at all levels within the Medicare ESRD program, as well as within facilities, physicians' offices, and other sites of care. We look forward to sharing this document with you in the coming months. We hope that it will help resolve the long-standing problems that plague the current process and threaten its acceptance within the kidney care community.

2. KCP cannot provide meaningful comment on the proposed future measures because the preamble does not provide sufficient information to understand what the Agency may be considering

KCP supports working with CMS to develop the appropriate domains for future measure development; yet, as we have noted in the past, setting forth a list of potential topics for consideration is not an appropriate way to engage with the community in such an important dialogue. The preamble lists seven areas for future inclusion in the QIP on which the Agency seeks comments. The lack of specificity and definition of these topic areas makes it impossible to evaluate or compare them to other potential topic areas. As a guiding principle, we strongly urge the Agency to work with the community to identify a few, key domains and provide a sufficient detail to allow for prioritization and the allocation of limited resources to develop measures in those areas.

As a threshold matter, KCP reiterates our previous recommendations that CMS establish a transparent framework for adopting and updating measures for the QIP, as well. For each of the previous payment years and the proposed PY 2016, CMS has selected measures without providing

insight into the criteria it has used to do so. KCP is troubled by this approach and recommends that CMS state its criteria clearly in the final rule. Congress clearly favored including measures endorsed by a consensus-based organization.⁶⁵ Yet, we understand and agree that there may be occasions when no endorsed measures exist and still the Agency or the community believes it is important to monitor a particular aspect of care. In these cases, we recommend that CMS follow the NQF measure evaluation criteria.

As a threshold matter, a measure should: (1) have a verified entity responsible to maintain and update it on a schedule commensurate with the rate of clinical innovation (at least every three years); and (2) be fully and clearly specified and tested for reliability and validity. In sum, the NQF criteria require that a measure be evaluated as:

- Having a high impact on an aspect of dialysis care, address a demonstrated performance gap and present an opportunity for improvement in dialysis care, and be grounded in evidence supporting the relationship of the outcome to a process or structure of care **(Impact, Opportunity and Evidence)**;
- Containing data elements that produce the same results a high proportion of the time when assessed in the same population in the same time period; having specifications that are consistent with the evidence to support the focus of the measure; having been the subject of testing validating that the data elements and measure scoring are correct; containing necessary exclusions supported by clinical evidence or sufficient observation; for outcomes-based measures, including a specified evidence-based risk-adjustment strategy; demonstrating that methods for scoring and analysis are statistically significant; and allowing for identification of disparities if identified through stratification of results **(Reliability and Validity)**;
- Demonstrating that the intended audience (beneficiaries, purchasers, providers, and policymakers) can understand the results and find them useful for decision-making **(Usability)**;
- Having data that are readily available or could be captured without undue burden **(Feasibility)**; and
- Being harmonized with related measures or justifying the differences in the specifications **(Comparison to Related or Competing Measures)**.⁶⁶

Additionally, CMS should turn to the Measure Applications Partnership (MAP) for identifying how measures should be weighted in the QIP. The MAP is a public-private partnership convened by the NQF under contract to the Department of Health and Human Services for this

⁶⁵See 42 U.S.C. § 1395rr(h)(2)(B)(i).

⁶⁶For a complete description of the NQF measure evaluation criteria, *see* http://www.qualityforum.org/docs/measures_evaluation_criteria.aspx.

purpose in other health care sectors. For measures not-yet endorsed, we urge CMS to use the criteria described above and work with the MAP and community.

In addition, given that CMS adopts measures and specifications through rulemaking, the Agency should also adopt modifications or updates to measures using the same process. Not only is it required by the Administrative Procedures Act, but it also allows for full transparency and provides all interested parties with the opportunity to offer comments.

Finally, we also urge CMS to establish a systematic, phased-in process for incorporating new measures into the QIP. First, if there are no valid or reliable data to support the development of appropriate performance standards, attainment thresholds, improvement thresholds, and benchmarks, CMS should require that the measure be reported outside of the QIP for at least one year before it is incorporated into the QIP. CMS should provide clearly expressed measure specifications, data definitions, and reporting requirements during this period. CMS seems to suggest it is using this approach in the context of the mineral metabolism metric, but the Agency should make this process clear by expressly stating it as an overarching approach.⁶⁷ Then, when a new measure is added, facilities should be judged by the lesser of the facility's performance or one based on the national performance rates for at least the initial year. Congress recognized the need to allow facilities to adjust to the new QIP by establishing the Special Rule;⁶⁸ a similar adjustment period should be used to allow facilities to adjust to new measures, especially as the measures extend beyond those traditionally reported through previous initiatives. Furthermore, it is recommended that CMS state the objective and intent as well as define criteria that need to be met by candidate reporting measures.

In terms of the specific measures and domains proposed for future measure development, KCP appreciates the opportunity to comment, but again urges CMS to review each of these proposed areas in light of the criteria described in this section. As noted, there is insufficient specificity in the preamble to allow for comment on the areas identified with one exception. In terms of the proposal to include a transfusion measure in future QIPs, we reiterate our comments that we submitted to CMS and the contractor earlier this year in response to the anemia management TEP proposal for: (1) a standardized transfusion ratio (STrR) measure; and (2) a ESA management to avoid transfusion measure. In sum, KCP would oppose including these measures in the QIP because of significant concerns about the measures as specified by the TEP.

Standardized Transfusion Ratio (STrR). KCP has several significant concerns and questions about the specifications proposed earlier this year. First, the documentation makes reference to a co-morbidity index, but it is not entirely clear about the details. Is the developer referring to the Charlson Comorbidity Index?

The STrR does not adjust for hospital- or physician-related factors. The literature notes that both hospital and physician factors impact transfusion rates in other areas; there is no reason to

⁶⁷See 77 Fed. Reg. at 40972.

⁶⁸See 42 U.S.C. § 1395rr(h)(4)(E).

think transfusions related to ESRD patients are any different. The developer should review CMS's data and document why the risk model should not account for these variables—i.e., the burden is on the developer to conduct the analyses and show that accounting for hospital-level and physician-level factors is not important in this area. Such details are particularly important because facilities do not have access to transfusion data; the Measure Justification and Measure Information Forms must therefore provide transparency.

Also, we are concerned with the approach and assumptions for the predictive model that posits to reveal an actual versus predicted rate when the basis for the ratio comes from claims data and not EMR data. The documentation fails to demonstrate it accurately predicts and identifies those who have had transfusions. Additional analytic rigor must be brought to bear for this measure.

ESA Management to Avoid Transfusion. KCP also has several significant concerns and questions about the specifications as currently drafted. First, the specifications submitted to the NQF's MAP excluded patients receiving dialysis <90 days, but the proposed measure does not. The developer should be transparent about this change and provide data related to incorporating the exclusion vs. not incorporating it so that the implications of the shift can be assessed. Similarly, the same should be done for the exclusion of patients who received more than one type of ESA or dialysis during both the reporting month and the subsequent month, which was in the MAP version of the measure but not the proposed draft specifications.

Second, the evidence basis for defining a "low dose" as <75 units/kg per session of Epoetin alfa or <25 mcg/kg per session of Darbepoetin alfa is unsupported. KCP is not aware of any trials supporting a specific dose threshold for everyone and so believes the measure lacks an evidence base for the specifications.

Finally, it is KCP's understanding that this measure also was not discussed or proposed at the in-person TEP meeting. As with the informed consent measure, we object that this measure has even been advanced for comment if such is the case.

In sum, the KCP urges CMS to meet with the kidney care community and identify a few, key domains that reflect both the clinical priorities of both the community and the Agency outside of the TEP process. As we have noted previously, KCP is preparing a consensus-based quality blueprint that we hope will help facilitate the necessary dialogue about quality in kidney care, as well as measure development.

VI. KCP urges CMS to modify the structural components of the ESRD QIP Proposed Rule to address three significant areas of concern

KCP appreciates the Agency's willingness over the years to adjust the structural components of the QIP to address concerns raised by the community. For PY 2016, we highlight three important aspects of the structure and recommend specific changes. First, KCP urges CMS to modify the minimum sample size to resolve unintended and harmful consequences that result from the current methodology for addressing small sample sizes. Second, we encourage CMS to modify the proposed weights and not distribute weight equally across all measures and categories. Finally,

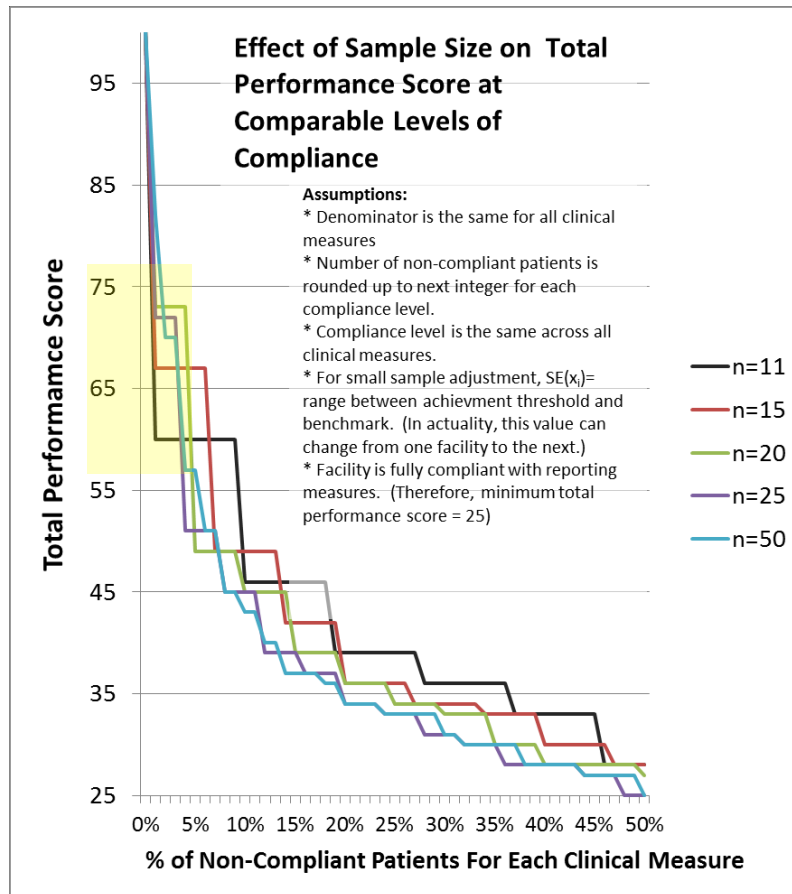
CMS should develop a different scoring model for measures with highly compressed performance ranges with narrow room for achievement.

