KIDNEY CARE PARTNERS

August 31, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G2
200 Independence Avenue, SW
Washington, D.C. 20201

RE: CMS-1352-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for All Medicare Providers; Proposed Rule

Dear Ms. 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).[1] KCP is an alliance of members[2] 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).

KCP supports many aspects of the Proposed Rule. Specifically, the community appreciates that CMS recognizes the need to modify the outlier policy, provides an update to the base rate, and proposes to maintain the transition adjustor at zero. We also are pleased that CMS has proposed to continue using the Payment Year (PY) 2014 structure for the PY 2015 Quality Incentive Program (QIP). KCP seeks to work in partnership with CMS to develop a strategic vision for future years of QIP.

In terms of the PPS (Part 1 of this letter), we unfortunately are limited in our ability to provide comprehensive and meaningful comments due to the lack of a rate-setting file, which would enable the kidney care community to communicate constructively with the Agency in regard to the ESRD PPS. As we have previously noted, without the rate-setting file, stakeholders cannot analyze fully the impact of the Proposed Rule because of limited available data. The Agency should provide for greater transparency in the rulemaking process by providing a rate-setting file, as it does for other Medicare providers. The characteristics of a file adequate to evaluate the policies set forth in the Proposed Rule would include:

- Dialysis facility claims for all patients receiving dialysis treatments during the year upon which rates are based (specific to the NPRM 2013) linked to an encrypted patient identifier and to the facility providing the services;

[1] *See* 77 Fed. Reg. 40952 (July 11, 2012).

[2] *See* Appendix A for list of members.

- Dates of service so that services can be sequenced;

- The data used by CMS's contractor, the University of Michigan Kidney Epidemiology and Cost Center, to develop and assign case-mix adjustors when any changes are proposed to adjustors or new adjustors are proposed;

- Patient-level data, including a unique flag for each specific case-mix, comorbidity, low volume, start of dialysis, home dialysis training, or other payment adjustors assigned by CMS as the basis for rate setting. This flag should be associated with the treatments to which it will apply. This is particularly important for the payment adjustors that are temporary and associated with an acute event in time and those that will apply for a limited time period;

- The start date for dialysis to calculate the number of adjusted treatments; and

- Outlier payments should also be flagged.

CMS provides such files to other providers with prospective payment systems. For example, it has provided such data to hospitals and skilled nursing facilities. We do not understand why there continues to be no release of such a file for ESRD because, prior to the implementation of the PPS, the Agency provided a rate-setting file for ESRD as well. We urge CMS to release these data prior to the release of the final rule.

In terms of the QIP (Part 2 of this letter), we are again pleased that CMS has modified the QIP in many of the ways we have historically suggested; however, there continue to be some unresolved issues. As described in more detail below:

- For the QIP overall, CMS should:
  - Establish a consistent minimum set of exclusions that apply to all structural reporting measures;
  - Adopt measure specifications and data definitions that are clear and precise through the rulemaking process and provide a regular process for collecting and responding to questions related to the interpretation of measure specifications and data definitions; 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 to allow stakeholders to have the opportunity to assess the impact on facilities.

- For PY 2014, CMS should:
  - Change the mineral metabolism reporting requirement by adopting appropriate exclusions that CMS already defined during an earlier National Quality Forum (NQF) endorsement cycle;
  - Adjust the weighting for the composite vascular access measure to eliminate the disincentive to provide clinically appropriate grafts;
  - Refine the reporting requirements implementing the ICH CAHPS measure to minimize the burden on patients and providers; and
  - Provide clarity as to the rate of improvement assumed to establish the distribution of penalties.

- For PY 2015, CMS should:
  - Maintain the proposed PY 2015 QIP domains, but modify the measures specifications and weights to align them better with high quality clinical care; and
  - Modify the methodology used to calculate the total performance score.

- 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.

Part 1: KCP Comments on the ESRD PPS CY 2013 Proposed Rule

I. CMS Should Modify the Proposals for the CY 2013 ESRD PPS before Finalizing Them in the Final Rule.

KCP remains concerned about some specific aspects of the ESRD PPS for CY 2013 that the Agency has not addressed. We are concerned that the Agency has not responded to several of our previous comments on the past two the ESRD PPS proposed rules and which we reiterate in this letter. Those include concerns about the documentation requirements of the comorbidity case-mix adjustors, the need to modernize the ESRD cost report, and technical concerns related to the establishment of the base rate. Specifically, we also recommend that CMS:

1. Recalculate the standardization factor using 2011 data, similar to its recalculation of the outlier parameters and the correction to the transition adjustment;

2. Suspend the use of the comorbidity case-mix adjustors unless or until the Agency provides dialysis facilities and providers with information necessary to document these adjustors;

3. Protect the integrity of the ESRD PPS bundle by gathering the true cost of providing dialysis items and services through the cost report;

4. Provide a clear process for expanding the bundle and incentivizing new technology;

5. Address technical calculations related to the base rate; and

6. Recognize the impact the bad debt changes will have on Medicare margins.

Finally, and of utmost importance for CY 2014, we believe that it is incumbent on the Agency to provide guidance as to how it plans to incorporate oral-only drugs into the ESRD bundle to allow for a transparent and cooperative process with the kidney care community.

A. CMS Should Use Data from 2011 to Re-calculate the Standardization Factor to Avoid the Inappropriate Loss of Funding for this Beneficiary Population in CY 2013.

Even though KCP supports the development of the ESRD PPS base rate, we remain deeply concerned that while CMS has adjusted the outlier parameters based upon more recent data and experience, it has not applied the same approach to the standardization factor for the base rate. Using impact files released with the CY 2012 final and CY 2013 proposed rules, The Moran Company has calculated that by not adjusting the standardization factor, the base rate is reduced by approximately $3.12 per treatment (or 1.25 percent), as shown below. When finalizing the CY 2013 base rate, CMS should use 2011 claims, consistent with its recalculation of the outlier parameters, and recalculate the standardization factor to ensure that there is no inappropriate reduction in the base rate.

Comparison	CY 2012 Policy using pre-PPS Data (as released in CY2012 Final Rule)	CY 2012 Policy Using 2011 Data (post-PPS Implementation)	$ Leakage per Tx	% Leakage per Tx
Raw – All Facilities	$ 252.51	$ 249.39	$ 3.12	1.25%
Excluding Facilities which were not in 2012 Impact File	$ 252.55	$ 249.34	$ 3.21	1.29%
After Incorporating Decreased Outlier Thresholds, and excluding Facilities not in 2012 Impacts File				
All Facilities	$ 252.55	$ 250.40	$ 2.15	0.86%
Excluding Facilities which CMS incorrectly predicted Low Volume Status	$ 252.35	$ 250.31	$ 2.04	0.81%
Only Facilities Paid Under 100% PPS (excluding transitioning facilities)	$ 252.64	$ 250.98	$ 1.66	0.66%
100% PPS, Correct Low Volume Prediction by CMS	$ 252.44	$ 250.89	$ 1.55	0.62%
100% PPS, LDO	$ 251.19	$ 249.68	$ 1.51	0.60%
100% PPS, Regional Chain	$ 254.18	$ 252.62	$ 1.56	0.62%
100% PPS, Independent	$ 257.66	$ 254.65	$ 3.01	1.18%
100% PPS, Hospital-Based	$ 259.76	$ 258.88	$ 0.88	0.34%
100% PPS, Rural	$ 238.28	$ 237.15	$ 1.13	0.48%
100% PPS, Urban	$ 255.48	$ 253.68	$ 1.80	0.71%
100% PPS, Majority Pediatric	$ 288.30	$ 278.70	$ 9.60	3.44%

The current standardization factor is based upon estimates made by the contractor that designed the ESRD PPS using 2007 claims data. Part of the estimate is based upon estimates as to how adjustors would be claimed by providers. Based upon The Moran Company's analysis of more recent data and the experience of KCP members, it is clear that the contractor's estimates do not reflect how the adjustors are being used. We have outlined the reasons for under-funding of the comorbidity case-mix adjustors. In addition, The Moran Company has identified errors in the identification of low volume facilities likely to be eligible for that adjustor. These problems lead to a significant difference between the proposed base rate and what it would be if these problems were addressed.

It is critically important to address this problem to avoid perpetuating the loss of funding. Thus, KCP recommends that CMS use 2011 data to recalculate the standardization factor. This modification is consistent with the Agency's approach to addressing data differences between anticipated and actual application of the outlier policy. When addressing this problem, we also ask that CMS explain its approach to the standardization of payments each year and strive to use the best data available to ensure that its calculations reflect the actual mix of adjustors that providers claim during a particular year.

B. CMS Should Address Concerns with Documenting Co-Morbid Case-Mix Adjustors.

Consistent with our prior comment letters, KCP remains deeply concerned that CMS has not acknowledged the difficulties dialysis facilities have in obtaining the required documentation to allow them to claim the comorbid case-mix adjustors. The Agency must be as aware of the differential between

what was anticipated versus actually paid for comorbidity case-mix adjustors as it is aware of the differential with regard to the outlier payments. Because of the difficulty in claiming the adjustors, critically important funding is being removed from the program. If a facility or provider were to claim an adjustor without sufficient documentation, it would risk substantial sanctions and punishment under the federal fraud and abuse laws. Simply put, these adjustors do not accurately reflect the care patients receive at dialysis facilities and do not account for the current practices that facilities use to collect information about their patients.

To review our previous comments, it remains true that:

- Dialysis providers have historically not recorded many of the co-morbid case-mix adjustor 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;
- Facilities and providers would need at least two years of access to 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 it can be obtained at all, often requires facilities to re-bill their claims.

These hurdles are significant and often frustrate both dialysis facilities and providers when they submit their claims for payment.

In light of the fact that the Agency has not responded to this reality and given the ongoing economic challenges facilities will face in light of potential sequestration and reductions to allowable bad debt, CMS should suspend the use of the current comorbidity adjustors for PY 2013 until it can determine ways that providers and facilities can have access to the requisite data.

C. CMS Should Reform the Cost Report to Address the Inappropriate Restrictions on Medical Director Fees, Inequitable Treatment of Bad Debt, and Cost of Supporting ESRD Networks, as well as Recognize the Cost of Items and Services that are Likely To Be Added to the Bundle.

While we appreciate that the Agency has already made some changes to the ESRD cost report, we are disappointed that these changes do not address the areas most critical to ensuring the appropriate payment for providing care to beneficiaries with kidney failure. Cost reports provide the foundation for setting payment rates and margin analyses that affect updates to account for inflation. If the cost reports do not reflect the true cost of providing services and supplies, it will be next to impossible to establish payment rates and evaluate annual updates in a manner that is accurate and protects beneficiary access to life-saving dialysis services.

The cost reports also should reflect the same core principle of the new PPS – providing flexibility to allow for innovation. An overly restrictive approach to the cost reports would eliminate the Agency's

goal of having the new PPS help drive innovation in this sector of health care. Specifically, we believe that cost reports: (1) must be useful and accurate tools for providers, CMS, the Medicare Payment Advisory Commission (MedPAC), the Congress, and other analysts; (2) should include all the costs providers incur when providing care under the PPS; and (3) should reinforce clarity and consistency. To this end, we urge CMS to use the Final Rule as an opportunity to finally address the concerns the kidney care community has raised about the limitations on medical director fees, the treatment of bad debt, the acknowledgment of network fees, and the recognition of new items or services that are likely to be added to the bundle in the future.

1. CMS Should Eliminate the Artificial Limitation on Medical Director Fees

First, CMS should eliminate the restriction on medical director fees. The allowable amounts are based upon the costs associated with internists and do not reflect the true cost of hiring medical directors, who are primarily nephrologists. The current limitation does not provide CMS and other policymakers with an accurate picture of the true cost of providing care.

The Conditions for Coverage for End-Stage Renal Disease Facilities (CfC)[3] 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."[4] If such a physician is not available, another physician may direct the facility, subject to the approval of the Secretary.[5] Under the Agency's own regulations, nephrologists are the preferred candidates for serving as dialysis facility medical directors, even if CMS 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 nephrologists.

Yet, 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.

A 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.[6] Given the legal obligations to provide compensation at the fair market value, there is no need for a limitation.

Although it is true that CMS imposes limitations on the allowable costs of medical directors with regard to other providers, it also allows for more flexibility. For example, hospitals that demonstrate that they cannot recruit a physician at the RCE amount may request an exception to the limitation.[7] In

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[3] *See* 42 C.F.R. Pt. 494.

[4] *Id.* at § 494.140(a)(1).

[5] *Id.* at § 494.140(a)(2).

[6] *See generally,* 69 Fed. Reg. 16092 & 42 C.F.R. § 411.351.

[7] 42 C.F.R. § 415.70(e).

addition to not recognizing that the market compensation rate may exceed the RCE, CMS does not recognize that the RCE for internists is not equivalent to compensation for nephrologists.

The medical director compensation 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 does not accurately reflect the true cost of hiring medical directors, calculations of payment rates and inflationary updates will artificially underfund the program.

Although we have raised these concerns frequently, CMS has yet to address them. Thus, KCP strongly urges CMS to eliminate the limitation and allow for an exceptions process (similar to that recognized under Part A).

