



August 30, 2011

Dr. Donald Berwick
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1577-P: Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014; Ambulance Fee Schedule; and Durable Medical Equipment Proposed Rule

Dear Dr. Berwick:

Kidney Care Partners (KCP) appreciates the opportunity 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 for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014 (Proposed Rule).¹ KCP is an alliance of members of the kidney care community that includes patient advocates, dialysis care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with both chronic kidney disease (CKD) and irreversible kidney failure, known as End-Stage Renal Disease (ESRD).

Overall, KCP supports CMS's proposal for the Calendar Year (CY) 2012 Prospective Payment System (PPS); however, we remain concerned about the co-morbidity case-mix adjusters and the lack of sufficient data to evaluate the Proposed Rule and offer our suggestions to improve the bundled payment system. In developing these comments, we worked with The Moran Company, a Washington-based health care research and consulting firm focused on the boundary between the public and private sectors in health care. Specifically, we recommend that CMS:

- Provide Dialysis Facilities and Providers with the Information They Need to Document the Co-Morbid Case-Mix Adjusters;

¹See 76 *Fed. Reg.* 40498 (July 8, 2011).

- Ensure the Integrity of the ESRD PPS Bundle by Addressing Concerns with the ESRD Cost Report, Providing a Clear Process for Expanding the ESRD PPS Bundle, and Establishing a New Technology Adjustor;
- Provide the Rate Setting File and an Impact File at the Provider Level To Allow for a More Transparent Process; and
- Resolve the Technical Concerns Raised in 2011, as well as Address New Concerns Raised by the Proposal to Update the Drugs and Productivity Adjustor and Training Add-On.

We have more serious concerns about CMS's proposals for the Quality Incentive Program (QIP). In developing these comments, we worked with Discern, a health care policy consulting firm dedicated to improving health system performance through the strategic intersection of incentives and high-quality care. Discern has extensive experience developing and implementing value-based purchasing programs that focus on payment reform, including pay-for-performance, patient-centered medical home, transitions of care, consumer incentive and value-based benefit design initiatives. KCP is most troubled by CMS's plan to modify the payment structure in a way that delinks quality performance from the penalties in both Payment Years (PYs) 2013 and 2014. More specifically, KCP strongly recommends that for PY 2013, CMS:

- Restructure the Total Performance Score Methodology so that it Achieves the Goal of Incentivizing Quality Care and is Consistent Across Payment Years;
- Revise the Performance Standards and Performance Period so that They Meet the MIPPA Requirements for a Prospective QIP;
- CMS Should Continue to Track Hemoglobin Levels;
- Develop a Clear, Transparent, and Timely Process for Developing and Publishing Standardized Measure Specifications and Definitions, as well as Data Submission Requirements;
- Provide Incentive Payments under the QIP; and
- Adopt Clarifying Language for the Public Reporting Requirement.

For PY 2014, the community recommends that CMS:

- Adopt a Revised Set of Measures for PY 2014;
- Provide for a Clear, Transparent, and Timely Process for Developing and Publishing Standardized Measure Specifications and Definitions, as well as Data Submission Requirements;

- Not Weight All Measures within the Outcomes Categories Equally;
- Maintain 2012 as the Performance Period, as Long as the Agency Finalizes the Actual Performance Standard before that Year Begins;
- Address Technical Concerns with the Methodology for Establishing Performance Standards; and
- Refine the Total Performance Score Methodology and Allow for Additional Comments when Performance Standards are Established before Finalizing the Methodology.

Finally, looking forward, KCP appreciates the opportunity to comment on potential domains for future measure development. We also suggest that the Agency outline in the final rule a clear process and criteria for developing and adopting new measures and their weights, as well as establish a phase-in process for introducing new measures to the QIP.

I. CMS Should Refine the ESRD PPS CY 2012 Proposals to Ensure Accuracy and Protect the Integrity of the New Payment System.