A. KCP recommends that CMS adopt a minimum sample size of 26 patients for reporting and exclude the small numbers adjustment. The small sample size adjustment exposes facilities to anomalous results beyond their control

KCP appreciates CMS's goal of including as many facilities in the QIP as possible. We further recognize that CMS has adopted a methodology to give small facilities "the benefit of the doubt" regarding their performance. However, our analysis demonstrates that the volatility associated with small sample sizes persists – especially for measures with compressed performance ranges – and that this volatility may create unintended and harmful consequences for facilities providing ESRD services. We therefore urge CMS to discard the small sample size adjustment and set a minimum sample size of at least 26.

First, we note that the methodology to adjust results for small samples sizes is complex and opaque. In particular, the value $SE(x_i)$, which is part of the adjustment, varies for every facility and is calculated concurrently during the performance period. Facilities cannot know in advance what the value will be (even if they understood it). As we shall show, that value can have a very significant impact on the final score, even though it is outside a facility's control.

To analyze the small numbers issue, we developed a model that simulates the QIP scores for facilities of similar performance levels, but with different measure sample sizes. The goal was to determine whether the small facility adjustment factor compensates for the potential penalties associated with small samples. The model found that at very high compliance levels, small facilities' scores tend to be worse than larger facilities with similar performance levels. This is because, at such a low sample size, the penalty for missing even one patient is so large that the CMS small size adjustment may not offset the penalty. As the following graph depicts, at low sample sizes there is a pronounced "step function" in the Total Performance Score for small facilities, in which their score drops significantly for each non-compliant patient. The yellow-shaded area highlights the performance range where small facilities scores are lower.



Additionally, the small sample size adjustment exposes facilities to anomalous results beyond their control. Small differences in $SE(x_i)$ have a significant impact on facility scores, and facilities have no ability to manage or monitor $SE(x_i)$. Small differences in sample size can also make the difference between 1 and 10 achievement points.

KCP explored the effect of $SE(x_i)$ values and sample size on two individual measures: Hemoglobin >12 and hypercalcemia. We selected the Hemoglobin >12 measure because it has a highly compressed performance range, with a 2016 achievement benchmark of 0%, and an achievement threshold of 1.2%. Accordingly, even small differences in compliance might have a significant impact on facility scores. In the 2016 Proposed Rule, Hemoglobin >12, along with anemia informed consent, make-up the anemia clinical measure. Last year, Hemoglobin >12 was a solo measure, and it accounted for 15%; this year, if the anemia informed consent is adopted the weight of Hemoglobin >12 will be 7.5%. We selected hypercalcemia because: (1) it could account for a full 15% of the Total Performance Score; and (2) it also has a compressed performance range, with 6% achievement threshold, and 0% benchmark threshold. The hypercalcemia measure is proposed as a new measure for 2016.

The table below illustrates how the Hemoglobin >12 adjusted compliance score varies as a function of sample size and $SE(x_i)$ (assuming that there is always one non-compliant patient). In the table, the red cells indicate combinations of sample size and $SE(x_i)$ where a facility would earn 0

achievement points. The green cells indicate combinations of sample size and SE (x_i) where a facility would earn 10 achievement points. The yellow cells indicate outcomes between 0 and 10 achievement points. As is apparent from the table, the band of performance that would allow partial credit on the measure is extremely narrow. In most combinations of sample size and SE (x_i) the facility will either get full credit or no credit on the measure. Very small differences in both sample size and SE (x_i) can cause the achievement score to “jump” from 10 to 0 points (or vice versa).

Sensitivity Analysis: Hgb<12 Measure																	
Adjusted Measure Score as a Function of SE(x_i) and Measure Denominator (Assuming Constant Numerator)																	
Red highlight indicates score below achievement threshold					Yellow highlight indicates score between achievement threshold and benchmark					Green highlight indicates score above achievement benchmark							
Measure Denominator Size (Assumes Numerator = 1)																	
		11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
Value of SE(x_i)	0.10	3.3%	2.9%	2.7%	2.5%	2.4%	2.4%	2.4%	2.5%	2.6%	2.7%	2.8%	3.0%	3.2%	3.4%	3.6%	3.8%
	0.12	2.2%	1.9%	1.7%	1.6%	1.6%	1.6%	1.7%	1.9%	2.0%	2.2%	2.5%	2.7%	3.0%	3.2%	3.5%	3.8%
	0.14	1.0%	0.8%	0.7%	0.7%	0.7%	0.9%	1.0%	1.2%	1.5%	1.8%	2.1%	2.4%	2.7%	3.1%	3.5%	3.8%
	0.16	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%	0.3%	0.6%	1.0%	1.3%	1.7%	2.1%	2.5%	2.9%	3.4%	3.8%
	0.18	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.4%	0.8%	1.3%	1.8%	2.3%	2.8%	3.3%	3.8%
	0.20	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.4%	0.9%	1.5%	2.0%	2.6%	3.2%	3.8%
	0.22	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.5%	1.2%	1.8%	2.5%	3.2%	3.8%
	0.24	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%	0.9%	1.6%	2.3%	3.1%	3.8%
	0.26	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.5%	1.3%	2.2%	3.0%	3.8%
	0.28	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.2%	1.1%	2.0%	2.9%	3.8%
	0.30	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.9%	1.9%	2.8%	3.8%
	0.32	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.7%	1.7%	2.8%	3.8%
	0.34	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.4%	1.6%	2.7%	3.8%
	0.36	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.2%	1.4%	2.6%	3.8%
	0.38	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.2%	2.5%	3.8%
	0.40	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.1%	2.5%	3.8%
0.42	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.9%	2.4%	3.8%	
0.44	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.8%	2.3%	3.8%	
0.46	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.6%	2.2%	3.8%	
0.48	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.5%	2.2%	3.8%	

There are several important take-aways from this analysis. While we don't know the value of SE (x_i) for individual facilities, scoring anomalies persist across a range of different values for SE (x_i). At SE(x_i) = .38 the difference between 0 points and 10 points is a single patient. Small differences in SE(x_i) are very likely to have a significant impact on facility scores and facilities have no ability to monitor or manage SE(x_i). For example, at a sample size of 15, a small difference in SE(x_i) can result in going from full credit to no credit. There is a very narrow range where a small facility is able to earn intermediate achievement credit for the Hemoglobin >12 measure. This is because there is such a narrow achievement threshold for Hemoglobin >12 – just 1.2%. For a small facility, a single patient is likely to generate more than a 2% difference, making Hemoglobin >12 an “all or nothing” measure.

KCP conducted a similar analysis for the hypercalcemia measure, this time assuming two non-compliant patients (which is consistent with typical performance on the measure). The results of the analysis for hypercalcemia are consistent with the Hemoglobin >12 analysis. There is a broader range where small facilities may earn partial credit on the measure (the yellow areas in the table below). This is because the hypercalcemia measure itself has a greater range (about 6%) between the achievement threshold and the benchmark. Still, a difference in sample size of just a few patients or a small difference in $SE(x_i)$ can have a significant impact on the measure score and take a facility from full credit to no credit. It bears repeating that sample size and $SE(x_i)$ are variables over which the facility has no control, and yet these variables may substantially determine the facility's score.