2. CMS Should Eliminate the Inequitable Treatment of Bad Debt in the Cost Report

KCP urges CMS to treat all dialysis facilities consistently when it collects data through the cost report. Implementing the Congressional provisions that modify the allowable bad debt policy provides CMS with the opportunity to review its bad debt policies and level the playing field among all providers. In the case of *Kidney Center of Hollywood v. Shalala*,[8] the U.S. District Court for the District of Columbia Circuit determined that use of a cost cap on bad debt only in the context of outpatient dialysis was arbitrary and capricious. As a result of this court case, certain dialysis facilities are no longer subject to the bad debt cost cap. Instead, they are reimbursed at the payment level applicable to hospitals and other providers that file cost reports. KCP strongly urges CMS to treat all dialysis facilities in the same manner and pay them for their qualifying bad debt at the percentage of incurred costs applicable to the time period of the cost report under 42 C.F.R. § 413.89. Historically, that rate was 70 percent. We recognize that Congress has changed this amount through legislation. However, this change makes it even more important to provide a level playing field for all dialysis providers by eliminating the cost cap for bad debt and follow the rules that apply to other Medicare providers.

3. CMS Should Recognize the Cost Associated with Supporting the ESRD Networks

Currently, the cost report fails to recognize the fifty-cent per treatment fee removed from payments that funds the work of the ESRD networks. Mandated by statute, 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 collect data on it. Therefore, we urge the Agency to add a line item recognizing this cost to the ERSD cost report.

4. CMS Should Permit Facilities to Itemize in a Consistent Way Costs of Items or Services that, While Currently Not Covered, Could Be Added to the ESRD Bundle in the Future

Cost reports play a critical role in setting appropriate reimbursement rates and evaluating the need for updates to account for inflation. To serve as the foundational data source for these calculations, cost reports must provide accurate information on the cost of providing all items/services required to furnish

[8] 133 F.3d 78 (D.C. Cir. 1998).

high-quality dialysis services to beneficiaries. The policies that underlie cost reports should encourage efficiency and innovation, not stifle them.

To accomplish these goals, there must be a transparent, straightforward process for recognizing changes in the PPS market basket of items/services. We strongly recommend that CMS outline the process it plans to follow in incorporating new or innovative items/services into the cost report.

Additionally, because CMS has stated that the expanded bundle in the PPS should provide facilities with new flexibility in the care they provide, we also encourage CMS to allow facilities to report items/services even if they are not technically covered. There is some precedent in the hospital cost report for reporting such costs. Following this path would provide better incentives for coordinating care and improving quality, such as creating incentives to provide nutritional supplements.

When new or innovative items/services become available, CMS should allow for their immediate recognition on the cost report. Doing so would permit the Agency to collect data as early as possible about the adoption of these new or innovative items/services. These data could lead to more rapid modification of payment rates and avoid a 2-3 year lag period between the introduction of such an item/service and its incorporation into the PPS.

Although KCP recognizes that CMS's primary interest in collecting cost data is evaluating the items/services it covers, cost reports also serve as a data collection tool that can provide the Agency with useful information about trends in dialysis care. For example, MedPAC has consistently noted the need to improve nutritional outcomes of beneficiaries. If dialysis facilities could provide nutritional supplements to beneficiaries, outcomes would improve and Medicare would ultimately save money. CMS should track the costs dialysis facilities incur for providing these services through the cost report. It would then have the necessary data to evaluate the true cost of providing care because all items/services would be included in the data.

Thus, KCP urges CMS to improve the accuracy of the cost report to ensure that new or innovative items/services are incorporated into the cost report data as quickly as possible and to develop a transparent and straight-forward process that can serve as the basis for future modifications to covered items/services and payment rates.

D. CMS Should Protect the Integrity of the ESRD PPS Bundle by Addressing How It Plans to Add New Items or Services to the PPS Bundle and by Incentivizing the Development and Adoption of Technology

Currently, there is no defined process to provide transparency as to how new items or services will be added to the bundle. Another related area of concern is how the bundle will incentivize the adoption of new technologies without undermining the funding of the base rate. Addressing these concerns will provide important transparency and protect the integrity of the ESRD PPS for the future.

1. CMS should establish a transparent process for adding existing items and services to the bundle.

KCP continues to encourage the Agency to set forth clearly the criteria and process it will use to determine whether or not to add new items and services. To ensure that the PPS continues to serve the needs of patients, it must be clear how the Agency plans to expand the bundle of items and services in the future. The criteria and process used should be open and transparent and should account for the costs of such additions in the base rate.

We urge CMS to state that it will rely upon notice and comment rulemaking to expand the scope of the bundle and not rely upon guidance, which provides no formal opportunity for input from the kidney care community. Expanding the bundle would have a substantial economic impact on the base rate and adjustors; thus, it should be evaluated fully as part of the regulatory impact analysis that the Agency must undertake within rulemaking before such changes are adopted. While the flexibility of guidance may make it an attractive alternative, it would not allow for the predictability that facilities need for operating effectively and efficiently. Thus, we encourage CMS to state explicitly that it will use notice and comment rulemaking rather than some other approach for making modifications to the ESRD PPS bundle.

2. CMS should incentivize the development of new technology in this sector by creating a technology adjustor that is not budget-neutral.

Protecting the integrity of the bundle includes providing incentives for the development of new technologies. To accomplish this goal, KCP recommends that CMS establish a new technology adjustor that would allow for additional payments in a non-budget neutral manner. Encouraging innovation by adding new money to the ESRD PPS would for the first time create incentives for innovation in an area that historically has seen few changes.

CMS has sufficient legal authority under MIPPA to establish such an adjustor. Specifically, the Agency may "include such other payment adjustments as the Secretary determines appropriate."[9] As we have raised in previous letters, the Ambulatory Surgical Center (ASC) context, as well as hospital outpatient payments, provide precedent for the Agency using general authority to establish a new technology adjustor.

Establishing a new technology adjustor is the right policy decision because of the need to incentivize the development of new technologies in this sector. Beneficiaries receiving dialysis services should not be left behind. New technologies can lead to better diagnoses, enhanced treatment options, and ultimately better outcomes for patients. The historically narrow margins and lack of an annual update resulted in little focus on this sector. Margins remain narrow, as MedPAC has recognized. Without an adjustor recognizing the additional cost associated with adopting new technology, those who develop new items and processes may not find sufficient incentive to move forward with such work.

Consistent with our previous comment letter, KCP recommends that a new technology adjustor contain the following elements:

- The adjustor should allow for new money to be incorporated into the program. It should not be budget neutral given the already narrow margins and problems with a loss of funding related to the current adjustors, as noted throughout this letter.

[9] 42 U.S.C. § 1395rr (b)(14)(D)(iv).

- The adjustor should be an add-on to payment amounts, similar to the drug add-on adjustor.

- The adjustor should apply to items and services (meaning drugs, devices, other items, and procedures or services).

- The adjustor should be limited to only truly "new" items or services that have been approved by the Food and Drug Administration or the appropriate specialty society and are innovative. It should not include replacement items or services.

- Manufacturers should be responsible for applying for and providing the data supporting an application for a new technology add-on.

- The amount of the adjustor should be set initially using industry data (similar to, but not necessarily identical to, the process used in the APCs). For drugs, it would be set using ASP+6 percent or WAC+6 percent, if no ASP is available, similar to other payments for new technology in the hospital and physician office settings.

- The amount of the add-on should be 100 percent of the incremental amount by which the new technology increases the cost of providing services to a beneficiary above the cost of doing so without the new technology.

- The add-on should be available for 2-3 years.

- CMS headquarters should oversee the add-on adjustment, not the carriers.

- CMS should track the new technology costs through the ESRD cost report.

- CMS should set forth a process for incorporating new technology into the PPS bundle that accounts for the costs incurred for providing it at the time the new technology is incorporated.

We look forward to working with the Agency to develop such an adjustor.

E. CMS Should Address the Series of Technical Issues with the Calculation of the ESRD PPS Base Rate that Remain Unresolved

KCP appreciates CMS's recognition of the need to adjust the outlier payment parameters. We strongly encourage CMS to finalize the modifications to the outlier parameters. In terms of the other technical issues raised by the Proposed Rule, KCP strongly urges CMS to:

- Refine the home dialysis training add-on by updating it annually;
- Maintain the critically important AY Modifier to protect patients;
- Provide more transparency in its monitoring activities; and
- Resolve technical errors that are estimated to result in $1.50 being removed from the base rate.

1. CMS should update the home dialysis training adjustor.

Consistent with our previous comments, KCP strongly encourages CMS to update the home dialysis training add-on. Simply put, the update applied to the base rate must also be applied independently to the home dialysis training adjustor because it is a fixed dollar amount. Because the home dialysis training adjustor is not part of the base rate, the annual update mechanism does not automatically apply to it. Applying the update to this adjustor directly would address this problem. Unless updated, this adjustor will continue to lag behind the costs it was defined to capture. Ensuring that the adjustor reflects inflationary costs would reflect CMS's commitment to encouraging expanded use of home dialysis modalities.

2. CMS should maintain the AY modifier to ensure that beneficiaries with kidney failure can continue to receive crucial health care services in the dialysis setting even if they are unrelated to their dialysis treatments.

KCP appreciates CMS's adoption of the AY modifier to distinguish between dialysis-related services and non-dialysis-related services provided in the dialysis setting. The AY modifier remains extremely important to beneficiaries with kidney failure because it protects patient access to services without increasing the number of physician visits for which they must pay and injections that they must receive. Limiting the number of injections is an important factor in preserving patients' vascular access and eliminates costs associated with additional physician office or outpatient hospital visits.

We share the Agency's interest in ensuring that the modifier is applied appropriately. However, we are concerned that the preamble implies that there has been some abuse of the modifier, yet does not provide sufficient data to describe the scope or breadth of the problem. Because of the substantial negative impact on patients, KCP strongly urges CMS not to eliminate the AY modifier. Rather than adopt such an extreme approach, we encourage CMS to share the data that have led to its concern with the kidney care community and to develop guidance or other options to ensure the appropriate application of this important modifier.

Additionally, KCP supports expanding the AY modifier to include Daptomycin. As the preamble acknowledges, it may be appropriate in certain circumstances to provide this drug during the dialysis session to assist in preserving patients' vascular accesses. We recommend that the Agency finalize this policy in the final rule.

3. CMS should be more transparent about its monitoring activity.

KCP supports CMS's efforts to monitor the implementation of the ESRD PPS. The kidney care community continues to support outcome data collection efforts to evaluate the effect of payment policy changes. To improve the monitoring program, CMS should increase the transparency of the program. This open approach would clarify the metrics the Agency reviews as part of this effort, as well as how it considers recommendations from the community to allow the monitoring program to evolve over time. Additionally, we encourage the Agency to make the data available to dialysis facilities, as well as to the overall community, to allow for a more complete assessment of the program.

4. CMS should address technical concerns raised in 2011 and 2012.

Finally, KCP encourages CMS to address the series of unresolved errors 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. In sum, we urge CMS to address the following discrepancies identified in previous comment letters:

- 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.[10]
- 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.
- The Moran Company's calculations of payments per treatment for components of the 2007 MAP are mostly higher than those reported by CMS.[11]
- 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 in laboratory test payments to facilities in the 72x claims. If these payments are not included in the 2007 MAP and repriced 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 injectables" 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.

F. CMS Should Consider the Impact of the Statutory Bad Debt Changes on the ESRD Program

While KCP understands that CMS proposes to implement the statutorily required bad debt reductions, we are deeply troubled by the decision to apply bad debt reductions to this aspect of the

[10] *See* Appendix B; *see also* 75 Fed. Reg. at 49068-69.

[11] *See* Appendix B.

Medicare program. Medicare cuts disproportionately affect the kidney care community because dialysis providers are among the most Medicare-intensive provider types. More than 80 percent of dialysis patients are fee-for-service beneficiaries and more than 40 percent of these patients are dually eligible for Medicare and Medicaid. Because of steep budget cuts, more than 20 states no longer reimburse providers for the full 20 percent coinsurance, meaning that dialysis providers receive less than the full Medicare reimbursement rate in the case of most dually eligible beneficiaries. Thus, while it might appear that cuts, such as the reduction in bad debt, that apply across multiple Medicare providers seem equitable, it actually will result in dialysis facilities being hit the hardest.

There is also very little margin available to sustain a two percent cut due to potential sequestration. MedPAC projects that dialysis facility margins for 2012 will be 2.7 percent. This projection does not take into account the reduction in allowable bad debt or the legislated 2 percent sequestration, both of which will severely reduce, if not eliminate, the Medicare margin.

KCP encourages CMS to work with the kidney care community and the Congress to preserve funding for the Medicare ESRD program to maintain the overall successful implementation of the ESRD PPS. Cuts to the program jeopardize the ability of providers to cover the cost of providing life-sustaining dialysis services to Americans with kidney failure. One way CMS can do this is to take sequestration into account when calculating bad debt. If there is sequestration, then there needs to be a reduction in the revenue added to the bad debt calculation. Pre-sequestration amounts should not be used.