Overall, KCP supports the implementation of the ESRD PPS; however, we remain concerned that some of the proposed policies continue to result in a loss of funds from the Medicare ESRD program that exceeds the Congressionally-mandated haircut of two percent for CY 2011. Historically, our primary focus centered on getting the transition adjustment correct; we applaud the Agency for addressing this early in 2011 to account for the actual number of facilities that decided to accept fully PPS payments beginning in 2011.² Thus, we are pleased that the Agency maintains the transition adjustment at zero for CY 2012³ and urge CMS to finalize this policy as proposed. Additionally, we support the Agency's clarification that laboratory tests performed for Medicare ESRD beneficiaries in a hospital emergency room are not renal dialysis services for purposes of the ESRD PPS payment bundle.⁴

Yet, there are several proposed provisions that raise serious concerns with our members. First, if the case-mix adjustors and other technical issues are not resolved and implemented as proposed, there will be a significant loss of funds. As described in detail below, it is extremely difficult for dialysis facilities and providers to document the adjustors. Second, we call on CMS to protect the integrity of the ESRD PPS bundle by addressing concerns with the ESRD cost report, providing a clear process for expanding the ESRD PPS bundle, and establishing a new technology adjustor.

²76 Fed. Reg. 18930 (Apr. 6, 2011).

³76 Fed. Reg. at 40506.

⁴*Id.* at 40517.

In addition and as noted in our recent letter to Jonathan Blum, we remain concerned that the kidney care community cannot fully evaluate and effectively comment on the Proposed Rule because the Agency has not released a rate setting file for the new PPS or an impact file at the provider level, the latter of which CMS released for the CY 2011 Proposed Rule. Rate-setting files have historically been developed by CMS and released for public use under data use agreements with CMS's privacy office when proposed and final rules are released for public comment.⁵ We have not been able to evaluate the Proposed Rule policies, especially the outlier and the low-volume adjustor, completely because we do not have access to these data. We appreciate that producing such files requires the Agency to commit scarce resources to the project. That said, we strongly urge CMS to develop and execute a detailed plan for the development and release of appropriate analytic files, structured to be as useable and transparent as possible, at the time of the release of the final rule for this cycle and for proposed and final rules in future rulemaking cycles.

Finally, we remain concerned about the technical issues because of their impact on the base rate for CY 2012 as well as future years.

A. CMS Should Provide Dialysis Facilities and Providers with the Co-Morbid Case-Mix Adjustors.

While we support CMS's decision not to increase the number of co-morbid case-mix adjustors in the ESRD PPS and its commitment to monitor the prevalence of the co-morbidity diagnoses,⁶ KCP remains concerned that as currently designed the co-morbid case-mix adjustors cannot be documented by dialysis facilities and providers and, thus, not claimed in many instances. This problem, if not addressed, could result in a one to two percent per treatment loss to facilities and providers. Therefore, we strongly encourage CMS to provide facilities and providers with access to the information necessary to document the case-mix adjustors. Finally, CMS should update the case-mix adjustor component to the standardization applied to the unadjusted base rate based upon the actual number of adjustors claimed and paid out to ensure that funds are not unnecessarily withheld from the base rate.

1. Dialysis facilities and providers do not have access to the beneficiary data needed to document the co-morbid adjustors.

In finalizing the case-mix adjustors for CY 2011, CMS indicated that it anticipated dialysis facilities and providers would have access to the required documentation because the co-morbidity conditions on which they are based are critical to designing an individual

⁵The rate setting file developed for the composite rate payment system and the drug-spread add-on is not adequate to evaluate the new PPS policies.

⁶76 *Fed. Reg.* at 40516-17.

beneficiary's plan of care. KCP raised concerns in its comments on the CY 2011 rules that this assumption does not take into account that even if a facility or provider knows or suspects that a beneficiary has one of the co-morbidities being used as a case-mix adjustor, it does not follow that there is sufficient documentation to permit the facility or provider to claim the adjustor. Eight months into the first year of the ESRD PPS, dialysis facilities and providers have found that their fears were warranted.