Sensitivity Analysis: Hypercalcemia Measure																	
Adjusted Measure Score as a Function of $SE(x_i)$ and Measure Denominator (Assuming Constant Numerator)																	
Red highlight indicates score below achievement threshold					Yellow highlight indicates score between achievement threshold and benchmark					Green highlight indicates score above achievement benchmark							
Measure Denominator Size (Assumes Numerator = 2)																	
	7.2%	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
Value of $SE(x_i)$	0.10	12.4%	11.3%	10.4%	9.7%	9.1%	8.7%	8.3%	8.0%	7.8%	7.7%	7.6%	7.6%	7.5%	7.6%	7.6%	7.7%
	0.12	11.3%	10.2%	9.4%	8.7%	8.3%	7.9%	7.6%	7.4%	7.3%	7.2%	7.2%	7.2%	7.3%	7.4%	7.5%	7.7%
	0.14	10.1%	9.1%	8.4%	7.8%	7.4%	7.1%	6.9%	6.8%	6.8%	6.8%	6.8%	6.9%	7.1%	7.3%	7.5%	7.7%
	0.16	9.0%	8.1%	7.4%	6.9%	6.6%	6.3%	6.2%	6.2%	6.2%	6.3%	6.4%	6.6%	6.8%	7.1%	7.4%	7.7%
	0.18	7.8%	7.0%	6.4%	6.0%	5.7%	5.6%	5.5%	5.6%	5.7%	5.8%	6.1%	6.3%	6.6%	6.9%	7.3%	7.7%
	0.20	6.6%	5.9%	5.4%	5.1%	4.9%	4.8%	4.8%	5.0%	5.1%	5.4%	5.7%	6.0%	6.4%	6.8%	7.2%	7.7%
	0.22	5.5%	4.8%	4.4%	4.1%	4.0%	4.0%	4.1%	4.3%	4.6%	4.9%	5.3%	5.7%	6.2%	6.6%	7.2%	7.7%
	0.24	4.3%	3.7%	3.4%	3.2%	3.2%	3.3%	3.5%	3.7%	4.1%	4.5%	4.9%	5.4%	5.9%	6.5%	7.1%	7.7%
	0.26	3.2%	2.7%	2.4%	2.3%	2.3%	2.5%	2.8%	3.1%	3.5%	4.0%	4.5%	5.1%	5.7%	6.3%	7.0%	7.7%
	0.28	2.0%	1.6%	1.4%	1.4%	1.5%	1.7%	2.1%	2.5%	3.0%	3.5%	4.1%	4.8%	5.5%	6.2%	6.9%	7.7%
	0.30	0.9%	0.5%	0.4%	0.4%	0.6%	1.0%	1.4%	1.9%	2.4%	3.1%	3.8%	4.5%	5.2%	6.0%	6.8%	7.7%
	0.32	0.0%	0.0%	0.0%	0.0%	0.0%	0.2%	0.7%	1.3%	1.9%	2.6%	3.4%	4.2%	5.0%	5.9%	6.8%	7.7%
	0.34	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.6%	1.4%	2.2%	3.0%	3.9%	4.8%	5.7%	6.7%	7.7%
	0.36	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.8%	1.7%	2.6%	3.6%	4.5%	5.6%	6.6%	7.7%
	0.38	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.3%	1.2%	2.2%	3.2%	4.3%	5.4%	6.5%	7.7%
	0.40	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.8%	1.8%	2.9%	4.1%	5.3%	6.5%	7.7%
	0.42	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.3%	1.4%	2.6%	3.8%	5.1%	6.4%	7.7%
0.44	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.1%	2.3%	3.6%	4.9%	6.3%	7.7%	
0.46	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.7%	2.0%	3.4%	4.8%	6.2%	7.7%	
0.48	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.3%	1.7%	3.2%	4.6%	6.2%	7.7%	

Hypercalcemia represents 15 points of Total Performance Score in the 2016 Proposed Rule, and this could present significant unintended negative consequences for facilities. For example, a facility near the threshold of a payment tier could go from 10 to 0 achievement points based on variation in the $SE(x_i)$, and this could drop a facility two full payment tiers (if the facility was already near a payment tier threshold).

Discern was unable to conduct a similar analyses for the NHSN bloodstream infection measure because the data for facilities' performance benchmarks are not included in the 2016

Proposed Rule. However, the impact of the measure would be similar to hypercalcemia, as the NHSN bloodstream infection counts for 15% of the Total Performance Score.

Overall, the conclusions of our analysis are:

- Small sample sizes can produce anomalous results in the Total Performance Score, even with CMS's adjustments for small sample size.
 - Small differences in sample size may quickly change a facility's achievement score on a measure from 0 to 10 (or vice versa), even when the facility misses compliance on just one or two patients.
 - Small differences in the $SE(x_i)$ may quickly change a facility's achievement score on a measure from 0 to 10 (or vice versa). This is especially problematic given the "black box" nature of the $SE(x_i)$ calculations.
- While the CMS sample size adjustment generally does seem to benefit smaller facilities, that result may not hold true for facilities near (but not quite at) perfect performance.

B. CMS should adjust the proposed weights

In developing the proposed 2016 QIP, CMS appears to have elected to give all measure categories equal weight, regardless of their clinical impact or whether the measure or measure category has an established track record within the QIP. We are concerned with this approach for two reasons. First, 47.5% of the total weight is assigned to measures that are new proposed measures for the QIP. Second, equal category-level weighting may place undue emphasis on certain measures to the detriment of other, clinically more important measures. For example, since the catheter measure is a sub-measure within the VAT category, it only counts for 7.5%, despite its significant, evidence-based impact on morbidity and mortality.

We would prefer to see a weighting model that begins with a set of principles for assigning relative importance to measures, and then assigns weight based on those principles. Such a set of principles might stipulate that more importance be assigned to measures:

- That are tested in the QIP (*e.g.*, benchmarks for achievement and improvement are provided based on at least a full year of data);
- Where significant room for improvement still exists (*e.g.*, the achievement threshold is below 90%);
- Have a significant clinical impact; or
- That affect large numbers of patients.

Applying these principles would result in weighting assignments similar to those presented in the table below. KCP urges CMS to adopt a systematic set of principles for differential weighting going forward that will make the QIP score more reliable and clinically significant, and that will provide a foundation for expansion to new measures in the future.

Measure	CMS Proposed Weight	Alternative Weight (if all proposed measures are adopted)	Alternative Weight (If certain proposed measures are not adopted as proposed – KCP’s preferred position)
Hgb > 12 (Clinical)	7.5%	15.0%	15.0%
*Anemia Informed Consent (Clinical)	7.5%	5.0%	Not applicable (NA)
Kt/V - Adult Hemodialysis (Clinical)	Combined 15%, with relative weight allocated based on patient volume	Combined 15%, with relative weight allocated based on patient volume	Combined 15%, with relative weight allocated based on patient volume
Kt/V - Adult Peritoneal Dialysis (Clinical)			
Kt/V - Pediatric Hemodialysis (Clinical)			
*Bloodstream Infection (NHSN) (Clinical)	15.0%	10.0%	NA
Bloodstream Infection (NHSN) (Reporting)	NA	NA	5.84%
*Hypercalcemia (Clinical)	15.0%	10.0%	NA
Hypercalcemia (Reporting)	NA	NA	5.84%
VAT – Fistula (Clinical)	7.5% ⁶⁹	7.0%	10.0%
VAT - No Catheter (Clinical)	7.5% ¹⁶	13.0%	25.0%
Anemia Management (Reporting)	5.0%	6.67%	5.83%
*Pediatric Iron Therapy (Reporting)	5.0%	3.0%	0%
ICH CAHPS (Reporting)	5.0%	6.66%	5.83%
*Comorbidity (Reporting)	5.0%	3.0%	0.0%

⁶⁹ In actuality, the weights of the VAT measures could vary by patient volume (i.e., denominator for each measure). However, the two VAT measures have very similar denominator definitions, and the weights will tend to be equal, or nearly so.

Measure	CMS Proposed Weight	Alternative Weight (if all proposed measures are adopted)	Alternative Weight (If certain proposed measures are not adopted as proposed – KCP’s preferred position)
Mineral Metabolism (Reporting)	5.0%	6.66%	5.83%

C. CMS should use a different scoring model for measures with highly compressed performance ranges and narrow room for additional achievement

KCP understands the purpose of the QIP scoring model for achievement and improvement. However, we believe that the model, which awards partial credit for score between the performance thresholds and benchmarks, may not work very well when the performance range for a measure is very compressed and there is little room for additional achievement. CMS should consider employing different scoring models for measures, particularly Hemoglobin >12 and hypercalcemia, which have highly compressed performance ranges (*e.g.*, under 10%) and little room for additional improvement. This may also be a factor for NHSN blood stream infection measures, but since no data are presented we are unable to assess this.

Consider the hemoglobin measure. The entire achievement range is just 1.2%. Even at a sample size of 75, non-compliance for a single patient can “jump” over the entire achievement range, going from 10 points to 0 points. That is, a facility with 75 patients and zero non-compliant patients will score 0% (lower is better) on the Hemoglobin >12 measure, thereby earning 10 achievement points. A facility with 75 patients and 1 non-compliant patient will score 1.3% on the measure and earn 0 achievement points. Given the weight for the Hemoglobin >12 measure, that single patient could easily drop a facility down a payment tier.

Other measures with compressed ranges, such as the proposed hypercalcemia, have higher weights so that missing one or two patients might drop a facility two full payment tiers. For example a facility with the full 10 points on the proposed hypercalcemia might have a Total Performance Score of 50, and therefore receive no payment penalty. But if that same facility gets 0 points for the proposed hypercalcemia – possible due to the laboratory value of just one or two patients – their Total Performance Score would drop to 35, and their payment penalty will be 1.0%. Such a significant penalty for small differences in performance seems inconsistent with the overall purpose of the QIP.

We recommend that CMS consider alternative scoring methodologies for compressed measures where the achievement range is narrow to ensure that such penalties do not occur. Such an alternative scoring methodology would focus on “quality maintenance” since facility performance is all compressed at high-performance levels, rather than “quality improvement” for measures where significant opportunities still exist. Options for “quality maintenance” scoring” include:

- Retain the achievement/improvement scoring model, but give the facility a pass for the one non-compliant patient. That way, scoring penalties won't apply until there is a real difference in performance.
- Start scoring the measure by granting a full 10 points, and then subtract 1 point for each non-compliant patient. This model could work for the hemoglobin and hypercalcemia measures.

VII. Conclusion

In sum, we appreciate the opportunity to provide comments on the proposed modifications to the QIP for PY 2016. While we have noted serious concerns about some of the proposals, KCP continues to support the implementation of this first Medicare value-based purchasing program and looks forward to working with CMS to refine its proposals to ensure the successful implementation of the QIP.

Part 3: Conclusion

KCP appreciates the opportunity to provide comments on the PPS CY 2014 and QIP PY 2016 proposed regulations. Please feel free to contact Kathy Lester at 202-457-6562 or klester@pattonboggs.com if you have any questions or would like additional details.