II. CMS Should Signal How It Plans To Incorporate Oral-Only Drugs into the ESRD PPS for CY 2014 in the Final Rule

While KCP appreciates that CMS focuses the Proposed Rule on CY 2013, we strongly urge the Agency to provide some indication in the final rule as to how it plans to incorporate oral-only drugs into the ESRD PPS in CY 2014. Specifically, we request that CMS clarify that it will use the most currently available data (which we estimate will be CY 2011 data) and use a methodology to calculate the amount added to the base rate that reflects the cost of acquiring the drugs, the utilization of the drugs, and the cost of providing the drugs. In addition, we urge CMS to clarify in the final rule that the oral-only drugs that will be included in the ESRD PPS for CY 2014 will be limited to drugs to control calcium and phosphorous levels.

Given the importance of adding the right amount to the base rate, we urge CMS to provide clarity in the final rule as to how it plans to incorporate oral-only drugs into the ESRD bundle. Providing such clarity will allow for transparency and permit the kidney care community the opportunity to work cooperatively with the Agency to ensure that the base rate does not inadvertently create a disincentive for providing these critically important drugs to beneficiaries living with kidney failure.

A. In the CY 2013 Final Rule, CMS Should Use the Most Currently Available Data to Determine the Utilization of Oral-Only Drugs for Inclusion in the ESRD PPS Bundle for CY 2014

KCP urges CMS to clarify that it will use the most currently available data to determine the utilization of oral-only drugs for inclusion in the ESRD PPS bundle in the Final Rule to address concerns raised by a random statement in a recent Government Accountability Office (GAO) report. In this report,[12] a CMS official indicated that the Agency is

[12]GAO, "End Stage Renal Disease: CMS Should Assess Adequacy of Payment When Certain Oral Drugs Are Included and Ensure Availability of Quality Monitoring Data" GAO-11-365 (2011).

> limited to using data on payments under Medicare's Part D program to account for oral-only ESRD drugs in the bundled payment. In particular, CMS officials stated that federal law limits the agency to using data on payments under Medicare for dialysis and related items and services such as oral-only ESRD drugs in 2007, 2008, or 2009 to calculate the bundled payment for dialysis care.[13]

Attorneys for KCP have reviewed the relevant statutory authority and case law and concluded that it appears highly unlikely that CMS would be limited to using data from 2007, 2008, or 2009 for either cost or utilization. In addition, the Agency is not limited to using only Part D data as its data source for estimating the appropriate payment amount to add to the PPS base rate. Case law specifically requires CMS to use the best available data, and both the GAO and CMS have concluded that the historical data and Part D data would not be the best data available.

1. The Authorizing Statute Does Not Restrict CMS to Using Data from 2007, 2008, or 2009

The statement described in the GAO report suggests that CMS must use data from 2007, 2008, or 2009 to establish the payment rate for oral-only drugs. This conclusion is likely based in the language of section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). In addition to establishing a case-mix adjusted bundled PPS for "renal dialysis services"[14] beginning on January 1, 2011,[15] it requires the Secretary to ensure that "the estimated total amount of payments under this title for 2011 for renal dialysis services shall equal 98 percent of the estimated total payments for renal dialysis services . . . that would have been made under this title with respect to services furnished in 2011 if such system had not been implemented."[16] In making this estimate, "the Secretary shall use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization."[17]

This interpretation is incorrect. In determining a payment amount for oral-only drugs, CMS must consider the cost to providers and the utilization of the drug. First, the section does not apply to data used to calculate payment costs. Second, even though it mentions utilization, the provision does not apply to payment amounts established after 2011.

When interpreting a statute, one must start with the plain meaning of the text.[18] If the plain meaning of the text is clear, no further analysis is required.[19] In this case, the text of MIPPA is clear. The

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[13] *Id.* at 19.

[14] "Renal Dialysis Services" includes: "other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this title, and any oral equivalent form of such drug or biological." *See* 42 U.S.C. §1395rr(b)(14)(B)(iii). CMS has interpreted this provision to include oral-only ESRD-related drugs that were provided under Part D.

[15] 42 USC §1395rr(b)(14)(A)(i).

[16] *Id.* §1395rr(b)(14)(A)(ii).

[17] *Id.*

[18] *See Regions Hosp. v. Shalala*, 522 U.S. 448, 457 (1998).

limiting provision speaks only to utilization and not to cost to providers; thus, CMS is not limited as to the base year for establishing the cost to the provider component of the payment amount.

Similarly, a plain reading of the text also indicates that CMS is not restricted to using the lowest per patient utilization data from 2007, 2008, or 2009 in the utilization portion of the payments for renal dialysis services added to the bundle after 2011. The limiting language applies only to the estimated total amount of payments that CMS makes in 2011 for renal dialysis services. Because CMS delayed the implementation of the oral-only drugs into the bundle until 2014, the estimated amount of payments will be made for 2014, not 2011. Thus, the limitation does not apply to the calculation because these payments will be made after 2011.

Contrary to some assertions, CMS is not restricted by the fact that it "included" oral-only drugs in the ESRD PPS bundle in 2011 and delayed implementation until 2014. There is no language in MIPPA that makes such a distinction and, thus, as noted, the statute's silence requires CMS to exercise its discretion in determining how to address pricing of oral-only ESRD-related drugs beginning in 2014.

In addition, the limitation does not apply because oral drugs were not furnished in 2011. The provision applies only to services "furnished in 2011 if such system had not been implemented." Prior to the implementation of the ESRD PPS, oral-only drugs were not furnished as renal dialysis services. Even if one were to argue that these drugs were provided under Part D (thus "under this title"), these drugs were not defined as "renal dialysis services" nor "furnished" by dialysis facilities – the only providers being paid under the new PPS – in 2011.[20] Finally, given that only two-thirds of ESRD beneficiaries had Part D coverage during the period in question, oral-only ESRD drugs "furnished" to them (and the remaining beneficiaries) were not paid for fully, if at all, "under this title."

Even if CMS viewed the statute as ambiguous, it would not be required to follow the limitation because it would have the authority to exercise its own discretion.[21] When a "statute does not specify how the Secretary should construct the [payment rates], nor how often she must revise [them]," Congress has "through its silence delegated these decisions to the Secretary."[22] As described in detail below, CMS must exercise this discretion within the constraints of how the courts interpret it. Case law is clear that CMS must exercise its discretion in a way that relies upon the best data available. Both the GAO and CMS acknowledge that utilization data from 2007, 2008, or 2009 is neither the most recently available nor the most accurate at predicting the true utilization of oral-only ESRD drugs.[23]

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[19]If "the intent of Congress is clear" regarding "the precise question at issue . . . that is the end of the matter." *Id.* (quoting *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 842 (1984)).

[20]The GAO noted that the four large dialysis organizations it surveyed had provided some oral drugs, including some oral-only ESRD drugs, to 2 to 22 percent of their patients, including some Part D participants, through arrangements with community or mail-order pharmacies. *See* GAO Report, *supra* note 1, at 15. By contrast, none of the 16 small dialysis organizations in its review provided oral-only ESRD drugs to Medicare beneficiaries in 2010. *Id.*

[21]*See County of Los Angeles v. Shalala*, 192 F.3d 1005 (D.C. Cir. 1999) (finding statute ambiguous because "the phrase 'payments made' hardly conveys a single meaning").

[22]*Methodist Hospital of Sacramento v. Shalala,* 38 F.3d 1225, 1230 (D.C. Cir. 1994) (emphasis added).

[23]*See generally,* GAO Report, *supra* note 1; 75 Fed Reg. at 49033.

2. CMS Must Use the Best Available Data for Establishing the Payment Amount for Adding Oral-Only Drugs into the ESRD PPS Base Rate

Given that the authorizing statute does not require CMS to limit the base year data to the lower of 2007, 2008, or 2009, the Agency must exercise its discretion in determining the appropriate payment amount to account for the addition of oral-only drugs to the bundle in 2014.[24] CMS could seek to use the 2007, 2008, or 2009 data and inflate it forward or to look to Part D data – both the negotiated price to establish ingredient costs and utilization. If it chose either path, the Agency would not be following the legal precedent requiring it to use the best available data given that GAO and the Agency have raised concerns about the Part D data set.

CMS must exercise its discretion consistent with judicial precedent,[25] which in this case requires it to use the best available data. In *Methodist Hospital*, the D.C. Circuit noted that, where the Agency had used "the most reliable data available" in determining a regional wage index, it would not be required to recalculate Medicare payments for past years based on corrected data. Similarly, in *Mt. Diablo Hospital v. Shalala*, the court found that, where the Agency used "the most reliable data available at the time," it would not be ordered to recalculate the wage index even though it failed to account for part-time workers.[26] "These cases teach that the accuracy of any particular index (or) payment . . . cannot be weighed in a vacuum, but must instead be evaluated by reference to the data that was available to the agency at the relevant time."[27] Thus, if the Secretary intended to ignore certain data, she was obligated to "provide a reasoned explanation" for that rejection.[28] The D.C. Circuit likewise pointed out in *Cape Cod Hospital v. Sebelius* that, once the Secretary is made aware of data inaccuracies, she may not continue to rely on erroneous data.[29]

If the Agency's interpretation runs afoul of these principles, the courts will not defer to it. CMS cannot avoid its obligation to examine all relevant data, especially when it has already concluded that the data at hand may not be appropriate. "Ignoring the existence of more reliable data that is available before

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[24] *Chevron*, 467 U.S. at 844.

[25] *Baystate Med. Ctr. v. Leavitt*, 545 F. Supp.2d 20, 41 (D.D.C. 2008) (quoting *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1230 (D.C. Cir. 1994)); *see also Regions* at 463 (emphasizing the difference between a one-year determination and "a base-year determination to be carried forward into the unlimited future").

[26] *See* 3 F.3d 1226, 1233 (9th Cir. 1993); *see also Alvarado Comm. Hosp. v. Shalala*, 155 F.3d 1115, 1125 (9th Cir. 1998) (approving standard requiring "the most reliable data available," and noting that the most recent data available was "highly significant to an accurate determination"); *cf. Southeast Alabama Med. Ctr. v. Sebelius*, 572 F.2d, 912, 921 (D.C. Cir. 2009) (in estimating total national costs to develop wage index, "HHS only had to possess sufficiently valid and reliable aggregate data – from whatever source – on which to base its figures. For this purpose, HHS found, statistics developed by outside entities . . . were appropriate.").

[27] *Baystate,* 545 F. Supp.2d at 41.

[28] *Id.* at 47; *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 30 (1983) (Agency must "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made").

[29] *See* 630 F.3d 203, 214-15 (D.C. Cir. 2010) (noting that any refusal to correct the wage index that was based on the inaccurate data going forward would be "impermissible").

the [payment] is finally determined . . . simply cannot be reconciled with the standard of reasoned decisionmaking."[30]

> [U]se of the best available data is firmly recognized by the case law and, indeed, by the [CMS] Administrator to be essential to the standard of reasoned decisionmaking in Medicare reimbursement decisions. It is, as a practical matter, well within that which can "reasonably be delivered" by the agency.[31]

Given that the courts have clearly established an affirmative duty to correct errors once discovered, it would be inconsistent to conclude that the Agency could knowingly base initial payments for oral-only ESRD drugs solely on incomplete and inaccurate data.

CMS has suggested that the "under this title" language of section 153(b) of MIPPA could restrict the Agency to using Part D data because oral-only drugs were mostly reimbursed under that program prior to 2014. This conclusion would also be erroneous because, as noted, that language applies only to payment rates set in 2011.

Even if the language were ambiguous as to the time-limited nature of its applicability, CMS still could not limit its review of data sources to Part D data. If CMS intends to utilize only Part D data from a year that is not indicative of the actual utilization of these drugs, the Agency must give a reasoned explanation for rejecting other potentially relevant and valuable data sources.[32] Both the Agency and the GAO have concluded that the Part D data are not the best available data.[33] The Agency's rationale for not using more current data as expressed in the GAO report is not "a reasoned explanation" in light of the silence of the statute as to how CMS should establish appropriate funding for oral-only ESRD drugs if the implementation of including them were delayed until 2014, as the Agency chose to do.

This situation is analogous to that in *Caritas Medical Center v. Johnson.*[34] In *Caritas*, the court analyzed the Department of Health and Human Services' (HHS's) interpretation of statute that, on its face, provided that both the blended and reasonable cost rates for certain outpatient facilities would expire on January 1, 1999, when a PPS for outpatient services was to go into effect. Due to concerns about a potential "Y2K crisis," HHS postponed implementation of the outpatient PPS until mid-2000.[35] In the interim, the Agency published a rule that continued to apply the blended rate. The plaintiffs sued, arguing that the rule violated the plain meaning of the statute under *Chevron*.[36]

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[30] *Baystate,* 545 F. Supp.2d at 50.

[31] *Id.* at 50.

[32] *See State Farm*, 463 U.S. at 43; *Baystate*, 545 F. Supp.2d at 47.