When CMS turned to the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop the adjustors, it provided the contractor with data beyond that available to dialysis facilities or providers. Limiting the data to that which dialysis facilities and providers have access leads to results that are much different than those CMS assumed they would be. The Moran Company has tested the dialysis, hospital, and physician claims and found that:

- Dialysis providers have historically not recorded 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;
- The identification of the acute condition adjustors can be increased with access to one year of prior hospital claims;
- Most evidence of the chronic adjustor diagnoses in claims is derived from specialty physician claims other than nephrology; and
- The probability of identification of a co-morbid condition increases with access to specialty physician and hospital claims in the prior year for the acute conditions and in multiple past years for the chronic conditions.⁷

In order to get close to the prevalence of adjustors reflected in CMS's adjustor calculations, facilities and providers would need at least two years of access to hospital, specialty, and primary care physician claims for their patients. Even with these data, The Moran Company estimates that the prevalence would remain lower than that estimated by CMS.

The experience of KCP members reflects this analysis and raises additional concerns. Despite their best efforts to collect the evidence, dialysis facilities have encountered systemic roadblocks. Beneficiaries are primarily diagnosed with these conditions outside of the dialysis facility or provider/nephrologist context. For example, The Moran Company found the following data breakdown:⁸

⁷The Moran Company, "Review of 5% random sample of Medicare SAF file for 2007, 2008 Industry Claims. Outpatient Claims include Rural Health Centers, Federally-Qualified Health Centers, Rehab Facilities, and Psychiatric Facilities" (available upon request).

⁸The data in this chart are available from The Moran Company. *See id.*

Source of Medicare CMS Related Claims					
Co-Morbidity	ESRD Facilities	After Including Nephrologists	After Including Physician Offices of All Other Specialties	After Including Inpatient and Outpatient Hospital Claims	After Including Home Health, Hospice, DME, and Skilled Nursing Facility
Bacterial Pneumonia	0.01%	0.15%	1.64%	2.34%	2.44%
GI Bleed	0.00%	0.03%	0.72%	1.16%	1.19%
Pericarditis	0.00%	0.05%	0.35%	0.42%	0.43%
Sickle Cell	0.08%	0.08%	0.22%	0.32%	0.33%
Monoclonal Gammopathy	0.27%	0.29%	1.06%	1.21%	1.22%
Myelodysplastic Syndrome	0.17%	0.21%	1.22%	1.44%	1.46%

As this chart demonstrates, facilities and providers must rely heavily upon non-nephrologists to identify the chronic conditions. The physicians who most often diagnose these conditions are: oncologists, hematologists, primary care physicians, hospital physicians, gastroenterologists, and cardiologists.⁹ Facilities have hired additional staff dedicated to calling hospitals and physicians to obtain the required information. Often, these providers refuse to provide the data citing concerns about the HIPAA Privacy Rule.¹⁰ One small dialysis organization found that for its 1415 dialysis beneficiaries, it was able to obtain documentation from physicians for only 42 of those beneficiaries.¹¹ Even if a hospital or physician responds, they may not have the appropriate documentation because in some cases the documentation requirements do not reflect clinical practice. For

⁹*Id.*

¹⁰In many instances, dialysis facilities have encountered strong opposition from hospitals and physicians when asked to provide the required data. These entities claim that the HIPAA Privacy Rule prohibits them from sharing this information. While we understand that this information may be disclosed without first obtaining a patient authorization form because it is clearly for the purposes of either "treatment" and/or "payment," dialysis facilities have found that even with the assistance of legal opinions many entities reject this analysis and refuse to provide the documentation.

¹¹Data provided by Northwest Kidney Centers and available upon request.

example, the documentation requirements for bacterial pneumonia require an X-ray referral, which is not something that diagnosing physicians typically do. Rather, clinical practice dictates that once symptoms are observed (without an X-ray or sputum culture), physicians prescribe the antibiotic that day.