Sincerely,



Ronald Kuerbitz
Chairman
Kidney Care Partners

Appendix A: List of KCP Members

AbbVie Laboratories
Affymax
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners, Inc.
Dialysis Patient Citizens
Dialysis Clinic, Inc.
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Kidney Care Council
Mitsubishi Tanabe Pharma America
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Renal Physicians Association
Renal Support Network
Renal Ventures Management, LLC
Satellite Healthcare
Takeda Pharmaceuticals U.S.A (TPUSA)
U.S. Renal Care

**Appendix B: Technical Appendix: Comparison of Moran Company Replication to CMS
 Reported 2007 Payments**

From "Table 9. Medicare Allowable Payments (MAP) for composite rate and separately billable services, 2007-09", pgs 206 -207 of the Display Copy, 2011 Final ESRD Rule	CMS Reported (Rptd.) Total Values in Table 9	Avg. MAP per Treatment	UNINFLATED TMC Replicated Values Using 2007 SAF		Difference Between CMS Reported Total Values & TMC Replicated Total Values	
			Total	Avg. MAP per Treatment	Absolute Difference	Percent Difference
Dialysis patients	328,787	--	331,877	--	3,090	0.9%
Hemodialysis (HD)-equivalent dialysis treatments	36,747,662	--	36,948,251	--	200,589	0.5%
MAP for services in the expanded ESRD PPS						
Total for Part B and Part D services	\$8,809,732,068	\$239.88	\$ 8,914,724,131	\$ 241.42	\$ 104,992,063	1.2%
Total for Part B services	\$8,799,031,984	\$239.45	\$ 8,904,024,047	\$ 240.99	\$ 104,992,063	1.2%
Composite rate services	\$5,719,657,831	\$155.65	\$ 5,784,756,819	\$ 156.56	\$ 65,098,988	1.1%
Separately billable services (Part B)						
EPO	\$1,876,926,573	\$51.08	\$ 1,907,861,344	\$ 51.64	\$ 30,934,771	1.6%
Darbepoetin	\$167,935,970	\$4.57	\$ 170,799,558	\$ 4.62	\$ 2,863,588	1.7%
Calcitriol	\$3,125,613	\$0.09	\$ 3,150,404	\$ 0.09	\$ 24,791	0.8%
Doxercalciferol	\$76,901,723	\$2.09	\$ 77,463,793	\$ 2.10	\$ 562,070	0.7%
Paricalcitol	\$322,849,348	\$8.79	\$ 325,049,404	\$ 8.80	\$ 2,200,056	0.7%
Iron sucrose	\$166,219,339	\$4.52	\$ 167,418,741	\$ 4.53	\$ 1,199,402	0.7%
Sodium ferric gluconate	\$68,086,707	\$1.85	\$ 68,598,634	\$ 1.86	\$ 511,927	0.8%
Levocarnitine	\$5,026,446	\$0.14	\$ 5,084,114	\$ 0.14	\$ 57,668	1.1%
Alteplase	\$26,697,321	\$0.73	\$ 26,911,757	\$ 0.73	\$ 214,436	0.8%
Vancomycin	\$3,583,504	\$0.10	\$ 3,621,242	\$ 0.10	\$ 37,738	1.1%
Daptomycin	\$1,234,405	\$0.03	\$ 1,240,141	\$ 0.03	\$ 5,736	0.5%
Other injectables	\$4,943,934	\$0.13	\$ 4,966,563	\$ 0.13	\$ 22,629	0.5%
Laboratory tests	\$295,508,409	\$8.04	\$ 296,683,828	\$ 8.03	\$ 1,175,419	0.4%
Ultrafiltration	\$2,563,656	\$0.07	\$ 2,563,656	\$ 0.07		
Dialysis facility supplies and IV fluids	\$38,263,239	\$1.04	\$ 38,263,239	\$ 1.04		
Durable medical equipment and supplies (method II)	\$18,060,483	\$0.49	\$ 18,060,483	\$ 0.49		
Dialysis support services (method II)	\$1,447,484	\$0.04	\$ 1,530,328	\$ 0.04	\$ 82,844	5.7%
Dialysis patients with Part D spending	221,154	--	221,154	--		
HD-equivalent dialysis treatments for patients with Part D spending	24,737,326	--	24,737,326	--		
MAP for Part D services	\$10,700,084	\$0.43	\$ 10,700,084	\$0.43		
Calcitriol (oral)	\$2,678,711	\$0.11	2,678,711	\$0.11		
Doxercalciferol (oral)	\$4,965,189	\$0.20	4,965,189	\$0.20		
Paricalcitol (oral)	\$3,008,544	\$0.12	3,008,544	\$0.12		
Levocarnitine (oral)	\$47,639	<\$0.01	47,639	<\$0.01		

NOTE: Green highlighted cells represent values that TMC could not replicate and used the CMS reported values.

Appendix C: History of KCC & KCP Comments on Proposed and Final ESRD PPS Rules & CMS Response

Issue	Rule in which the issue first arose	Year(s) raised by commenters	CMS Response	Notes
CMS appears to have unnecessarily excluded paid claims from facilities without a valid county code from the base rate calculation.	ESRD PPS Proposed Rule, CY 2011	2010 ⁷⁰	No Response	
CMS does not explain why it excluded approximately 15 percent of the facilities from the 2004-06 data used in the regression to determine the adjusters	ESRD PPS Proposed Rule, CY 2011	2010 ⁷¹	No Response	
There is incomplete information on how CMS arrived at its “sample” of facilities used to calculate adjusters and potential bias from excluding hospital-based facilities	ESRD PPS Proposed Rule, CY 2011	2010 ⁷²	No response	

⁷⁰ KCP FY 2011 comment letter, p. 20; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 10-11

⁷¹ KCP comment letter for CY 2011 Proposed Rule, p. 70

⁷² KCP comment letter for CY 2011 Proposed Rule, p. 70; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 11

HCPCS code Q4081 (injectable Epoetin alfa, 100 units) appears to have been left out of the analyses for the CY 2011 Proposed and Final Rule	ESRD PPS Final Rule, CY 2011	2010 ⁷³	No Response	
Iron Dextran has not been included in the Final Rule (with one exception)	ESRD PPS Final Rule, CY 2011	2010 ⁷⁴ , 2011 ⁷⁵ , 2012 ⁷⁶	No Response	
The Final Rule states that pediatric patients and facilities are not eligible for low volume adjustments, but the impact analysis continues to include them (which could mean the standardization adjustment is overstated)	ESRD PPS Final Rule, CY 2011	2010 ⁷⁷	No Response	
CMS appears to have used an	ESRD PPS	2011 ⁷⁸ , 2012 ⁷⁹	No Response	

⁷³ KCP follow-up letter to release of CY 2011 Final Rule, p. 4

⁷⁴ KCP follow-up letter to release of CY 2011 Final Rule, p. 4

⁷⁵ KCC comment letter for CY 2012 Proposed Rule, p. 19-20; KCP comment letter for CY 2012 Proposed Rule, p. 16

⁷⁶ KCP comment letter for CY 2013 Proposed Rule, p. 12

⁷⁷ KCP follow-up letter to release of CY 2011 Final Rule, p. 4

⁷⁸ KCC comment letter for CY 2012 Proposed Rule, p. 20; KCP comment letter for CY 2012 Proposed Rule, p. 16

⁷⁹ KCP comment letter for CY 2013 Proposed Rule, p. 12

inflation factor of 1.905 percent for “Other Injectables” in Table 19 of the CY 2011 Final Rule, but Table 12 provides an inflation factor of 1.7 percent.	Final Rule, CY 2011			
For the 2007-09 inflation factor for laboratory tests in the CY 2011 Final Rule, CMS appears to have used 4.47 percent instead of 4.5 percent, as stated in the Final Rule.	ESRD PPS Final Rule, CY 2011	2011 ⁸⁰ , 2012 ⁸¹	No Response	
CMS does not specify what it includes in its definition of “average payment per treatment,” namely, does this refer to patient utilization based on volume of services or payments for services	ESRD PPS Proposed Rule, CY 2011	2010 ⁸²	No Direct Response but Clarification Provided in Rule	CMS spells out its average payment per treatment calculation but does not directly respond to the comment
The impact file does not include enough detail to analyze case-	ESRD PPS Proposed Rule,	2010 ⁸³ , 2011 ⁸⁴ , 2012 ⁸⁵	Acknowledge but No Action	CMS consistently responds that the data they release is detailed enough to analyze the proposed and final rules:

⁸⁰ KCC comment letter for CY 2012, p. 20; KCP comment letter for CY 2012 Proposed Rule, p. 16

⁸¹ KCP comment letter for CY 2013 Proposed Rule, p. 13

⁸² KCP comment letter for CY 2011, p. 19

⁸³ KCP comment letter for CY 2011 Proposed Rule, p. 35-36

⁸⁴ KCC comment letter for CY 2012, p. 18; KCP comment letter for CY 2012 Proposed Rule, p. 12

⁸⁵ KCC comment letter for CY 2013 Proposed Rule, p. 8

<p>mix adjusters, low-volume facility adjusters, etc. In lieu of a more detailed, patient-level file with a unique flag for patient adjusters, CMS should expand its impact analysis to provide an accounting of the number of treatments at each facility to which each case adjuster is applied</p>	<p>CY 2011</p>		<p>Taken</p>	<p>In the CY 2011 Final Rule CMS notes that, “with regard to the lack of transparency in sharing the data that was used in developing the ESRD PPS proposed rule, we note that the files to which commenters refer contain patient-specific data. To maintain patient confidentiality and privacy we are unable to share such data. However, we posted detailed information by facility which was used for purposes of assessing facility-level impact.”⁸⁶</p> <p>Similar responses in the CY 2012 and CY 2013 Final Rules.⁸⁷</p>
<p>CMS did not release a detailed rate-setting file along with the proposed rule or final rule. In particular, CMS should release a “beneficiary-level rate-setting</p>	<p>ESRD PPS Proposed Rule, CY 2011 (and subsequently)</p>	<p>2010⁸⁸, 2011⁸⁹, 2012⁹⁰</p>	<p>Acknowledge but No Action Taken</p>	<p>CMS repeatedly says that it cannot release this information because it contains patient-specific information and that the information released should be sufficient. For example, in the CY 2012 Final Rule, CMS responds that: “We have not made the rate setting file available because the release of</p>