[33] *See* GAO Report, *supra* note 1; *see also* 74 Fed. Reg. 49922, 49938, 49941-42 (Sept. 29, 2009).

[34] 603 F. Supp.2d 81 (D.D.C. 2009).

[35] *Id.* at 85.

[36] *Id.* at 87.

The court disagreed, finding that the statute was silent as to what payment method should apply in the event the PPS was not implemented by the statutory deadline.[37] Because HHS had acted to fill the resulting gap, the court examined the rule to determine whether its interpretation of the statute was reasonable.[38] It concluded that "continuing the use of existing methodologies until the PPS could take their place" was a reasonable decision that "best effectuated Congress's intent."[39]

Similarly, MIPPA is silent as to how CMS should develop payment rates in the event a component of PPS implementation is delayed. CMS delayed implementation because of concerns about using the data sources that were available in 2011. Following the analysis of *Caritas*, it would be entirely reasonable for CMS to look at or use data sources, such as pricing proxies like Average Manufacturer Price, other than Medicare Part D negotiated pricing amounts. A similar argument could be made for estimating utilization for these drugs.[40]

Even if CMS did not view the statute as silent with regard to this point, the Supreme Court often has noted that, where following the express words of a statute would lead to an unreasonable result "plainly at variance with the policy of the legislation as a whole," it will follow the purpose, rather than the literal words of the statute.[41] "Over and over we have stressed that, '[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.'"[42]

Even if MIPPA clearly and unambiguously required CMS to use Part D or Medicare-only data (which it does not), the Agency could not advance an interpretation that on its face is absurd and irrational.[43] There is no doubt that limiting the data analysis for oral-only drugs related to ERSD services would be inappropriate given the GAO's findings and report[44] that clearly outlines the incomplete nature of the Medicare-only data and how it would negatively affect the care beneficiaries would receive under the Medicare ESRD program. Instead, CMS should reasonably assume that Congress would have

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[37] *Id.* at 90.

[38] *Id.* at 91.

[39] *Id.*; *see also Hardy Wilson Mem. Hosp. v. Sebelius*, 616 F.3d 449 (5th Cir. 2010) (finding the Secretary's decision to base payment amounts pending PPS implementation on prior capped amounts reasonable even though the statutory caps had expired).

[40] *See Los Angeles,* 192 F.3d at 1021 (holding it was arbitrary and capricious for the Secretary to base outlier estimates on 1981 MEDPAR data, when she already had collected more recent, though preliminary, data since the PPS was implemented); *Alvarado,* 155 F.3d at 1122 (same). In *Los Angeles*, the D.C. Circuit agreed with the Ninth Circuit's conclusion in *Alvarado* that the Secretary's "explanation that there was no evidence of an outlier shortfall was simply not supported by the record before her and did not explain her failure to use the more recent data." *Los Angeles*, 192 F.3d at 1021 (quoting *Alvarado*, 155 F.3d at 1122).

[41] *See United States v. American Trucking Ass'n*, 310 U.S. 534, 543 (1940) (quoting *Ozawa v. United States*, 260 U.S. 178, 194 (1922)).

[42] *United States National Bank v. Independent Insurance Agents of America,* 508 U.S. 439, 455 (1993) (*quoting United States. v. Heirs of Boisdore,* 49 U.S. 113, 122 (1849)).

[43] *See, e.g, Green v. Bock Laundry Machine Co.*, 490 U.S. 504 (1989).

[44] *See generally,* GAO Report.

intended it to use the most reliable available data, had it specifically addressed the issue of bundling oral-only ESRD drugs into the base payment rate.[45]

3. Conclusion

Because the authorizing statute is silent as to how CMS must set payment amounts for oral-only drugs added to the base rate in 2014, the Agency must use its discretion to establish these payment amounts. Case law limits this discretion by requiring the Agency to use the best available data. Given both the Agency's own conclusions, as well as those of the GAO, neither data from 2007, 2008, or 2009, nor Medicare Part D data alone would be sufficient to meet this standard. Thus, CMS has sufficient authority and arguably a legal obligation to use the most recently available data and to look at data beyond Medicare Part D when establishing the payment amount for oral-only ESRD drugs when they are implemented into the ESRD PPS for 2014.

B. To Determine the Appropriate Amount to Add to the ESRD PPS Base Rate, CMS Should Adopt a Methodology that Accounts for all of the Costs Associated with Providing These Drugs

Working with The Moran Company, KCP has developed a series of recommendations as to how CMS should calculate the appropriate payment amount for oral-only drugs that would be added to the ESRD payment rate when these drugs are incorporated into the ESRD PPS.

First, CMS should measure the actual utilization on a per treatment basis. Specifically, CMS should use drug volume per treatment as the measure of utilization that is used to value the oral drugs to be included in the PPS. This approach would promote transparency and would better enable the kidney community to monitor the calculation of the value of oral drugs in the future.

Second, and as noted earlier, KCP recommends that CMS use the most recent full year of Part D data available to measure utilization defined as drug volume per treatment for those beneficiaries whose treatments are delivered at the same time that they have Part D coverage. For 2014 rates, which will be developed in 2013, the most recent full year of available data will likely be 2011.

Third, we urge CMS to implement the following parameters of methodology and ask CMS to explain the methodology it implements in detail in the final rule for CY 2013:

a) Match patients with prescription drug data to the same patients who undergo dialysis treatments during the same period. KCP recommends selecting patient months with dialysis treatments as the anchor measure and then looking at the prescription drugs for those patient months only. This means that the numerator and denominator in the calculations will be for the same patients;

b) Define utilization for a time period that is long enough to be representative of patients' complete profile of drug use. KCP recommends using a year, but the period should not be less than six months;

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[45] *See Administrators of Tulane Educ. Fund v. Shalala*, 987 F.2d 790, 797 ("The agency's belief that Congress would resist permanently ingraining misclassified and nonallowable costs in future reimbursements to health care providers can hardly be deemed unreasonable or inconsistent with the congressional purpose of erecting a new and more accurate reimbursement methodology.").

c) Reduce all drug volume to a common measure (*e.g.,* milligrams), rolling NDC level volume up so that calculations can be performed at the product level;

d) Calculate total mean drug volume for patients in the study population for the time period by individual product. Next, CMS should apply price proxies to the mean volume of each drug so it can be converted to dollars and the dollars could be added together to calculate mean ingredient value; and

e) Describe the methodology and the data "trimming" criteria used by CMS in the Proposed Rule.

Fourth, KCP recommends that CMS develop a measure of demand elasticity based on the out-of-pocket costs for Medicare Part D patients with and without low-income subsidies. KCP also recommends that CMS adjust utilization projected for 2014 based on historical utilization to account for the different mix of out-of-pocket costs under Part B.

Fifth, CMS should rely upon price proxies that reflect pharmacy acquisition costs most similar to the costs facilities will likely incur. Specifically, KCP recommends using Wholesale Acquisition Cost (WAC) for branded drugs and Average Manufacturer Price (AMP) for generic drugs. If Part D data are available not only to CMS, but also to interested stakeholders, KCP recognizes that it could be an appropriate proxy for both branded and generic drugs. It is crucial that CMS make public the price proxies at the product level for those it selects, using the most recent price proxies available, and, if AMP is selected, using 12 month rolling average AMP.

Sixth, we recommend that CMS include dispensing and administrative costs when it calculates the per-treatment value of oral-only drugs. KCP also recommends that CMS ensures the value placed on these costs is sufficient to cover medication management services in addition to routine dispensing services (*e.g,* packaging, documentation, and delivery costs).

Seventh, KCP recommends that CMS use the producer price index (PPI) to inflate data to 2014. Given that the most recently available data likely available are from 2011 and price proxies will be available for 2013, the Agency will need to project that data forward to 2014.

Finally, we encourage CMS to work with the kidney care community to identify the factors that could influence adherence and utilization so the Agency will be prepared to monitor those factors and make adjustments in the future as needed. These factors are important because, for example, retail pharmacy patterns will not be reflected in current data because facility management of the drugs will likely result in higher utilization by patients.

In sum, KCP urges CMS to adopt a methodology that addresses the key issues as described in this section. Not only will this ensure an accurate estimate of the costs associated with providing these drugs, but it will also promote transparency that will make this unprecedented expansion of the bundle easier to implement.

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. 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 and the kidney care community, we are encouraged by the refinements to the QIP during these initial years of implementation. Our members remain committed to working with the Agency and the broader kidney care community to ensure that the QIP achieves the aim of the National Quality Strategy to "promote better care for the individual thereby enhancing the health of the entire [ESRD population] while also reducing costs."

Even though we believe much has improved in regard to the QIP since the first proposed rule, much more can and should be done in terms of: (1) the development, adoption, implementation, and retirement of measures; (2) the collection of data; and (3) the methodology for calculating the total performance score. In this regard, we recommend that CMS adopt the following recommendations in the final rule for PY 2014 and PY 2015. Additionally, we have provided a set of overarching recommendations that we encourage the Agency to adopt for PY 2014 and subsequent years.

- In terms of the QIP overall, CMS should:
  - Establish a consistent minimum set of exclusions that apply to all structural reporting measures;
  - Adopt measure specifications and data definitions that are clear and precise through the rulemaking process and provide a regular process for collecting and responding to questions related to the interpretation of measure specifications and data definitions; 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 to allow stakeholders to have the opportunity to assess the impact on facilities.

- For PY 2014, CMS should:
  - Change the mineral metabolism reporting requirement by adopting appropriate exclusions that CMS already defined during an earlier NQF endorsement cycle;
  - Adjust the weighting for the composite vascular access measure to eliminate the disincentive to utilize grafts when clinically appropriate;
  - Refine the reporting requirements implementing the ICH CAHPS measure to minimize the burden on patients and providers; and
  - Provide clarity as to the rate of improvement assumed to establish the distribution of penalties.

- For PY 2015, CMS should:
  - Maintain the proposed PY 2015 QIP domains, but modify the measures specifications and weights to align them better with high quality clinical care; and
  - Modify the methodology used to calculate the total performance score.

- 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 encourage CMS to work with the community to make appropriate changes to the QIP program to enable participation of pediatric programs.

I. In the final rule, CMS should address three overarching issues to bring consistency and transparency to the QIP in PY 2014 and future years.

KCP applauds the Agency for its efforts to define a forward-looking process by proposing criteria for retiring measures and suggesting domains for future measure development. We provide specific comments on these issues in Part 2, Section IV. We also believe there are three other aspects of the QIP that expand beyond a single payment year that the final rule should address. These are: (1) developing and applying a consistent set of exclusions for structural reporting measures; (2) defining the process for adoption of implementing measure specifications and clarifying them; and (3) improving transparency and 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, to allow stakeholders to have the opportunity to assess the impact on facilities.

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

One of the greatest challenges of measure development centers on identifying which patients should be included or excluded from the measure in question. As participants in the Kidney Care Quality Alliance, which developed a starter set of measures for use in value-based purchasing programs and obtained the endorsement from the NQF for many of them, KCP members appreciate that in many instances these decisions must be made on a measure-by-measure basis. However, this experience also shows us that there should be a global set of exclusions that would be applied to all structural reporting measures related to the treatment of ESRD. These exclusions should be automatically applied to all structural (reporting) measures, unless there is a specific clinical or operational reason they should not be. In addition, we emphasize that, when appropriate, some measures may require additional exclusions, such as those related to the number of days a patient has been receiving treatment (either as new patients or when returning to dialysis after transplant). We support such exclusions and urge CMS to ensure that when clinically appropriate additional exclusions are considered as well.

To this end, KCP recommends that CMS adopt the following global exclusions and apply them to the PY 2014 measures, as well as to those for PY 2015 and subsequent years (as appropriate):

- 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;[46]
    - 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;[47]
- Pediatric patients (unless the measure is specific to pediatric patients); and
- Kidney transplant recipients with a functioning graft.

[46] *See* 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).

[47] *See, 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).

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 NQF endorsed in 2007, CROWNWeb, and the urea reduction ratio (URR) reporting specification.[48]

These exclusions differ from the inclusions CMS recommends, for example, for the mineral metabolism structural measures for PY 2014 and 2015 in the proposed rule.[49] First, exclusions are preferable to inclusion criteria because exclusions are more consistent with the construction of measures within the national consensus process. Shifting to inclusions creates confusion and inconsistency with measure development and the approach to NQF endorsement.

In terms of the specific recommendations, we support excluding patients who die during the month for which the measure is being reported, but we strongly encourage CMS to reconsider the suggestion of including beneficiaries who receive at least <u>two</u> treatments during the relevant month. The preamble recognizes, and we agree, 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.[50] It takes more than two treatments to properly manage and impact patient outcomes. More consistent interaction is required to monitor patient conditions, modify treatment protocols, and evaluate the impact of such changes. Similarly, if a beneficiary receives only two treatments in a particular month, it is likely he/she will miss the scheduled blood draw. 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. This is particularly true if the laboratory results were just 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.