Even if the data are captured, the significant time lag requires rebilling. It can take up to eight weeks or more to obtain the necessary documentation to support claiming co-morbid adjusters. For example, one KCP member estimated that to document bacterial pneumonia, it takes three to five additional days to obtain an X-ray referral (something that diagnosing physicians typically do not do).

2. CMS could resolve the documentation problem by providing facilities and providers with access to the necessary data.

We believe the Agency's interest and ours are aligned in trying to obtain appropriate documentation for claiming these co-morbid adjusters. Given that dialysis facilities and providers have not been able to obtain the required documentation to support claiming these adjusters, KCP strongly urges CMS to provide access to the data necessary to document these adjusters. CMS could do this by: (1) adjusting dialysis claims based upon CMS data; (2) creating a case-mix adjuster data table that dialysis facilities and providers could access; or (3) providing automated access to the common working file (CWF) ESRD ICD-9 data to dialysis facilities and providers so that they can appropriately document the diagnoses using a valid and trusted data source.

First, CMS could apply the co-morbid adjusters after it receives the claims from dialysis facilities. As evidenced by the data that UM-KECC used to establish the basis for the co-morbid adjusters, CMS has in its databases the information necessary to document the adjusters. CMS could match a beneficiary's claim to the ICD-9 codes in other CMS files related to the beneficiary. This option is similar to that CMS already uses in the Medicare Advantage Program and would assure the accurate application of the adjusters.

Second, CMS could provide dialysis facilities with the data necessary to document the co-morbid adjusters through a web-based or similarly accessible access portal. For example, CMS could establish a table with the necessary information and allow facilities to obtain the relevant information and include it in a beneficiary's medical record as documentation supporting the claim of a co-morbid adjuster.

A third option is providing organized access (*i.e.*, pre-developed query) to the CWF. As you know, the CWF includes all Medicare fee-for-service Part A and Part B claims processing data, including eligibility, demographic, and payment information, as well as other information, such as hospice election forms. CMS already shares this information with its contractors. Regulations also indicate that providers are eligible for access to the CWF specifically "to establish the validity of evidence, or to verify the accuracy of information presented by the individual as it concerns the individual's entitlement to

benefits under the Medicare program, including proper reimbursement for services provided.”¹² CMS has allowed the MACs to offer access to the CWF to SNFs and hospices when it required these providers to use information not normally available to them, consistent, as we understand, with a recommendation from the Medicare Payment Advisory Commission (MedPAC).

This option would work if CMS creates a data feed of relevant medical records on the ESRD patients assigned to a facility. The facility could then electronically sort the data. This access would allow dialysis facilities to search a patient’s claim history for the list of ICD-9 codes associated with the adjustors to verify the documentation of the diagnoses. The CWF search results could then be included in a beneficiary’s medical record as documentation supporting the claim of a co-morbid adjustor. If CMS is not able to address the information issue through one of the suggested solutions, it should suspend applying the co-morbid adjustors until it is able to provide the necessary data to dialysis facilities and providers. We welcome the opportunity to work with the Agency to establish a process and timetable for implementing any of these options. We also encourage CMS to undertake retrospective claims repayment for CY 2011 to the extent facilities and providers have been unable to claim co-morbid adjustors because of an inability to document that they were entitled to claim them because of a lack of the required information.

3. CMS should use actual data to establish the case-mix adjustor standardization adjustor.

Finally, CMS should update the case-mix adjustor portion of the standardization adjustor based upon the actual number of adjustors being claimed so that the base rate is not unnecessarily reduced. The standardization adjustor for CY 2011 was understandably based upon estimates that the Agency made based upon a previous analysis performed by UM-KECC. Given that CMS has substantial data on the actual prevalence of the adjustors as claimed by dialysis facilities and providers, the Agency should adjust the standardization to reflect this actual prevalence as reported by dialysis facilities and providers in CY 2011.