⁸⁶ CY2011 Final Rule, p. 49036

⁸⁷ CY 2012 Final Rule, p. 70254; CY 2013 Final Rule, p. 67469-70

⁸⁸ KCP comment letter for CY 2011, p. 23; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 2

⁸⁹ KCC comment letter for CY 2012 Proposed Rule, p. 18; KCP comment letter for CY 2012 Proposed Rule, p. 12-14

⁹⁰ KCC comment letter for CY 2013 Proposed Rule, p. 5-6; KCP comment letter for CY 2013 Proposed Rule, p. 1-2

file including a unique flag for each patient adjuster assigned by CMS as a basis for rate-setting”				patient identifiable data is not necessary to accomplish the purpose of analyzing our proposals.” ⁹¹
The use of a monthly capitated payment (MCP) list to identify laboratory test payments may understate the payments for the published list of laboratory services paid for patients on dialysis. In particular, TMC found an additional \$0.44 per treatment in laboratory test payments to facilities in the claims files.	ESRD PPS Proposed Rule, CY 2011	2010 ^{92, 93} , 2011 ⁹⁴ , 2012 ⁹⁵	Acknowledge But No Action Taken	<p>In the CY 2011 Final Rule, CMS uses a list of CY 2007 MCP physicians in conjunction with 2007 claims for this purpose (instead of the CY 2006 list, as used for the proposed rule), and explains the origin of the list. However, they do not explicitly address concerns about the inclusivity of the MCP list and whether the list corresponds to the same time period as the claims data, so it is unclear how this methodology will be applied in the future.⁹⁶</p> <p>In the CY 2012 Final Rule, CMS notes ongoing concerns with calculation of the FY 2011 base rate, but declines to make changes: “We believe that some of the concerns raised by the commenters are related to the assumptions we made in computing the final base rate for CY 2011 where we standardized the base rate to account for the projected</p>

⁹¹ CY 2011 Final Rule, p. 499035-36; CY 2012 Final Rule, p. 70254; CY 2013 Final Rule, p. 67469-70

⁹² KCP comment letter for CY 2011, p. 16-17, 53-54; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 15-18

⁹³ KCP follow-up letter to release of CY 2011 Final Rule, p. 4

⁹⁴ KCC comment letter for CY 2012 Proposed Rule, p. 19; KCP comment letter for CY 2012 Proposed Rule, p. 16

⁹⁵ KCP comment letter for CY 2013 Proposed Rule, p. 12

⁹⁶ CY 2011 Final Rule, p. 49054-55

				payments for the ESRD PPS adjustments. These concerns are beyond the scope of this final rule.” ⁹⁷
Unaccounted for exclusion of beneficiaries and payments from calculation of the MAPs for the CY 2011 base rate. In its analysis following the release of the final 2011 rule, TMC found 3,090 (0.9%) more patients and 200,589 (0.5%) more treatments than were included in CMS’s calculation.	ESRD PPS Proposed Rule, CY 2011	2010 ⁹⁸ , 2011 ⁹⁹ , 2012 ¹⁰⁰	Acknowledge But No Action Taken	<p>In the CY2011 Final Rule, CMS notes that given these concerns, they revisited their calculation of the CY 2007 base year amount and “all payments made on behalf of Medicare ESRD beneficiaries as reported on type 72X claims have now been included,” with a few exceptions that they discuss subsequently.¹⁰¹ However, the numbers still did not match those from TMC.</p> <p>In the CY2012 Final Rule, CMS notes that there are remaining concerns with the calculation of the final base rate for CY2011, but will decline to address them: “We believe that some of the concerns raised by the commenters are related to the assumptions we made in computing the final base rate for CY 2011 where we standardized the base rate to account for the projected payments for the ESRD PPS adjustments. These concerns are beyond the scope of this final rule.”¹⁰²</p>

⁹⁷ CY 2012 Final Rule, p. 70255

⁹⁸ KCP comment letter for CY 2011 Proposed Rule, p. 55-56; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 10-11

⁹⁹ KCC comment letter for CY 2012 Proposed Rule, p. 19-20; KCP comment letter for CY 2012 Proposed Rule, p. 16

¹⁰⁰ KCP comment letter for CY 2013 Proposed Rule, p. 12

¹⁰¹ FY 2011 Final Rule, p. 49067-68

¹⁰² CY 2012 Final Rule, p. 70255

<p>Unexplained difference of \$1.56 (0.6%) between the MAP that TMC calculated using a combination of CMS values and SAF data (\$245.21 per treatment) and the MAP that CMS calculated (\$243.65 per treatment)</p>	<p>ESRD PPS Final Rule, CY 2011</p>	<p>2011¹⁰³, 2012¹⁰⁴</p>	<p>Acknowledge But No Action Taken</p>	<p>In the CY2012 Final Rule, CMS notes that there are remaining concerns with the calculation of the final base rate for CY2011, but will not address them (same quote and citation as above).</p>
<p>CMS does not specify how ESRD PPS payment policies – e.g., determining the base rate, setting the case mix adjusters – will change in subsequent years, nor does CMS specify how it will update its lists of specific items and services and the amount of reimbursement allocated to each item in the bundle as clinical practices change and new products and services enter the</p>	<p>ESRD PPS Proposed Rule, CY 2011</p>	<p>2010¹⁰⁵, 2011¹⁰⁶, 2012¹⁰⁷</p>	<p>Acknowledge but No Action Taken</p>	<p>CMS regularly acknowledges this concern but has not provided additional details.</p> <p>In the CY 2011 Final Rule, CMS notes that it will update its lists of specific services annually and that this should be adequate; if not, they will consider other options in the future: “We believe that these mechanisms of updating ESRD-related drugs and biologicals and laboratory tests, will address any changes that may arise in the future. However, should the technologies and treatments for ESRD change significantly at some point in the future, we could</p>

¹⁰³ KCC comment letter for CY 2012 Proposed Rule, p. 20; KCP comment letter for CY 2012 Proposed Rule, p. 16

¹⁰⁴ KCP comment letter for CY 2013 Proposed Rule, p. 13

¹⁰⁵ KCP comment letter for CY 2011 Proposed Rule, p. 39-40; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 8

¹⁰⁶ KCC comment letter for CY 2012 Proposed Rule, p. 14-16; KCP comment letter for CY 2012 Proposed Rule, p. 10

¹⁰⁷ KCP comment letter for CY 2013 Proposed Rule, p. 3, 9-10

market				consider whether other mechanisms may need to be incorporated through future rulemaking to ensure that Medicare ESRD patients continue to have access to important advances in care.” ¹⁰⁸
Requirement for facilities to provide documentation that they do not have access to in order to claim co-morbidity adjusters. CMS should provide access to the data necessary to document these adjusters.	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁰⁹ , 2011 ¹¹⁰ , 2012 ¹¹¹	Acknowledge But No Action Taken	<p>In the CY 2011 Final Rule, CMS acknowledges receiving comments that facilities do not have access to this information but respond that, “historically, there has not been a financial incentive for ESRD facilities to document the presence of co-morbidities. We believe that by including co-morbidity adjustments under the ESRD PPS, ESRD facilities will implement more active processes for gathering diagnostic information, which will facilitate care planning,” and that facilities should be “proactive in obtaining co- morbidity information from other health care providers.”¹¹²</p> <p>In the CY 2013 Final Rule, CMS responds that comments about the difficulty of securing the necessary documentation to claim the co-morbidity adjusters are</p>

¹⁰⁸ CY 2011 Final Rule, p. 49174

¹⁰⁹ KCP comment letter for CY 2011 Proposed Rule, p. 33-34; 72; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 4, 22-24

¹¹⁰ KCC comment letter for CY 2012 Proposed Rule, p. 4-6; KCP comment letter for CY 2012 Proposed Rule, p. 4-8

¹¹¹ KCC comment letter for CY 2013 Proposed Rule, p. 6-8; KCP comment letter for CY 2013 Proposed Rule, 3-5

¹¹² CY 2011 Final Rule, p. 49100-01; 49104

				outside of the scope of the proposed rule and so will not be addressed. ¹¹³
Although TMC found that separately billed payments were higher during the first 120 days of dialysis, the analyses do not indicate anything on the scale of the proposed start-up adjuster	ESRD PPS Proposed Rule, CY 2011	2010 ¹¹⁴	Acknowledge But No Action Taken to Address Concerns with Underlying Methodology	CMS acknowledges concerns that the adjuster is overstated but declines to take action noting that, “the multiplier amounts for the onset of dialysis adjustment, as well as all other adjustments, are the result of the regression models for composite rate and separately billable services.” ¹¹⁵
The calculation of the low-volume facility adjuster is based on a number of assumptions about which facilities will qualify for it, and CMS does not discuss if and how the adjuster will be updated once CMS receives actual data about the number of facilities claiming this adjuster	ESRD PPS Proposed Rule, CY 2011	2010 ¹¹⁶ , 2011 ¹¹⁷ , 2012 ¹¹⁸	Acknowledge, Agree to Monitor But No Action Taken	In the CY 2011 Final Rule, CMS acknowledges concerns about how the low-volume facility adjuster is calculated, but declines to change the methodology. Instead, they say they “will be monitoring the use of the low-volume adjustment to ensure that appropriate ESRD facilities, which have not exceeded the 4,000 treatment threshold, will receive the low-volume payment adjustment, and “believe using the adjustment derived from the regressions analysis is a better measure of the costs of low-volume facilities.” ¹¹⁹