NQF-endorsed measures, such as those upon which the mineral metabolism composite structural measure is based, expressly exclude transient patients.[51] Similarly, the quality measure specifications for the urea reduction ratio (URR) measure exclude patients with fewer than seven dialysis sessions per month.[52] The claims form also distinguishes reporting URR values for patients who receive dialysis six days or less in a facility in a month.[53] We recommend that CMS apply these exclusions, which are based upon its own measures and definitions, to all structural measures rather than create a two-treatment minimum inclusion criterion that has never been vetted by a consensus-based organization. We encourage the adoption of exclusions for pediatric patients (unless the measure is specific to pediatric patients) and kidney transplant recipients with a functioning graft that the NQF-endorsed measures also

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[48] *See id.*

[49] *See* 77 Fed. Reg. at 40968 & 40971.

[50] *See id.* at 40968.

[51] *See* NQF #0261 Measurement of Serum Calcium Concentration & NQF # 0255 Measurement of Serum Phosphorous Concentration.

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

[53] *See* 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).

contain. Thus, we urge CMS not to adopt a two-treatment minimum, but rather to adopt exclusions already endorsed by NQF for the structural QIP measures.

We offer one additional recommended exclusion to address a 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. 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.[54] Thus, we believe this compromise would address CMS's desire to make sure facilities work with home dialysis patients to receive medically necessary monitoring, while not penalizing the facilities if a patient refuses to come in.

Establishing appropriate exclusions is consistent with the voluntary consensus-based measure development structure and 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 structural reporting measures to ensure that these beneficiaries are not included in the denominator.

B. The Agency should adopt measure specifications and data definitions that are clear and precise through the rulemaking process and provide a regular process for collecting and responding to questions related to the interpretation of measure specifications and data definitions.

KCP is pleased that CMS is considering how to address issues raised regarding the QIP measures. While we agree that sub-regulatory guidance would be an efficient mechanism to address questions related to the data elements, we oppose the Agency making changes to the measure specifications or data definitions through any process other than rulemaking.

Our experience with measure development and maintenance has taught us that very few, if any, changes to the measure specifications (meaning the numerator, denominator, inclusions, or exclusions) do not have implementation ramifications and hence are not substantive. Even updates to measures through the maintenance process often substantively change the population being measured or other parameters. Many changes to data definitions may also affect parameters in a meaningful way. Thus, consistent with the requirements of the Administrative Procedures Act, we urge the Agency to use rulemaking in such instances.

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[54]For 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.

As we have discussed previously, KCP encourages CMS to use sub-regulatory guidance as part of an established regular and transparent process for collecting and responding to questions related to the interpretation of measure specifications and data definitions. Specifically, we request that the Agency provide a timeline in the final rule that establishes a quarterly update that answers questions submitted during the previous three months. We urge CMS to work with the community formally and informally to develop the responses so that they are clear and direct and, most importantly, allow for the consistent interpretation of measures and their data elements.

We recognize that deciding between using rulemaking and sub-regulatory guidance may be a very fact-specific exercise, making it difficult to develop a bright-line rule. That said, KCP encourages CMS to use rulemaking for any change to measure specifications. In terms of data definitions, we recommend rulemaking for any change that would alter the parameters for the measures; however, if the issue is an interpretation that seeks to clarify how the data elements should be reported, we recommend using sub-regulatory guidance. KCP would welcome the opportunity to help refine this policy as the QIP matures. Our goal, which we know the Agency shares, is to make sure that the measures are defined with enough specificity and clarity to support consistent and transparent implementation, and hence reporting, that will allow for valid comparison of metrics among facilities and the accurate development of performance standards.

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 earlier this year with the CMS QIP staff, 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. For example, as we have previously discussed (and describe the issue again below in Part 2, Section II.D.) we have been unable to replicate the impact of the total performance score described in the final rule for PY 2014 without assuming that the rate of improvement for the vascular access composite measure is almost 20 times greater than the observed rate of improvement in publicly available data. In this case, 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, 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.

II. CMS should revise the proposals for PY 2014 to address concerns with the mineral metabolism, vascular access type composite, and ICH CAHPS measures, as well as to provide greater transparency with regard to the calculation of the total performance score.

KCP appreciates the modifications CMS made for PY 2014 between the proposed and final rules, such as those to address laboratory variation, reinstate the five-tier penalty structure, adjust the attainment threshold methodology, and resolve other technical issues. These refinements will significantly improve the program.

We are pleased that the Agency proposes modifications to the requirement that each facility attest that it monitored serum calcium and serum phosphorous at least once a month for each Medicare ESRD patient, but these modifications do not completely address the problem.[55] In addition to changing the threshold for attestations, we suggest that the Agency revise the composite vascular access measure to promote clinically appropriate care and address concerns related to lack of transparency in determining the distribution of penalties. The Agency should also refine the reporting requirements implementing the ICH CAHPS measure to minimize the burden on patients and providers and should provide clarity as to the rate of improvement assumed to establish the distribution of penalties.

A. CMS should change the mineral metabolism reporting requirement by adopting appropriate exclusions or, alternatively, by lowering the attestation percentage.

KCP supports the mineral metabolism structural measure and is pleased that the Agency recognizes that it may not always be possible to measure a beneficiary's serum calcium and serum phosphorous once a month.[56] Our members know first-hand that beneficiaries may miss treatments or be at a facility only transiently, thus, making it difficult, if not impossible, to draw his/her blood to monitor these levels and impact outcomes.

However, as noted in Part 2, Section I.A., KCP does not believe the proposed policy will appropriately address this practical reality of treating individuals. The inclusion criteria proposed do not address the problem other than in the case of deceased patients. A more comprehensive approach and one that is consistent with the basic tenets of measure development would be to establish specific exclusion criteria.

Adopting exclusion criteria in the case of the mineral metabolism measure would be fairly straight forward. This structural measure is based on two NQF endorsed measures for which CMS is the measure steward (NQF #0261 Measurement of Serum Calcium Concentration and NQF #0255 Measurement of Serum Phosphorous Concentration). The specifications for these measures contain three of the exclusions that we propose (dialysis patients who are absent in a month, pediatric patients (because it is an adult measure), and kidney transplant recipients with a functioning graft). We agree with CMS that beneficiaries who die within the applicable month should not be included.[57] We also agree that beneficiaries included in the measurement should receive a minimum number of treatments;[58] however, two is too few treatments to allow facilities to have sufficient opportunity to draw patients' blood, let alone, impact outcomes. Patients who miss treatments be it for travel, transition between facilities, or other reasons, are rightly excluded from the denominator. When developing the serum calcium and serum phosphorous measures, CMS excluded transient patients. Similarly, patients who receive less than 7 treatments in a month should be excluded, as CMS recognizes in the context of the URR QIP measure. Dialysis facilities should not be held accountable for reporting on patients in the QIP who are not receiving treatment regularly at their facilities. The incentive to provide high quality care remains, but this formulation of the exclusion is more consistent with what a consensus-based group of experts believe to be appropriate.

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[55] 77 Fed. Reg. at 40968.

[56] *See id.*

[57] *See id.*

[58] *See id.*

In sum, we recommend that the Agency adopt the following exclusions for the mineral metabolism measure:

- 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;[59]
  - 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;[60]
- Pediatric patients (unless the measure is specific to pediatric patients); and
- Kidney transplant recipients with a functioning graft.

In adopting these exclusions, CMS should make clear that the attestation is based upon the monitoring for the Medicare beneficiaries included in the denominator, not all Medicare beneficiaries.

Alternatively, CMS proposes to establish an attestation threshold of 98 percent. While theoretically this approach could achieve the same outcome as the use of exclusions, it is less precise in its application. Exclusions provide a targeted approach that would clearly establish the specific beneficiaries who will be excluded. A percentage approach would not distinguish between beneficiaries legitimately excluded from monitoring and those who should have been monitored but were not. It is also extremely difficult to determine the appropriate percentage. The Proposed Rule does not provide the criteria or methodology used to arrive at 98 percent. One way to reach an appropriate percentage would be to identify the percentage of patients who meet the appropriate exclusion criteria. This number, however, would only be an average and not specific to a particular facility, making it less precise in terms of holding facilities accountable for monitoring the appropriate set of beneficiaries. If CMS were to adopt a specific percentage, the final rule should clearly describe the method used to calculate the percentage and provide the data used to reach it. There should also be an opportunity to comment on this information before it is finalized.

In addition, KCP seeks clarification as to the algorithm CMS will use to calculate performance on the structural reporting measures. That is, as defined, it is not clear whether the 98 percent means 98 percent of individual patients or 98 percent on a patient month basis.

Finally, we are troubled by the suggestion that dialysis facilities should monitor patients' serum calcium and serum phosphorous readings by obtaining laboratory results from other providers, including hospitals. This suggestion fails to recognize the operational reality that other providers simply do not share data with dialysis facilities. We have raised concerns about the lack of access to such data for more than 10 years. For example, KCP has consistently requested that CMS and/or the Congress require hospitals to provide discharge summaries for dialysis patients who are hospitalized because hospitals

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[59] *See* 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).

[60] *See, 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).

refused to provide such data on their own. We have experienced similar problems in terms of trying to obtain the documentation required to support claims for the comorbidity case-mix adjustors. We have shared these problems with suggested solutions in this letter (see Part 1, Section I.B.), as well as previous comment letters related to the ESRD PPS.

The reasons that other providers do not share patient information vary from misinterpretations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to a simple lack of responsiveness. Even if facilities could obtain such data, we could not be certain that the results of the tests conducted by other providers or laboratories would be consistent or reported under the same standards as those used by dialysis facilities. CROWNWeb does not permit facilities to submit data obtained from other providers if the lab result is outside of the admission or discharge date. In addition, there is no requirement that these providers test patient serum calcium or serum phosphorous, so there is no guarantee that they will have results for dialysis facilities to review. We strongly disagree with the suggestion that dialysis facilities can easily obtain such results and urge the Agency to eliminate this proposal in the final rule.

B. CMS should adjust the weighting for the composite vascular access measure to eliminate the disincentive to utilize grafts when clinically appropriate.

KCP strongly supports the inclusion of vascular access measures. Providing patients with the most appropriate vascular access is one of the most important factors in patients' overall outcomes. There is clear clinical consensus that catheters present serious problems and should only be used if a patient cannot maintain an AV fistula or synthetic graft.[61] As currently designed, however, the composite measure overemphasizes the use of fistulas, which are desirable, but in some cases, clinically inappropriate. Therefore, we urge the Agency to adopt the short-term solution of weighting the catheter measure more heavily when calculating the composite result and to work with the community to develop a graft measure that could be added in the future.

Our concern is rooted in the fact that CMS includes a measure to maximize the number of AV fistulas while ignoring synthetic grafts. We agree that fistulas are the "gold standard" of vascular access.[62] Even so, not every beneficiary is physically likely to be able to develop a mature fistula following surgical creation. For example, some patients have small veins or other conditions that do not support such maturation. Once a fistula has been placed, some patients develop stenosis (a narrowing of the width of the blood vessels) that can result in the need for an alternative access.[63] This historical emphasis, as evidenced by the Fistula First Initiative, grew in part out of the fact that graft placements out numbered fistulas, despite clear evidence that fistulas were clinically better. This discrepancy was due in part to Medicare payment policies that reimbursed surgeons more for placing grafts than fistulas. The community successfully worked with CMS to change this policy. More recently, there is increasingly an

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[61] Eduardo Lacson Jr. *et al.*, *Balancing Fistula First With Catheters Last*, 50 AM. J. KIDNEY DISEASE 379, 381-82 (2007) ("Although not necessarily causal, the relative risk of death associated with catheter use compared with fistulas is increased by 1.4- to 3.4-fold. . . . Catheters are associated not only with greater hospitalization rates because of sepsis, but also with greater rates of all-cause hospitalization.") (citing K. R. Polkinghorne *et al.*, *Vascular Access and All-Cause Mortality: A Propensity Score Analysis*, 15 J. AM. SOC NEPHROLOGY 477, 479-80 (2004)).

[62] *See* Arteriovenous Fistula First, *History of the Fistula First Project*, http://fistula.memberpath.com/AboutAVFistulaFirst/History.aspx.

[63] *See* American Association of Kidney Patients (AAKP), *Understanding Your Hemodialysis Access Options*, http://fistula.memberpath.com/LinkClick.aspx?fileticket=dS2HSHjdV4U%3d&tabid=202.

evolution in thinking that the focus should be on permanent access—fistulas or grafts first—and catheters last.

CMS should emphasize the placement of a permanent access for patients. While we believe it continues to be important to incentivize the use of fistulas, it is equally important to make sure that beneficiaries have the vascular access that is most appropriate for them. Including a maximizing AV fistula measure without similarly recognizing graft placement will likely have negative consequences for those patients who would be better served by the placement of a graft than the creation of a fistula.

The most appropriate solution is to include a graft measure within the vascular access composite measure; however, no such measure exists at this time. Therefore, we suggest that in the short-term CMS weight the catheter reduction measure at two-thirds for purposes of calculating the composite result. This will place the greater incentive on eliminating catheters (a temporary access) while rewarding the placement of a permanent access (either a fistula or graft). We also support the longer-term solution of developing a graft measure and would welcome the opportunity to assist the Agency with developing a clinically appropriate metric.