B. CMS Should Ensure the Integrity of the ESRD PPS Bundle by Addressing Concerns with the ESRD Cost Report, Providing a Clear Process for Expanding the ESRD PPS Bundle, and Establishing a New Technology Adjustor.

Maintaining the integrity of the ESRD PPS bundle is critically important to ensuring the stability of the Medicare ESRD program as dialysis facilities and providers transition to this new payment structure. To accomplish this goal, KCP urges CMS to: (1) address concerns related to the ESRD cost report, which provides the foundational data for establishing the ESRD PPS payment rates; (2) clarify the process it will use for expanding

¹²71 *Fed. Reg.* 64955 (Nov. 6, 2006).

the PPS bundle in the future; and (3) establish a new technology adjustor that incentivizes innovation in the program.

1. CMS should clarify the timeline for addressing concerns raised by the kidney care community in the cost report reform process launched earlier this year.

While we appreciate that cost report reform is a process independent of the ESRD PPS Proposed Rule, KCP believes it is important to modernize the cost reports so that they appropriately reflect the costs incurred by dialysis facilities to make sure that the data for adjusting the PPS on an ongoing basis are accurate and appropriate. To accomplish this goal, we believe that cost reports must be useful and accurate tools for providers, CMS, MedPAC, the Congress, and other analysts. They should also include all the costs providers incur when providing care under the PPS. In addition, modifications should reinforce clarity and consistency.

Cost reports establish the foundation for setting payment rates and margin analyses that affect inflationary updates. If they 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. In addition, cost reports should reflect the core principle of the ESRD 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.

As CMS continues to evaluate the Medicare ESRD cost report, we recommend three specific changes:

- The restrictions on medical director fees should be eliminated because they do not reflect the true cost of hiring medical directors. The reasonable compensation equivalents (RCEs) are tied to internists, not nephrologists (the preferred candidates for serving as dialysis facility medical directors) and the risk of overcompensation is extremely low because the compensation amount is already restricted by the Stark law;
- The requirement that facilities report the cost of items/services purchased from a related entity at cost should be modified to allow for a minimal profit margin, similar to how profits are determined in other parts of the Medicare program; and
- The Agency should specify as part of the cost report how the cost of:
(1) existing items/services added to the bundle; (2) innovative/new items/services; and (3) currently non-covered items/services will be calculated

and reported on the cost reports so that the data needed to incorporate such items/services into the PPS are readily available.

We look forward to working with CMS to help refine the cost reports so that they are consistent with the goals and objectives of the ESRD PPS. Absent reform, it will be difficult for CMS to evaluate objectively the adequacy of the new payment system.

2. CMS should clearly state in the final rule how the Agency plans to add existing items or services to the ESRD PPS bundle and how it plans to account for the changes in costs associated with such additions.

As the ESRD PPS matures, it will be important for CMS to establish an open and transparent process for adding existing items and services to the bundle, as well as how to account for the costs of such additions in the base rate. KCP recognizes that CMS has a great deal of experience with undertaking such efforts in other Medicare prospective payment systems. However, we strongly encourage the Agency to state in the final rule that it will use notice and comment rulemaking under 5 U.S.C. § 553 (section 553 of the Administrative Procedures Act) when it plans to make such additions.

We believe this approach is more appropriate than leaving such decisions to guidance because rulemaking is a well-established process that the Agency undertakes annually anyway. It also allows for transparency and community input. Relying on the rulemaking process is appropriate additionally because such changes will have an obvious impact on the items and services beneficiaries should expect, as well as on the costs dialysis facilities and providers incur in providing services to beneficiaries. Expansions of the bundle will affect the base rate and adjustors. This economic impact 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 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.

3. Under its authority to add new adjustors to the ESRD PPS, CMS should establish a new technology adjustment that is not budget neutral.