¹¹³ Final Rule CY 2013, p. 67470

¹¹⁴ KCP comment letter for CY 2011 Proposed Rule, p. 72

¹¹⁵ CY2011 Final Rule, p. 49092

¹¹⁶ KCP comment letter for CY 2011 Proposed Rule, p. 72-74; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 35-38

¹¹⁷ KCC comment letter for CY 2012 Proposed Rule, p. 8-9

¹¹⁸ KCC comment letter for CY 2013 Proposed Rule, p. 3, 8-9;

¹¹⁹ CY2011 Final Rule, p. 49123

				In the CY 2012 Final Rule, CMS declines to change their methodology and will continue to monitor the situation: “We did not propose to change or modify the low- volume adjuster methodology for CY 2012. We note that we are monitoring the extent to which the low-volume and other ESRD PPS adjustments are consistent with the assumptions we made in developing the ESRD PPS. We will address this issue in future rulemaking.” ¹²⁰
Unexplained discrepancy in the number of low-volume facilities used in the UM-KECC analysis (89) and listed in the impact file (166)	ESRD PPS Proposed Rule, CY 2011	2010 ¹²¹	Acknowledge But No Action Taken	In the CY 2011 Final Rule, CMS acknowledges this discrepancy and says that it is possible that there is a conflict due to different data sources and timing of when the analyses were completed, but does not address possible implications of this difference. ¹²²
Concerns with the methodology for calculating the outlier adjuster and that the payouts will be less than the projected value of 1%	ESRD PPS Proposed Rule, CY 2011	2010 ¹²³	Acknowledge But No Action Taken	In the CY 2011 Final Rule, CMS acknowledges concerns about the outlier adjuster but declines to adjust the base rate in future years to reflect differences between actual and projected outlier payments, noting that: “We disagree with the commenters’ recommendations. We have put forth our best effort to project the impact of a 1.0 percent outlier payment policy on the magnitude of the fixed dollar lost amounts for adult and pediatric patients in order to calculate the outlier payment thresholds...we do not intend to adjust

¹²⁰ CY 2012 Final Rule, p. 70255

¹²¹ KCP comment letter for CY 2011 Proposed Rule, p. 73; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 36

¹²² CY 2011 Final Rule, p. 49123

¹²³ KCP follow-up letter to release of CY 2011 Final Rule, p. 6

				<p>the base rate in future years to reflect the difference between actual and projected outlier payments.”¹²⁴</p> <p>In subsequent years, CMS has updated the fixed dollar loss amounts as they receive updated data; however, claimed outlier adjuster payments have consistently been below the 1% target.¹²⁵</p>
<p>Cost reports do not capture all of the information needed to implement, track, and update the ESRD PPS</p>	<p>ESRD PPS Proposed Rule, CY 2011</p>	<p>2010¹²⁶, 2011¹²⁷, 2012¹²⁸</p>	<p>Acknowledge and Promise Future Action, but No Action Taken</p>	<p>In each rule, CMS acknowledges these comments and says they will keep them in mind, but no action has been taken.</p> <p>In the CY 2011 Final Rule CMS notes that they “agree that changes to the cost report are necessary to reflect the ESRD PPS and to improve the accounting of ESRD facility costs. Any changes in cost reporting will be addressed in the future.”¹²⁹</p>

¹²⁴ CY 2011 Final Rule, p. p. 49144

¹²⁵ CY 2013 Proposed Rule, p. 40965; CY 2014 Proposed Rule, p. 40852

¹²⁶ Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 43-44

¹²⁷ KCC comment letter for CY 2012 Proposed Rule, p. 16-17; KCP comment letter for CY2012, p. 9-10

¹²⁸ KCC comment letter for CY 2013 Proposed Rule, p. 9-12; KCP comment letter for CY 2013 Proposed Rule, p. 3, 5-8

¹²⁹ CY 2011 Final Rule, p. 49175

				In the CY 2013 Final Rule, CMS notes that, “We thank the commenters for their suggestions. We plan to analyze the cost reports to determine if there are any changes required and will consider the suggestions provided.” ¹³⁰
CMS’s calculations of the use and cost of oral drugs relies on data that is incomplete, unstable and not publicly available.	ESRD PPS Proposed Rule, CY 2011	2010 ¹³¹	Acknowledge and Commit to Additional Monitoring, But No Action Taken	In the CY 2011 final rule, CMS notes that “with regard to the issue of inadequate data to price for payment oral drugs and biologicals, including oral-only drugs used for the treatment of ESRD, we agree with the commenters in part...we believe a careful assessment of the use of the Medicare Prescription Drug Plan Finder as a basis for pricing oral- equivalent ESRD drugs is appropriate before extending its application to oral- only drugs. Accordingly, we are delaying the implementation of oral drugs with no injectable equivalent or other form of administration (oral-only drugs), pending this evaluation.” ¹³² However, they have not yet discussed if they have conducted this evaluation and if so, what the results suggest.
The pediatric adjuster may	ESRD PPS	2010 ¹³³	Acknowledge	In the CY 2011 Final Rule, CMS acknowledged concerns

¹³⁰ CY 2013 Final Rule, p. 67470

¹³¹ KCP comment letter for CY 2011, p. 10-11

¹³² CY 2011 Final Rule, p. 49043

¹³³ KCP comment letter for CY 2011 Proposed Rule, p. 36-38; 74-75; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 38-41

<p>understate the costs that pediatric facilities face because most of the cost reports used for the calculation are for adult facilities treating (older) pediatric patients instead of for actual pediatric facilities</p>	<p>Proposed Rule, CY 2011</p>		<p>and Agree to Monitor and Do Further Research; No Action Taken</p>	<p>with the payment methodology and increased the size of the pediatric payment adjusters. They also note that “once we have completed the research necessary to determine if comorbidities prevalent among pediatric dialysis patients can be used to refine the pediatric payment adjusters adopted in this final rule, any proposed revisions would be implemented through rulemaking.”¹³⁴</p> <p>In subsequent rules, they say that this methodology for calculating the pediatric adjusters was finalized in the 2011 rule and direct commenters there.¹³⁵</p>
<p>The standardization adjustment relies on accuracy of assumptions about the frequency with which facilities will claim patient- and facility-level adjusters; if frequencies are overstated, then the standardization adjustment will reduce the base rate below</p>	<p>ESRD PPS Proposed Rule, CY 2011</p>	<p>2010¹³⁶, 2011¹³⁷, 2012¹³⁸</p>	<p>Acknowledge, Agree to Future Monitoring, But No Action Taken</p>	<p>In the CY 2013 Final Rule, CMS acknowledges ongoing concerns with the standardization methodology but declines to change it, “In the CY 2013 ESRD PPS proposed rule, we did not propose to change how the base rate is calculated or updated. We also did not propose in the CY 2013 ESRD PPS proposed rule to modify the payment adjusters. We do not believe that because we lowered the MAP and fixed dollar loss amounts to adjust for outlier payment</p>

¹³⁴ CY 2011 Final Rule, p. 49130

¹³⁵ CY 2013 Final Rule, p. 67470

¹³⁶ KCP comment letter for CY 2011 Proposed Rule, p. 23, 56-57; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 3-4

¹³⁷ KCP comment letter for CY 2012 Proposed Rule, p. 8

¹³⁸ KCC comment letter for CY 2013 Proposed Rule, p. 3-4; KCP comment letter for CY 2013 Proposed Rule, p. 3-4

<p>its statutorily-mandated level, and there is no process for reconciling based on actual data. In their CY2013 comment letters, both KCC and KCP point out that CMS now has 2011 claims data to identify actual low volume facilities and prevalence of reporting case mix and other adjusters and calls on CMS to re-calculate the standardization factor</p>				<p>expenditures that were below the 1 percent target, we must adjust the standardization factor for the ESRD PPS base rate. We will, however, continue to monitor our payments and consider if any changes need to be made in the future.”¹³⁹</p>
<p>CMS’s methodology for calculating the value of oral-only drugs is flawed (even after accounting for use of incorrect denominator) in that it does not rely on the most recently available data and only accounts for previous <i>Medicare</i> spending (which ignores other important sources of spending, such as private insurance) and does not fully account for utilization of</p>	<p>ESRD PPS Proposed Rule, CY 2011</p>	<p>2010¹⁴⁰, 2012¹⁴¹</p>	<p>Acknowledge but Disagree; Agree to Further Consideration of Comments, but No Future Action Taken</p>	<p>In the CY2011 final rule, CMS decided to delay inclusion of oral-only drugs in the bundle, due in part to lack of data from relevant payers.¹⁴²</p> <p>However, CMS also indicates that they do not agree that potential changes in utilization and payments from other sources should be included in the calculation, “Non-Medicare sources of payment for these drugs, such as employer groups, unions, private insurance, etc., could not be considered because we interpret section 1881(b)(14)(A)</p>

¹³⁹ CY 2013 Final Rule, p. 67470

¹⁴⁰ Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 14

¹⁴¹ KCC comment letter for CY 2013 Proposed Rule, p. 12-14; KCP comment letter for CY 2013 Proposed Rule, p. 13-21