C. CMS should refine the reporting requirements implementing the ICH CAHPS measure to minimize the burden on patients and providers.

KCP continues to support monitoring patients' experiences when receiving dialysis. However, we repeat our concerns as to the manner in which the ICH CAHPS survey must be administered to meet the attestation requirement. The CAHPS survey requires patients to answer 57 questions. Simply put, 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 them and that is likely to result in incomplete surveys that benefit no one.

Thus, we propose that, rather than mandate the completion of the entire survey, CMS allow facilities and providers to divide the survey into its 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 and 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. This approach would strike the appropriate balance between gathering important information and not overwhelming patients and caregivers.

Additionally, KCP remains concerned that CROWNWeb will not provide an adequate reporting system for the measure. KCP members continue to work closely with CMS to try to address the problems with the system. However, these problems have not yet been resolved. Thus, we recommend that CMS continue to work with the kidney care community to establish an electronic data collection system that is user-friendly, both in terms of allowing facilities and providers to submit measure data in a seamless manner and providing beneficiaries with easy access to the data.

Finally, we note that the requirement that the survey be collected and evaluated by a third party imposes significant costs on facilities. CMS should recognize this new mandate and allow facilities to include it as an allowable cost on the cost reports.

D. CMS should provide clarity as to the rate of improvement assumed to establish the distribution of penalties.

Overall, KCP supports the structure developed for PY 2014; however, as we have discussed, our review of the available public data raises questions about the assumptions related to the rate of improvement necessary to achieve the QIP scores estimated by CMS. Working with Discern, our review of the final rule[64] and the performance distribution data published by CMS earlier this year suggest that payment reductions under the QIP will be more significant than CMS predicts. This concern is borne out by the performance benchmarks proposed for the 2015 QIP, which show only modest improvement compared to 2014. The Agency estimates the distribution of QIP scores would result in an average 0.29 percent reduction in ESRD payments. The Discern analysis suggests an average payment reduction of 0.65 percent. At approximately $10 billion in total ESRD payments per year,[65] the difference amounts to approximately $36 million. Another way to think about this is that the maximum overall payment reduction under the QIP is theoretically 2 percent (if all facilities received the maximum penalty). The difference between CMS's estimate of an average 0.29 percent payment reduction and the Discern estimate of a 0.65 percent payment reduction represents 18 percent of the potential total impact of the program ((0.65 percent - 0.29 percent)/2 percent). This is not a trivial difference.

We understand that the estimates of the QIP's impact were based on historical data for the Hg>12 and URR measures and that assumptions based on Fistula First data were used for the vascular access measures. Using similar data sources, Discern had to assume rapid improvement on all four of the QIP process measures in order to replicate the QIP payment estimates published by CMS. For example, Discern had to assume that median performance on the Hg>12 measure would improve from 4 percent to 3 percent and that median performance on the VAT Fistula measure would improve from 58 percent to 83 percent. However, such assumptions are not supported by the publicly available data, in particular for the vascular access measure. Data published on the DOPPS Practice Monitor (http://www.dopps.org/DPM/) show that performance on the Hg>12 improved only slightly from August 2010 to August 2011. Data from Fistula First for the same period show only about a 3 percent improvement in vascular access type. This analysis suggests that these observed rates of improvement are not adequate to support CMS's QIP payment estimates. Moreover, the lack of facility-specific data in Fistula First makes it very difficult to estimate the facility-level impact of the QIP.

We have also compared the performance benchmarks that CMS proposes for the 2014 and 2015 QIPs, and observed that the apparent rate of improvement is modest. (This comparison is necessarily limited to those measures included in both 2014 and 2015.) As the table below suggests, performance improvement is mixed across the measures.

2014 QIP			
Measure	Achievement Threshold (15th Percentile)	Performance Standard (Median)	Benchmark (90th Percentile)
Hg > 12	10%	4%	0%
VAT - Fistula	46%	58%	74%

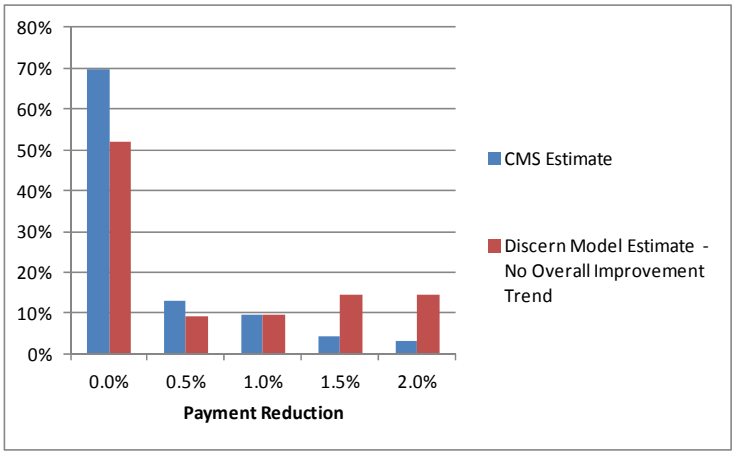
[64] 76 Fed. Reg. at 70308.

[65] MedPAC, *Report to the Congress: Medicare Payment Policy* (March 2012).

VAT - No Catheter	24%	14%	5%
2015 QIP			
Measure	Achievement Threshold (15th Percentile)	Performance Standard (Median)	Benchmark (90th Percentile)
Hg > 12	7%	2%	0%
VAT - Fistula	46%	59%	74%
VAT - No Catheter	23%	13%	5%
Improvement 2014-2015			
Measure	Achievement Threshold (15th Percentile)	Performance Standard (Median)	Benchmark (90th Percentile)
Hg > 12	3%	2%	0%
VAT - Fistula	0%	1%	0%
VAT - No Catheter	1%	1%	0%

The final rule acknowledges the uncertainty of the QIP estimates by stating that "[g]iven the lack of data for the reporting measures, and the use of Fistula First data, the actual impact of the PY 2014 ESRD QIP may vary significantly from the values provided here."[66] We appreciate that any estimate of future performance is necessarily uncertain. However, such estimates must still be rooted in appropriate expectations of performance that are based on the data and consistent with the goals of the program.

Our concern focuses on whether the distribution of penalties is based on a view of improvement rates, particularly in the area of the vascular access metrics, that are unrealistic. Discern's findings using publicly available data suggest strongly that they are. As the graph at right illustrates, making alternate assumptions about performance improvement trends results in a very different estimate of QIP payments. As described earlier in this letter, the impact for ESRD providers could be very substantial.



The kidney care community needs to better understand the data and assumptions CMS used in its model, and, thus, we request the opportunity to review with your team the details of the models and data you used to estimate QIP payment adjustments (and we would be happy to review with them our own models in more detail). Based on these discussions, we could work with you and the contractors to fine-tune the structure on a going forward basis to accomplish the following goals: (1) better understand the process used to estimate performance on the QIP measures; (2) make sure that the data used to develop the distribution of penalties are publicly available; (3) ensure that the cut points to determine the different penalty levels are set in a transparent and consistent manner over time; and (4) make sure that when the distribution of penalties is developed

[66] 76 Fed. Reg. at 70308.

for a particular year, the attainment and improvement rates are achievable based upon previous experience.

III. CMS should revise the proposals for PY 2015 to address concerns related to the proposed measures, the calculation of the performance standards, and technical issues related to the methodology used to calculate the total performance score, as well as to improve the transparency of the program overall.

While KCP supports many aspects of the proposals for PY 2015, we have concerns with some of the proposed measures, the calculation of the performance standards, and other technical concerns. We explain these concerns and propose recommendations below.

A. CMS should maintain the proposed PY 2015 QIP domains, but modify the measure specifications and weights to align them better with the goal of high quality clinical care.

Generally speaking, KCP agrees with the proposal to maintain measures once they are proposed in subsequent years, unless there is rulemaking to remove or replace them.[67] We provide comment on the criteria for adopting and removing or replacing measures in Part 2, Section IV of this letter. Thus, for the most part we agree with the proposal to continue the PY 2014 measures for PY 2015, with the exception that we strongly recommend that the Agency refine these measures and the reporting requirements along the lines described in Part 2, Section I.A. of this comment letter and reiterated briefly below. We also support replacing the URR dialysis adequacy measure with a composite Kt/V measure that includes hemodialysis and pediatric patients, but have concerns about the inclusion of a peritoneal dialysis clinical measure. We also have concerns about how the performance standard was determined. Finally, while we agree that there should be mineral metabolism measures in the QIP, we are concerned that the data used to establish the performance benchmarks for the hypercalcemia measure have not been validated; thus, we recommend including the hypercalcemia measure as a structural reporting measure, instead of as a clinical measure, for one year so that CMS can collect accurate data with which to establish performance benchmarks.

Additionally, we reiterate concerns raised earlier in this letter that CMS establish a regular and transparent process for collecting and responding to questions related to the interpretation of measure specifications and data definitions. As noted above, we believe full rulemaking is required to adopt measures and their specifications (numerators, denominators, exclusions, and data definitions), but that sub-regulatory guidance should be used to provide clarification.

We also caution the Agency against relying upon CROWNWeb pilot project data to establish performance benchmarks for attainment and improvement. The kidney care community generally, and dialysis facilities in particular, have worked closely with CMS and the contractor in an effort to make CROWNWeb a viable system for collecting data. Even so, CROWNWeb does not yet work. There are many inconsistencies in reporting both because of technical issues and interpretation issues. Additionally, the data are not representative of the sector as a whole; many facilities were not able to participate in the pilot creating the distinct possibility that the data are skewed. These inconsistencies make it inappropriate to rely on the CROWNWeb data to establish performance standards. Thus, we urge CMS to refrain from

[67] *See* 77 Fed. Reg. at 40969.

this approach and instead rely upon data collected through the claims until such time as there is consensus that CROWNWeb works.

1. While KCP generally supports the continued use of PY 2014 measures, with the replacement of Kt/V for the URR adequacy measure, we urge CMS to address the concerns raised with regard to the vascular access type composite and the mineral metabolism measures.

KCP supports the domains and measures proposed for PY 2015 that are part of PY 2014 as well, but urges CMS to make specific modification to how they are used within the QIP. Specifically, we support:

- The clinical Hemoglobin Greater Than 12 g/dL measure;
- The Vascular Access Type measure, but again recommend modifying the composite measure to acknowledge the inappropriate disincentive it creates for providing the most appropriate clinical care;
- A modified version of the ICH CAHPS survey measure that would reduce the burden on patients who must complete the survey;
- The proposed expansion of the NHSN measure, if the data submission problems are resolved in the immediate future; and
- A modified version of the mineral metabolism structural reporting measure.

a. KCP supports the continued use of the Hemoglobin Greater than 12 g/dL measure, but recommends that the Agency refine the Vascular Access Type composite measure and the ICH CAHPS survey.

KCP continues to support inclusion of the hemoglobin greater than 12 g/dL measure in the QIP.[68] Anemia management remains a crucially important aspect of care that affects quality of life and patient satisfaction.

KCP also strongly supports the inclusion of vascular access measures.[69] 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. However, as we note in detail in Part, 2, Section II.B., 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. 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).

[68] *See id.* at 40971.

[69] *See id.*

Finally, KCP supports monitoring patients' experiences of care when receiving dialysis. However, we remain concerned about the current implementation of the ICH CAHPS measure.[70] As we noted in our comments for PY 2014 in Part 2, Section II.C., we recommend that CMS adjust the measure specifications to lessen the burden on respondents by dividing the survey into its three independently verified domains when administering it. We propose that each one-third of a facility's patient population receive one of the three domains plus the core demographic questions.

In addition, we request that CMS clarify that facilities may provide patients with the survey at the dialysis facility and allow them to return the survey in a drop box or through the mail to a third party for scoring. We believe this simple change will improve response rates because it makes it less likely that a mailed survey will be ignored as junk mail. In addition, 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 other modalities. Thus, we urge CMS to work with the kidney care community to develop an alternative model. Finally, we reiterate our requests that the costs associated with complying with this requirement be considered allowable costs for purposes of the cost report.

b. KCP supports the proposed expansion of the NHSN dialysis reporting measure, if the problems with submitting the data are resolved.

KCP agrees that preventing infections is important and supports inclusion of the NHSN bloodstream infection measure (NQF #1460) as a structural measure. We also appreciate the ongoing efforts CMS has made to work with the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) to address the ongoing data submission issues. Yet, as you would likely agree, work remains to be done in this area.

KCP supports the proposal to adopt NQF #1460 bloodstream infection measures consistent with the specifications endorsed by NQF once there is sufficient data to allow for the development of performance standards, including achievement and improvement thresholds.[71] Until that time, we continue to support its use as a structural measure, including the proposal for continuing its use for PY 2015.[72] Monitoring the number of patients with vascular access-related infections remains an important part of efforts to reduce infection rates in this population. Including this measure will incentivize the use of this reporting mechanism and ultimately help the kidney care community achieve the goal of reducing infections.