¹⁴² CY 2011 Final Rule, p. 49042-44

these drugs				<p>of the Act as requiring that the ESRD PPS reflect payments under Title XVIII for renal dialysis services.”¹⁴³</p> <p>In response to future comments on this methodology, CMS notes that: “In the CY 2011 ESRD PPS final rule (75 FR 49038 through 49044), we responded to comparable comments regarding the inclusion of oral-only drugs in CY 2014. We received many suggestions from stakeholders on how oral-only drugs should be included in the ESRD PPS bundled payment. We have reviewed and will continue to review all of the comments, which we will consider as we formulate our proposals on this issue. We intend to address the inclusion of oral-only drugs in the ESRD PPS in the CY 2014 ESRD PPS proposed rule.”¹⁴⁴</p>
The proposed methodology for updating oral drugs portion of the ESRD PPS bundle rate (market basket minus productivity) is not technically correct, namely the productivity adjustment should not be applied to full transition blended payment. Nor is the method appropriate for the ESRD	ESRD PPS Proposed Rule CY 2012	2011 ¹⁴⁵	Acknowledge But Do Not Agree	In the CY 2012 Final Rule, CMS acknowledges the concern but conclude that their methodology is “appropriate,” and say that: “although drugs account for a larger proportion of expenses in the ESRD market basket than in some other provider-type PPS market baskets, we will continue to update the ESRD payments as statutorily mandated by the Congress.” ¹⁴⁶

¹⁴³ CY 2011 Final Rule, p. 49077-78

¹⁴⁴ CY 2013 Final Rule, p. 67469

¹⁴⁵ KCC comment letter for CY 2012 Proposed Rule, p. 9-10; KCP comment letter for CY 2012 Proposed Rule, p. 14

¹⁴⁶ CY 2012 Final Rule, p. 70231, 70234

bundle since the productivity factor is mostly derived from capital and labor measures, which are not appropriate for the ESRD bundle, where the cost of drugs represents such a large proportion of the bundle				
Use of cost report data to calculate patient- and facility-level adjusters	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁴⁷	Acknowledge But Do Not Agree	In the CY 2011 Final Rule, CMS acknowledges concerns with using cost reports for this purpose, but responds that they are an appropriate data source to use ¹⁴⁸
CMS also appears to have unnecessarily excluded paid claims for patients without a valid date of birth from the base rate calculation	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁴⁹	Response But the Response Does Not Provide Clarification	CMS responds that, the “elimination of patients with no valid date of birth is only relevant in connection with the development of the payment adjusters for the age variable in the two-equation model and not for purposes of the computation of the base rate. This was done in order to prevent any distortion in the age adjusters. We point out that the number of claims eliminated was extremely small. No claims were eliminated due to the lack of a valid date of birth in the calculation of the base rate because age is not a classification variable in computing that rate.” ¹⁵⁰

¹⁴⁷ KCP comment letter for CY 2011 Proposed Rule, p. 33, 70-71; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 22

¹⁴⁸ CY 2011 Final Rule, p. 49104

¹⁴⁹ KCP FY 2011 comment letter, p. 20; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 11

¹⁵⁰ CY 2011 Final Rule, p. 49070

<p>The proposed bundle does not adequately account for costs of home training</p>	<p>ESRD PPS Proposed Rule, CY 2011</p>	<p>2010¹⁵¹, 2011¹⁵², 2012¹⁵³</p>	<p>Take Action in Response to Initial Concern but Acknowledge Subsequent Comments Without Taking Action</p>	<p>In the CY 2011 Final Rule, CMS introduced a training add-on.¹⁵⁴</p> <p>However, CMS has not added an inflation update to the training add-on. In the CY 2012 Final Rule, CMS acknowledges the request for an update mechanism but does not take action: “We did not propose any change in the methodology or the training add-on adjustment. Thus, the suggestions and comments received are beyond the scope of this final rule. However, we will take these comments into account in future rulemaking.”¹⁵⁵</p>
<p>The case-mix adjuster for pediatric patients is based on regression methodology used for a larger (adult) population</p>	<p>ESRD PPS Proposed Rule, CY 2011</p>	<p>2010¹⁵⁶</p>	<p>Response and Initial Action Taken, but No Follow-up</p>	<p>In the CY 2011 Final Rule, CMS announced that it is no longer adopting co-morbidity adjusters for the pediatric population, nor are they using BSA, BMI, or the onset of dialysis adjusters.¹⁵⁷</p>

¹⁵¹ KCP comment letter for CY 2011 Proposed Rule, p. 17

¹⁵² KCC comment letter for CY 2012 Proposed Rule, p. 18-19; KCP comment letter for CY 2012 Proposed Rule, p. 15

¹⁵³ KCP comment letter for CY 2013 Proposed Rule, p. 11

¹⁵⁴ CY 2011 Final Rule, p. 49130

¹⁵⁵ CY 2012 Final Rule, p. 70252

¹⁵⁶ KCP comment letter for CY 2011 Proposed Rule, p. 37-38

¹⁵⁷ CY2011 Final Rule, p. 49129

				CMS said it would continue to research pediatric payment adjusters, but has not provided information on these efforts. ¹⁵⁸ In addition, in response to subsequent comments about pediatric co-morbidity adjusters, it says that these decisions were finalized in the 2011 rule and direct commenters there. ¹⁵⁹
Many of the co-morbidities included in CMS's list for the ESRD PPS are not relevant to pediatric patients, while many of the co-morbidities that are relevant are not on the list	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁶⁰	Response and Initial Action Taken, but No Follow-up	In the CY 2011 Final Rule, CMS acknowledges this concern and opts to use adjusters that do not rely on specific co-morbidities. ¹⁶¹ As noted above, they said they would revisit this issue but have not yet done so.
CMS does not clarify whether the per patient utilization calculation	ESRD PPS Proposed Rule,	2010 ¹⁶²	Response and Clarification	In the CY 2011 final rule, CMS explains and revises their per patient utilization calculation. ¹⁶³

¹⁵⁸ CY 2011 Final Rule, p. 49130

¹⁵⁹ CY 2013 Final Rule, p. 67470

¹⁶⁰ KCP comment letter for CY 2011 Proposed Rule, p. 37-38

¹⁶¹ CY 2011 Final Rule, p. 49129

¹⁶² Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 3

¹⁶³ CY 2011 Final Rule, p. 49072-73

used to determine the year for the base rate includes all of the services in the <i>proposed</i> bundle or just those services included in the pre-bundle payment system	CY 2011		Provided	
It is unclear whether CMS uses all treatments or just Medicare treatments in the low-volume adjuster calculation	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁶⁴	Response and Clarification Provided	In the CY 2011 Final Rule, CMS directly addresses this point, noting that they use total treatments. This also means that they are relying on costs report data, which they acknowledge raises some concerns. ¹⁶⁵
No discussion of methodology for excluding extreme/obviously incorrect values in data used to calculate the base rates and adjusters	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁶⁶	Response and Clarification Provided	In the CY 2011 Final Rule, CMS discusses using the “outer fence” method to address statistical outliers for composite rate calculations and for the case-mix models. ¹⁶⁷
With respect to the co-morbidity adjusters, CMS does not provide criteria for distinguishing between an old condition that will not affect ESRD treatment	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁶⁸	Response and Clarification Provided	In the CY 2011 Final Rule, CMS removed certain adjusters where this was a problem, such as the cardiac arrest adjuster, the cancer adjuster, the substance abuse adjuster and the HIV/AIDS adjuster. ¹⁶⁹

¹⁶⁴ KCP comment letter for CY 2011 Proposed Rule, p. 72-74

¹⁶⁵ CY 2011 Final Rule, p. 49122

¹⁶⁶ KCP comment letter for CY 2011 Proposed Rule, p. 74

¹⁶⁷ CY 2011 Final Rule, p. 49065

¹⁶⁸ KCP comment letter for CY 2011 Proposed Rule, p. 71

¹⁶⁹ CY 2011 Final Rule, p. 49095-96

and a condition that will, or for cases where the patient may not disclose a particular condition (e.g., substance abuse)				
Treatment of case-mix adjusters as independent variables when they may not be. Although these variables may be independent in a statistical sense, they may not be clinically independent, which would affect the prevalence calculation.	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁷⁰	Response and Remedy Provided Without Addressing Underlying Concern	In the CY 2011 Final Rule, CMS acknowledges concerns that certain case mix adjusters are not independent, but does not agree. ¹⁷¹ However, in this same rule, CMS adopts the policy that facilities can only claim one comorbidity adjuster at a time; this policy change mitigates the harm but does not address the underlying issue: flaws in the initial methodology that was used to come up with the adjusters. ¹⁷²
Use of incorrect denominator in calculating per patient spending for Part D oral drugs	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁷³	Response and Action Taken	In the CY 2011 final rule, CMS acknowledges the mistake and fixed the calculation: “We believe that the commenters are correct in concluding that our proposed methodology for calculating the base rate yielded an inappropriately low payment amount for the Part D component of the ESRD PPS payment bundle.” ¹⁷⁴
While CMS inflates other drug	ESRD PPS	2010 ¹⁷⁵	Response and	In the CY 2011 Final Rule, acknowledges and uses the PPI

¹⁷⁰ KCP comment letter for CY 2011 Proposed Rule , p. 33; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 21-22

¹⁷¹ CY 2011 Final Rule, p. 49103

¹⁷² CY 2011 Final Rule, p. 49106

¹⁷³ KCP comment letter for CY 2011, p. 12-13; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 14

¹⁷⁴ CY 2011 Final Rule, p. 49072

payments to 2011, it only inflates IV drugs to 2009 using the most recently available ASP + 6	Proposed Rule, CY 2011		Action Taken	to update the drugs to 2011 prices. ¹⁷⁶
In calculating the MAP for separately billable services to be used in the regression equation to produce the adjusters, CMS re-priced drugs but not any of the other payments and does not clarify how they chose which ASP values to use (Q1 2008)	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁷⁷	Response and Action Taken	In the CY 2011 final rule, CMS explains this decision and notes that the re-pricing is no longer necessary because they are now able to use data from CY 2006, 2007, and 2008, during which time drug prices consistently reflect the ASP + 6 percent pricing methodology. ¹⁷⁸
Unclear if and how blood transfusions will figure into the bundle based on CMS's definition of the bundle	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁷⁹	Response and Action Taken	In the CY 2011 Final Rule, CMS specifies that they “do not consider the furnishing of blood and blood products to be renal dialysis services under the statute and, therefore, these services would be excluded from the ESRD PPS payment bundle.” ¹⁸⁰
Arbitrary exclusion of paid	ESRD PPS	2010 ¹⁸¹	Response and	In the CY 2011 Final Rule, CMS gets rid of this trim. ¹⁸²