However, as noted in previous comment letters, we remain concerned about the manner in which data must be transmitted to CDC/NHSN. We appreciate the Agency's ongoing efforts to work with the CDC to develop a streamlined data entry system and would be pleased to assist the Agency in these efforts as appropriate. We understand that batch reporting should be available in August to eliminate facilities having to report the data twice, but as of yet, the issue with the CDC has yet to be resolved. Until the issue has been resolved, this means that participation in NHSN occurs through manual entry via an internet-based stand-alone NHSN system. Manual entry is not only burdensome, but subject to greater inaccuracies due to human error. We are especially concerned about the problems that can arise with

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[70] *See id.*

[71] *See id.* at 40972.

[72] *See id.* at 40971.

double data entry and the accuracy of the future baseline once the measure is implemented as an outcome measure. In fact, NQF's most current measure evaluation criteria related to feasibility favor electronic collection and data collected during the course of care. A means for facilities to directly download data from facility electronic records into the NHSN system would reduce burden on staff, permitting them to focus on patient care, and supply CDC/CMS with more accurate data. We urge CMS to resolve this issue before the end of the third quarter of 2012.

We also encourage CMS to avoid establishing reporting requirements that reduce the effectiveness of the NHSN as a surveillance system. For example, CMS's requirement that the data be finalized in 30 days which prohibits any changes is in stark contrast to the way surveillance systems operate. This compromises the purpose of the NHSN and fails to achieve the National Quality Strategy aim of advancing health for the entire population.

In terms of the reporting requirements, KCP supports expansion of providing a full 12 months of dialysis data,[73] but only so long as the requirement remains at the facility level and does not apply at the individual patient level. We also support providing a "grace period,"[74] however, recommend providing facilities with the option to electronically file the data quarterly and permit the data from previous quarters to be updated with new information facilities have received since the first filing. Facilities would still be evaluated on whether or not the monitoring occurred on a monthly basis, but the quarterly filing and updating options would be more consistent with electronic data submission and surveillance practices. Based upon our members' discussions with the CDC, it appears they would be open to this modification as well. We also ask that CMS clarify that facilities have until March 2014 to submit the final year data for 2013, similar to the timeline set forth for PY 2014.

c. Before expanding the reporting period to a full 12 months, CMS should refine the mineral metabolism reporting measure consistent with KCP's comments for PY 2014.

KCP supports the mineral metabolism structural measure and is pleased that the Agency recognizes that it may not always be possible to measure a beneficiary's serum calcium and serum phosphorous concentrations once a month.[75] However, as noted in Part 2, Section I.A., KCP does not believe the proposed policy will appropriately address the practical reality of treating individuals. We strongly recommend that CMS adopt exclusion criteria based upon the NQF-endorsed measures, as well as the QIP URR, that comprises the structural measure. Specifically, KCP recommends that CMS adopt the following exclusions and clarify that the attestation is based upon monitoring for the Medicare beneficiaries included in the denominator, <u>not all Medicare beneficiaries</u>:

- 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;[76]

[73] See *id.*

[74] *See id.*

[75] *Id.* at 40968.

[76] *See* 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).

- 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;[77]
- Pediatric patients (unless the measure is specific to pediatric patients); and
- Kidney transplant recipients with a functioning graft.

We repeat the rationale set forth in Part 2, Section II.A. supporting these exclusions. Excluding any patients who miss treatments, pediatric patients (when the measure is an adult measure), and kidney transplant recipients with a functioning graft is consistent with the NQF-endorsed measures, as well as the QIP URR measure specifications. We support the proposal not to include beneficiaries who die within the applicable month.[78]

A less optimal approach is to establish an attestation threshold. As noted in more detail in Part 2, Section II.A., this approach is less desirable because it is difficult to establish an appropriately precise threshold to address a very specific problem, whereas exclusions directly address the issue. A percentage approach would not distinguish between beneficiaries legitimately excluded from monitoring and those who should have been monitored but were not. We reiterate that if CMS were to adopt a specific percentage, it should clearly describe the method used to calculate the percentage, provide the data used to reach it, and provide an opportunity for comment on the proposed threshold.

Finally, we restate the concerns we raised in Part 2, Section II.A., which are related to the assertion in the preamble that dialysis facilities should monitor patients' serum calcium and serum phosphorous concentrations by obtaining laboratory results from other providers. Our experience in obtaining data from other providers demonstrates that such a policy is unlikely to succeed. If CMS believes this level of coordination is optimal, with which we do not disagree in theory, it must establish a clear mandate on other providers to share this information with dialysis facilities. Short of doing this, these other providers are highly unlikely to share the necessary information. Instead of having facilities tilt at windmills, CMS should focus on activities within facility control until such time as true integrated care is possible.

2. KCP supports with suggested refinements the replacement Kt/V measure for the URR measure and applauds the Agency for establishing an anemia management structural measure, but urges CMS to adopt the hypercalcemia measure as a structural reporting measure for PY 2015, not as a clinical measure.

KCP supports the proposal to add three new measures to the QIP for PY 2015 and to retire the URR measure so long as the Agency makes certain refinements to them. Specifically, we recommend that CMS:

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[77] *See, 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).

[78] 77 Fed. Reg. at 40968.

- Retire the URR measure, adopt the Kt/V hemodialysis and pediatric clinical measures, but finalize the Kt/V peritoneal dialysis measure as a structural reporting measure until data based upon a single methodology are available;

- Adopt the hypercalcemia measure as a structural reporting measure, not as a clinical measure, so that the Agency has time to collect valid data to allow it to set appropriate performance benchmarks; and

- Adopt an anemia management structural reporting measure with modifications to the attestation requirements and clarification of how data collected through it will be publicly reported.

a. CMS should adopt the Kt/V hemodialysis and pediatric metric as a clinical measure for PY 2015 and should retire the URR metric, with certain refinements, but should finalize the Kt/V peritoneal dialysis measure as a structural reporting measure.

Although we have concerns about the data used to calculate the performance standards (see Part 2, Section III.B.), KCP supports CMS's proposal to remove the URR measure from the FY 2015 QIP.[79] 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. We support adopting the Kt/V hemodialysis metric as a clinical measure. We also support the inclusion of pediatric patients in the composite Kt/V measure.

KCP is pleased that CMS recognizes the importance of monitoring home dialysis patients in the ESRD QIP, but because there is not a consistent methodology for the Kt/V peritoneal dialysis measure we do not support its adoption as a clinical measure at this time. Rather, we urge CMS to finalize it as a structural reporting measure, immediately define a single methodology for calculating it, and use the data from the reporting year to establish appropriate performance standards, as it did with the Kt/V hemodialysis measure previously.

Thus, we support adopting the Kt/V measure with this modification and the retirement of the URR metric.

b. CMS should adopt the hypercalcemia measure as a structural reporting measure to allow for the establishment of performance standards, attainment and improvement thresholds, and benchmarks that are based on valid data.

KCP agrees with CMS that the QIP should "encourage proper bone mineral metabolism management."[80] Thus, we continue 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. Currently, the only available measure that has been endorsed by the NQF is #1454: Proportion of patients with hypercalcemia. We acknowledge that the Kidney Disease: Improving Global

[79] *See id.* at 40973.

[80] *Id.*

Outcomes (KDIGO) Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention and Treatment of CKD-Mineral and Bone Disorder strongly recommends a change in therapy when patients' serum calcium levels exceed the normal range (8.6-10.2 mg/dL in most laboratories). However, this is not the best measure in this domain to impact patient outcomes, in the absence of metrics for other related mineral disturbances, such as phosphorous and PTH,[81] to encourage proper bone mineral metabolism management in a meaningful way. KCP is concerned that CMS has not collected the data elements that underlie this measure in a manner that is representative of the entire kidney care community or that would produce valid performance standards, attainment thresholds, or benchmarks to support it as a clinical measure for PY 2015.

CMS proposes to set the performance standards, achievement thresholds, and benchmarks for the hypercalcemia measure by utilizing the CY 2011 CROWNWeb data. These data represent only slightly more than half of all facility data. Only 63 percent of facilities submitted data to CROWNWeb in 2011. Even though they may treat 80 percent of the Medicare ESRD population, this sample of data under-represents medium and small dialysis organizations.[82] It also does not account for the differences that exist when data are voluntarily reported. Many of our members who have participated in the CROWNWeb demonstration project have raised serious concerns about the validity and reliability of the data collected thus far. They have voiced concerns about the lack of batch reporting for small and medium dialysis organizations, which, while in the process of being addressed, was not resolved in 2011. There have also been serious data collection problems for both those entering data manually and those who were batch submitting data because of the lack of clear data definitions and reporting requirements. We believe using these data will create inappropriate biases within the QIP.

Given these serious concerns, we urge CMS to adopt the hypercalcemia measure as a structural reporting measure for PY 2015, rather than as a clinical measure. During the reporting period, the Agency should clearly specify the data elements and reporting requirements, ideally using the ESRD claims form to collect the data. Once it has these data, CMS will be able to develop valid performance standards, achievement and improvement thresholds, and benchmarks that would permit the hypercalcemia measure to be adopted as a clinical measure for PY 2016. 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 future.

c. CMS should finalize the anemia management structural measure, but modify the attestation requirement consistent with our recommendations for other structural measures and clarify how the data will be reported.

KCP agrees that it is important to continue monitoring Medicare ESRD patient hemoglobin levels. We support the structural measure to require reporting these levels as well as ESA dosing levels.[83] However, we are concerned that CMS does not describe how it plans to report the data associated with this measure. We also believe that CMS should establish exclusions, consistent with those we recommend for other structural measures that require facilities to attest to monitoring patients. As noted in our discussion regarding the mineral metabolism measure, we do not agree with the suggestion that dialysis

[81]KCP has supported both a phosphorous and PTH measure for endorsement by the NQF.

[82]Discern, "Memorandum to Kidney Care Partners: 2015 QIP Analysis" (August 2012) (*available upon request from the author*).

[83]*See* 77 Fed. Reg. at 40974.

facilities are able to obtain such data from other providers and strongly urge CMS not to adopt this proposal.

First, CMS should clarify how it will make data collected through this measure publicly available. The Agency should work with the kidney care community to develop a model for disseminating these data in a manner that is most useful for patients.

Second, KCP does not support an attestation threshold that requires reporting on 100 percent of Medicare ESRD beneficiaries. As CMS recognizes, patients may not always be available to have the blood draws required to monitor these levels.[84] There is no question that facilities should monitor all Medicare beneficiaries who are receiving treatments in the dialysis facility, but if patients are hospitalized or miss treatments for other reasons, it is not appropriate to hold facilities responsible when the missed treatment is beyond their control. Therefore, we strongly recommend that CMS adopt global exclusion criteria we recommend in Part 2, Section I.A. that would apply to all structural measures. As noted, these are based upon exclusions included in measures the NQF has endorsed. These exclusions are:

- 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;[85]
  - 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;[86]
- Pediatric patients (unless the measure is specific to pediatric patients); and
- Kidney transplant recipients with a functioning graft.

Again, we believe exclusions are more consistent with the measure development process and these recommended suggestions are consistent with those already endorsed by the NQF and that CMS included in the specifications for the QIP URR measure.

To allow the exclusions to function appropriately, CMS should clarify that the attestation is based upon monitoring for the Medicare beneficiaries included in the denominator, not all Medicare beneficiaries.

A less optimal approach is to establish an attestation threshold. As noted in more detail in Part 2, Section II.A., this approach is less precise and less likely to encourage the right level of high quality care. We repeat that if CMS were to adopt a specific percentage, it should clearly describe the method used to calculate the percentage and provide the data used to reach it and provide an opportunity for comment on the proposed threshold.

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[84] *Id.*

[85] *See* 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).

[86] *See, 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).

Third, for the same reasons outlined in Part 2, Section I.A., we object to any requirement that dialysis facilities must obtain values for the QIP from other providers. Historically, these providers have refused to share such information. There is no requirement that these other providers share such information and as our experience with the comorbidity case-mix adjustors has demonstrated (see Part 1, Section I.B.), without such a requirement they will not share the data. This practical reality demonstrates that the proposal is not workable.

Finally, we encourage the Agency to include in the final an explanation as to how CMS plans to use the dosing information and whether or not it seeks to link it to the hemoglobin/hematocrit levels. If the latter is an aim, CMS should clarify how it will integrate patient weight into the analysis to make sure that any comparison is consistent with clinical norms.

B. Overall, KCP supports using the PY 2014 structure for PY 2015, but recommends certain modifications to refine it further to meet the overall goals of the program.

KCP is pleased with many of the adjustments CMS made to the PY 2014 structure aspects of the QIP and the continued use of this structure for PY 2015. However, as detailed below, we recommend a series of refinements that we believe will enhance the program overall.

1. CMS should retain the PY 2014 structure and scoring methodology for the PY 2015 QIP with recommended modifications to allow for partial credit on the structural reporting measures.

CMS proposes to maintain the PY 2014 performance scoring methodology that assesses facilities on both their achievement and improvement on clinical measures with some modifications for PY 2015.[87] While we comment on the specific modification proposals below, we generally support the continuation of the same methodology in subsequent years. It is important to create a consistent and predictable system. However, as noted previously, we remain concerned about the lack of detailed data and explanation related to the rate of improvement and how penalty reductions are calculated. (Please see Part 2, Section II.D. for a detailed description of these concerns).

In terms of the structural reporting measures, we appreciate CMS's proposal to adopt different categorical performance levels for the NHSN, Mineral Metabolism, and Anemia Management reporting measures. This proposed scoring provides facilities with the opportunity to earn "partial credit" for compliance with the reporting measures.

KCP recommends that CMS modify this proposed scoring algorithm for the three reporting measures to allow for more levels of partial credit. The scoring would continue to be on a zero to ten scale for each reporting measure, calculated by subtracting two from the number of months that the dialysis facility successfully meets the requirement (and rounding negative scores to zero). A facility that reported the measure all 12 months would receive a full score of 10. A facility that reported 11 months of data would receive a measure score of nine (11-2) and so on. A facility reporting two or fewer months

[87] 77 Fed. Reg. at 40976.

would receive a score of zero. This proposal would eliminate the requirement of reporting occurring in consecutive months, but still provide incentives for a facility to monitor patients consistently. A facility that misses reporting in multiple months would receive a lower score.

2. CMS should finalize CY 2013 as the performance period and use 2011 data from ESRD claims, but not CROWNWeb data to establish performance standards, attainment thresholds, improvement thresholds, and benchmarks.

KCP supports using CY 2013 as the performance period for PY 2015. Even though we generally support using CY 2011 as the source of data for developing the performance standards, we are concerned that some of the data collected during this period not reliable nor can it be validated.

By proposing CY 2013 as the performance period, CMS should be able to provide the performance standards prior to January 1, 2013, to allow the QIP to be prospective in nature for the first time since its implementation. We strongly encourage CMS to maintain this timeline so that facilities have a clear understanding of the expectations and can adjust their policies and procedures as needed to meet them. We also support a full 12-month performance period, which will account for the seasonal fluctuation in outcomes.

In terms of the performance standards, we generally support the use of CY 2011 data to establish the clinical performance benchmarks, attainment thresholds, and improvement thresholds. However, as noted elsewhere in this letter, we are concerned that CMS proposes to rely upon CROWNWeb data. These data are not representative of the community as a whole and, because of a lack of specificity in data definitions and reporting requirements, are not reliable. Thus, we strongly encourage CMS not to rely upon CROWNWeb data to establish performance standards, but rather collect data on the claims form from all facilities using clear measure specifications and data definitions.

3. CMS should maintain the overall weighting for clinical and structural measures, but should modify the weighting for the vascular access type composite measure

KCP supports the proposal to weight the clinical measures at 80 percent of the total performance score and the structural reporting measures at 20 percent. Even though KCP supports the inclusion of the Kt/V and vascular access type measures, our members have expressed concerns about the weighting of the component metrics within the composite measures. Therefore, consistent with our comments elsewhere in this letter, we urge the Agency to modify these measures.

a. CMS should adjust the weighting of the Kt/V composite measure.

CMS proposes adopting a composite Kt/V measure that includes separate hemodialysis, peritoneal dialysis, and pediatric dialysis metrics. We have concerns that the peritoneal dialysis measure does not have consistent reporting requirements and, thus, should be adopted as a structural reporting measure to allow for data to be collected using a single methodology. Given that, we suggest the weighting of the individual measures be adjusted accordingly.

KCP appreciates the Agency's effort to address the fact that there are fewer patients receiving peritoneal dialysis or under the age of 18 by attempting to proportionately weight each individual measure. CMS proposes a method to assign greater weight to measures with more patients in the sample,

regardless of whether the measure is more relevant to overall patient outcomes within the facility.[88] This method means that measures will have different weights for each facility. The weights will be dependent upon the relative sample sizes within each facility and will make it more difficult to compare scores across facilities.

We would prefer that CMS determine the weight for each measure based on clinical relevance. In this context, "clinical relevance" would include both the impact of measure compliance on individual patient outcomes, as well as the number of patients to whom a measure would apply in a typical ESRD population (*e.g.*, pediatric-focused measures would have less weight since they affect relatively fewer patients). This would result in a weighting method which is consistent across facilities and allow for meaningful comparisons, while also shifting weight to the more important measures.

b. CMS should adjust the weights for the individual measures that make up the vascular access type measure.

As noted in Part 2, Section II.B., KCP encourages CMS to modify the vascular access type composite measure by weighting the measure to minimize catheters at two-thirds the total value and the measure to maximize fistulas at one-third. We propose this modification to minimize in the short-term the inappropriate incentive to use fistulas even if a synthetic graft would be more clinically appropriate for an individual patient. In the longer-term, we would like to work with the Agency to develop an appropriate graft measure that could be included in the composite measure in the future. Thus, we urge the Agency not to use the proposed proportional methodology to establish the weights for these measures and, instead, adopt a standard and consistent weight for each individual measure.

4. CMS should adopt a simple and transparent approach to adjust for sample size.

KCP supports efforts to address the problem of small sample sizes, which we have raised in previous comments. While we appreciate the Agency's recognition that facilities with a small number of patients are potentially disadvantaged by random variation,[89] we would prefer that CMS adopt an approach that is easier to understand and more transparent by increasing the minimum number of cases to at least 20. If, however, CMS were to maintain the proposed adjustment method, we request that you publish the *sw* values for each measure, so that facilities can predict the impact of the rule on their own performance score.

The Proposed Rule outlines a methodology to make a positive adjustment to scores based on between 11 and 25 cases in order to offset any negative random variation associated with small sample size.[90] On behalf of KCP, Discern attempted to replicate the methodology to help the community better understand how it was derived and the impact it will have on facilities, if adopted in the final rule. The proposed equations to adjust the total performance scores for small facilities include a value (defined as "*sw*"), which is a measure of facility variation. The greater the facility variation for a given measure, the greater the value of *sw* and, hence, the larger adjustment that will be made for the facilities. KCP is concerned because the Proposed Rule does not provide a value of *sw* for each of the clinical measures,

[88] *Id.* at 40981.

[89] *Id.* at 40984.

[90] *Id.*

making it impossible to calculate the exact adjustment that will be made for any measure. If CMS were to maintain this approach in the final rule, we request that CMS publish a table of the *sw* value for each of the clinical measures to allow facilities with small sample sizes to better predict the impact of the QIP methodology on their payments.

KCP, however, would prefer that CMS simply increase the minimum number of cases, which would be a simpler and more transparent approach to addressing the small numbers problem. Previously, KCP has recommended that CMS adopt 20 as the minimum number of reportable cases. We derive the recommended number from an analysis that Discern prepared and which we shared with CMS during the PY 2013 and PY 2014 rulemaking cycle.[91] Twenty cases is also more consistent with the minimum number of cases used in commercial/private pay-for-performance programs. However, the Proposed Rule seems to suggest CMS might be looking at 25 as an appropriate threshold. Finally, we understand that the minimum number of reportable cases for physicians is 30. Thus, it seems clear that 11 is inconsistent with other programs and too low to address the problem of small sample size. Given these different data points, we recommend that CMS use a number between 25-30 as the minimum number of reportable cases required to participate in that measure of the QIP.

5. CMS should adjust the total performance score thresholds to ensure that the estimated payment reductions are realized.

KCP supports the design of the QIP, which is consistent with the PY 2014 structure. We encourage CMS to closely monitor measure performance as compliance data become available to check the accuracy of its payment estimates. If the estimates CMS made to determine the payment reduction distributions for PY 2015 are not consistent with the actual impact, we recommend that the Agency adjust the total performance score thresholds to maintain the payment distributions. For example, the Agency should adjust the total performance score threshold down to maintain the 85 percent "no payment reduction" estimate set forth in the proposed rule.

6. CMS should adopt the proposed change of ownership policies.

KCP applauds CMS for proposing a way to address the concerns we have raised about the ability of new facilities to participate in the QIP. We agree with the policy established for PY 2014 and its continuation in PY 2015.[92]

7. CMS should finalize the proposed modifications to the public reporting aspect of the QIP, but provide a meaningful way to address concerns facilities raise before certificates are finalized.

KCP supports the proposed modifications to the public reporting requirements, especially the adjustment to the timeframe for posting certificates and the inclusion of Spanish versions of these documents.[93] Our primary concern with the current requirements, however, is that while CMS does provide procedures for reviewing the information included on the certificates, it is not a meaningful

[91] *Available upon request from the author.*

[92] *See* 77 Fed. Reg. at 40985.

[93] *See id.* at 40987.

process. In many instances, concerns about accuracy were not addressed before the certificates had to be posted. Thus, we recommend that CMS provide a mechanism that allows facilities who have data supporting different results than those included on the certificates to have these data taken into account and the certificates modified.

IV. CMS Should Work with the Kidney Care Community to Adopt a Strategic Vision for the QIP.

KCP appreciates that CMS has begun to outline and requests comment on ideas for future measure domains and retirement/removal criteria for current QIP measures. However, we strongly encourage the Agency to take a more holistic approach and provide a clear overview of what the program will look like on a going forward basis, including addressing the criteria and process for adding measures – both clinical and structural; the criteria and methodology for adopting performance standards, attainment thresholds, and benchmarks for current and future measures, as well as how these will be modified over time; and how the reporting of measures will be used to empower beneficiaries. CMS should work with the community to develop this type of strategic vision. KCP would welcome the opportunity to discuss how we can help lead this effort as well.

Generally speaking, KCP supports the criteria CMS proposes for determining when to retire or remove a measure from the QIP. The seven criteria set forth are consistent with the NQF guidance to its Steering Committees for measure re-endorsement evaluation, reserve status criteria, or ad hoc reviews required for new evidence. We agree that it is important to set forth such criteria to provide transparency and allow the kidney care community to have a better understanding of the program. We assume, but encourage CMS to clarify, that it will rely upon rulemaking in each particular instance when it plans to remove or retire a measure, as it has done thus far with the QIP.

In a similar way, 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 2015, 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.[94] 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)**;

[94] *See* 42 U.S.C. § 1395rr(h)(2)(B)(i).

- 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).**[95]

If NQF has endorsed a measure, then these criteria have clearly been met; however, if CMS proposes to add non-endorsed measures, we urge the Agency to use a parallel evaluation process to ensure the integrity of the measure. We also encourage the Agency to request NQF endorsement as soon as possible once a non-endorsed measure is proposed. CMS could also apply these criteria to updating measures in future years.

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

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 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.[96] Then, when a new measure is added, facilities should be judged by the lesser of

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

[96]*See* 77 Fed. Reg. at 40972.

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;[97] 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.

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 in light of the criteria described in this section. We reiterate our concerns about the inclusion of the standardized hospitalization ratio (SHR) and appreciate the Agency's willingness to postpone its inclusion in the current QIP. In terms of the standardized mortality ratio (SMR) and domains, we would work with the Agency to develop a short-to-mid-term list of potential domains that would meet the aims of the National Quality Strategy, while also providing meaningful data to promote high quality care at both the individual patient and population levels.

First, we recommend against including the standardized hospitalization ratio for admissions (SHR) measure in the QIP in the near term. The kidney care community agrees that reducing hospitalizations is an important goal, but we continue to withhold our support for including the SHR measure (NQF #1463) in the ESRD QIP. The information upon which the measure is based is not specific to dialysis facilities and will not incentivize reductions in hospitalizations in the dialysis context. KCP recommends the specifications be modified to "Risk-adjusted standardized hospitalization ratio for dialysis access-related infections and fluid overload," with the numerator and denominator limited to the appropriate DRGs for dialysis access-related infections and fluid overload. Further, the methodology used to calculate the SHR is not transparent. In particular, the measure developer does not provide clarity with respect to the denominator of "expected" hospitalizations. Thus, KCP does not support inclusion of the measure in the QIP for reporting or payment purposes without modifications.

The preamble also discusses three potential domains for measure development and the SMR. Without a better sense of the direction CMS plans to take with regard to these areas, it is difficult for us to provide meaningful comments on them. Thus, rather than support or oppose them, we encourage CMS to work with KCP and others in the kidney care community to develop a limited set of domains and explore measure development in those areas. Specifically, we recommend that CMS identify a team of experts to meet quarterly (if not more frequently in the beginning) with representatives of KCP and other interested stakeholders to discuss the strategic vision for the program, as well as potential domains for measure development. These recommendations could be refined and presented for community review and response during the next rulemaking cycle. In this way, CMS and the community could form a partnership to provide a consistent and thoughtful plan for the future of the QIP.

Part 3: Conclusion

KCP appreciates the opportunity to provide comments on the PPS CY 2013 and QIP PY 2014 and PY 2015 proposed regulations. We look forward to meeting with the Agency in the coming weeks. 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,

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[97] *See* 42 U.S.C. § 1395rr(h)(4)(E).

Ronald Kuerbitz
Chairman
Kidney Care Partners

Appendix A
List of KCP Members

Abbott Laboratories
Affymax
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita, Inc.
Dialysis Patient Citizens
DCI, Inc.
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Kidney Care Council
Kidney TRUST
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
Sanofi
Satellite Healthcare
Takeda Pharmaceuticals U.S.A (TPUSA)
U.S. Renal Care
Watson Pharma, Inc.

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.