¹⁷⁵ KCP comment letter for CY 2011 Proposed Rule, p. 22, 56; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 14-15

¹⁷⁶ CY 2011 Final Rule, p. 49079

¹⁷⁷ Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 6-7

¹⁷⁸ CY 2011 Final Rule, p. 49084-85

¹⁷⁹ KCP follow-up letter to release of CY 2011 Final Rule, p. 5

¹⁸⁰ CY2011 Final Rule, p. 49055

¹⁸¹ KCP comment letter for CY 2011 Proposed Rule, p. 20

claims with more than 20 HD-equivalent sessions per patient, per month	Proposed Rule, CY 2011		Action Taken	
Arbitrary cap on claims for Epo utilization (30,000 units per treatment)	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁸³	Response and Action Taken	In the CY 2011 Final Rule, CMS brings methodology in line with their own ESA Claims Monitoring Policy. ¹⁸⁴
It appears that CMS relied on predicting facility behavior based on one year of performance data (2011), which misses important variables that factor into facilities' decisions on whether to choose the transition option, making it unlikely that their calculation will accurately reflect the decisions that facilities make, which affects the payment amount.	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁸⁵	Response and Action Taken	In the 2011 Final Rule, CMS acknowledges concerns with their methodology, noting that they "recognize that the transition budget-neutrality adjustment may not reflect actual choices made by ESRD facilities regarding opting out of the ESRD PPS transition," ¹⁸⁶ but say that they cannot wait for actual data before implementing the policy. In its CY 2011 interim rule with comment – " Changes to the ESRD PPS Transition Budget Neutrality Adjustment ," CMS revises this calculation to reflect the <i>actual</i> number of facilities who chose the transition (this number was much lower than they anticipated)

¹⁸² CY 2011 Final Rule, p. 49067

¹⁸³ KCP comment letter for CY 2011 Proposed Rule, p. 20-21; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 12-13

¹⁸⁴ CY 2011 Final Rule, p. 49067

¹⁸⁵ KCP comment letter for CY 2011 Proposed Rule, p. 28-29; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 18-21; KCP follow-up letter to release of CY 2011 Final Rule, p. 2-3

¹⁸⁶ CY 2011 Final Rule, p. 49083

CMS does not specify if and how they will reconcile the transition adjustment calculation with the actual decisions that facilities make on whether to seek the transition option	ESRD PPS Proposed Rule, CY 2011	2010 ¹⁸⁷	Response and Action Taken	In the CY 2011 Final Rule, CMS says that are considering whether to “prospectively correct for over or understatement of the number of facilities that choose to opt out of the transition when we update the adjustment for 2012.” ¹⁸⁸ As noted above, this issue is fully addressed in the CY 2011 interim rule with comment .
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¹⁸⁷ KCP comment letter for CY 2011 Proposed Rule, p. 28; Joint KCP-KCC comment letter for CY 2011 Proposed Rule, p. 18-21; KCP follow-up letter to release of CY 2011 Final Rule, p. 2-3

¹⁸⁸ CY 2011 Final Rule, p. 4908

Appendix D: Technical Appendix Interim Implementation of Corrections to Adjuster Frequencies and Values

CMS estimates certain parameters of payment systems in rate setting for a future year based on prior year data. In the ESRD payment system, this is done every year to estimate the outlier pool, and was done as part of the original 2011 Final Bundled Payment System Rule to estimate the adjustment for the transitioning facilities. In the latter case, when data showed that the estimate was incorrect and represented a substantial cut to the payment rate, CMS used interim rulemaking to implement a correction, citing concern about access to care if an inappropriately large cut were taken. Each year since 2011, CMS has underpaid the outlier pool, and so each subsequent year it produces new outlier parameters to increase the number of outlier payments.

CMS based its standardization factor on an estimated frequency of adjusters based on research performed by its contractor in developing the 2011 final rule. Every year, KCC and KCP have produced comments and documented in research provided to CMS, evidence that providers could not claim the frequency of adjusters used to calculate the standardization factor. When 2011 actual claims became available for 2013 rulemaking, The Moran Company calculated the difference between what CMS had expected to pay out and what it actually paid out using CMS's own impact analysis—a difference of \$5.31 per treatment—and KCC and KCP comments included this analysis, setting forth the following hypothesis:

The difference between what the government expected to pay out and what actually was paid out is attributable to the fact that providers claimed a lower frequency of adjusters than were estimated in the standardization factor.

CMS could have corrected this underpayment in response to comment to the proposed 2013 rule, but chose not to do so. Failure to correct this underpayment for 2013 carries the understatement of the base rate forward to 2014 rule making.

The value associated with every payment adjuster in the ESRD PPS was calculated using regression analysis that included either both cost report and separately billable data, or only separately billable data. The substantial reduction of the value of the separately billable data entailed by the ATRA cut, will mean that all of the adjusters >1.0 that rely upon that data will be overstated. The old adjuster value is included in the standardization factor, and failure to correct overstated adjusters will have the same effect that overstatement of frequency has had: it will inappropriately remove dollars from the base rate.

While CMS may claim that it does not have adequate resources to re-calculate the standardization value to account for these changes, failure to do so, leaves an effective cut to the base rate in place that is unaccounted for and reduces payment to providers in a way that is not visible to legislators and others concerned with accurate payment. Just as CMS uses estimation on a provisional basis as a routine part of rate setting when it does not have perfect information, it could use estimation methods to correct the standardization factors for these known and predictable types of error. The following discussion demonstrates how such correction can be done using estimation. CMS can

always re-calculate both frequency and value of all adjusters as part of its rate setting methodology using its preferred methods in future years.

We argue here that CMS should estimate the correct frequency and value of adjusters and adjust the standardization factor appropriately using the most recent available claims data and reasonable estimation methods as discussed below. This correction should be applied to the base rate back to 2013, and the 2014 base rate should be based on the adjusted base rate for 2013. This corrected base rate should be the basis against which the ATRA cut is applied.

CMS did not publish the revised adjuster values that were finalized in the 2011 final rule. In the proposed rule, it has shown the methodology for the larger number of adjusters it proposed. As a result, we cannot see the precise relative weights within each adjuster of cost report (CR) compared to separately billable (SB) dollars. To estimate the change to the adjuster values for all current adjusters, the following equation can be applied to data that CMS has available to it from the valuation of the original adjusters.

$$\text{Adjuster}_{\text{FINAL}} = (\text{Adjuster}_{\text{CR}}) * (\text{Weight}_{\text{CR}}) + (\text{Adjuster}_{\text{SB}}) * (\text{Weight}_{\text{SB}})$$

$\text{Adjuster}_{\text{CR}}$ and $\text{Adjuster}_{\text{SB}}$ are the results of the UM-KECC research CMS indicates it cannot afford to replicate, but $\text{Weight}_{\text{CR}}$ and $\text{Weight}_{\text{SB}}$ are very easy for them to change.

CMS originally calculated in the 2011 proposed rule that separately billables averaged \$82.45 per treatment and CR services were \$169.67, so $\text{Weight}_{\text{SB}} = .327$ and $\text{Weight}_{\text{CR}} = .673$. These weights can easily be recalculated by updating using the market basket and then deducting the drug reduction from the SB side only. We believe the value of these weights had to change between proposed and final rules in 2011 and they never published updated numbers in the final rule, so we cannot say precisely what the weights should be.

Of note, 4 of the 6 co-morbid adjusters were calculated assuming $\text{Adjuster}_{\text{CR}}$ was equal to 1 due to “lack of statistical significance or lack of stability over time” in that model. So those adjusters (Pericarditis, GI Bleed, Myelodysplastic Syndrome, Monoclonal gammopathy) will decrease the most.

Advocating this change will necessarily increase the value of the Low Volume adjuster because the separately billable model showed that low volume facilities used less separately billables than non-low-volume facilities. Consistent with our recommendation to use the most recent data, CMS should use the frequency of low volume facility treatments in the claims data, but may make adjustments prospectively if it has a plan to more appropriately apply low volume criteria to address the concerns about the application of that policy that have been raised in KCC and KCP comments as well as by the GAO.

Changing the value of the adjusters in this manner is a spreadsheet exercise that should not require a great deal of time. A computer analysis will need to be run to figure out how to “adjust” the standardization. CMS would run the simulation before and after this change in adjuster values. The ratio between total payments before and after the change (as seen in the impact file they already produce) will allow the calculation of standardization adjustment which will return total payments to the level they would have been without the change.

Marilyn Tavenner

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In the same manner, CMS can fix the incorrectness due to the leakage of adjuster volume by creating the following experiment. Attempt to reduce total payments by \$10 per treatment using the current standardization. Using the current standardization, this translates into a base-rate reduction of $(\$10) \cdot (.99) \cdot (.98) \cdot (.9407) = \9.13 . Then run a full-system impact run and produce the impact table. Calculate the actual reduction in total payments, which will be less than $(\$10) \cdot (.98) = \9.80 since the MIPPA cut was not designed to be paid back out. The ratio $(\$9.80) / (\text{TotalPayment}_{\text{EXPERIMENT}})$ is the standardization correction factor that resolves the issue with frequencies of adjusters.