Finally, KCP recommends that CMS use this opportunity to establish a new technology adjustor for CY 2011 and beyond that would allow for additional payments in a non-budget neutral manner. We believe there is sufficient legal authority in MIPPA to provide for such an adjustment and that it is appropriate and necessary to incentivize the development of new technology in this sector of health care.

MIPPA provides CMS with authority to “include such other payment adjustments as the Secretary determines appropriate.”¹³ While it admittedly provides a list of examples, this list is not exclusive. As you know, there is precedent in the Ambulatory Surgical Center (ASC) context for the Agency using general authority to establish a new technology adjustor. Therefore, to the extent CMS finds value in adopting a new technology adjustment, this provision of MIPPA would allow for its development.

A new technology adjustor is important to drive the development of new technologies in this sector. Historically, there have been few technology improvements in dialysis treatment given the limited reimbursement rates under the composite payment. New technologies can lead to better diagnoses, better treatment options, and ultimately better outcomes for patients. We are concerned that if there is no adjustor recognizing the additional cost associated with adopting new technology, those who develop new items and procedures may not find sufficient incentive to move forward with such work. The PPS augments the historic problem by shaving two percent off of the overall bundle in CY 2011, reducing the base rate in a way that acts as a disincentive to adopt any new technology that exceeds the PPS reimbursement amount.

We welcome the opportunity to work with CMS to develop such an adjustor, but at its base, we suggest that it 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.
- 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.

¹³42 U.S.C. § 1395rr (b)(14)(D)(iv).

- 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.

C. CMS Should Provide the Rate Setting File and an Impact File at the Provider Level to Allow for a More Transparent Process.

As noted in the introduction to this section, KCP strongly urges CMS to release a rate setting file that includes all of the elements needed to analyze the ESRD PPS and an impact file at the provider level to allow the kidney care community and others to evaluate this Proposed Rule and future rules more effectively. The lack of the provider level impact file is especially troubling because it makes it extremely difficult to evaluate the impact of the changes in the outlier policy and the low-volume adjustor. Without the data, our comments about these two proposals cannot be complete.

1. CMS should provide an ESRD PPS rate setting file to allow for a full evaluation of the impact of the proposed changes to the outlier policy.

KCP's evaluation of the proposed changes to the outlier policy is limited to our general observations because of the lack of an appropriate ESRD PPS rate setting file. For example, while it may be appropriate to recognize that antibiotics furnished in the home for catheter infections or peritonitis be eligible for outlier services,¹⁴ we cannot evaluate the impact of including these drugs without having an ESRD PPS-specific rate setting file to analyze the impact of doing so. We have a similar concern with offering comments on the exclusion of the automated multi-channel chemistry (AMMC) laboratory tests from the outlier calculation.¹⁵ Thus, we urge the Agency to provide the community with the appropriate data to allow for a full evaluation of the proposals before finalizing them.

Generally speaking, we support CMS's proposal to provide more flexibility in determining drugs and biologicals that are eligible for outlier payments by eliminating the list as part of the notice and comment rulemaking process.¹⁶ We continue to support the

¹⁴76 *Fed. Reg.* at 40513-14.

¹⁵*Id.* at 40514.

¹⁶*Id.*

creation of a list through guidance to allow for a transparent process, but recognize the burden rulemaking requirements place on the Agency. The kidney care community is in an area that can change outside the traditional rulemaking cycle. We encourage CMS to ensure that the process moving forward remains transparent and subject to input from the kidney care community and other interested parties.

CMS also proposes a series of modifications to the list of specific drugs as outlier services that results in a net increase in the Medicare Allowable Payment (MAP) amount that forms the baseline for the outlier payments for adults and decreases it for children.¹⁷ Overall, it is difficult to assess these policies because of the lack of data accompanying the Proposed Rule.

Given the sensitivity noted in the preamble of outlier payments in the pediatric dialysis setting, we again reiterate the need for more data to allow us to provide additional comments as to how the proposed changes could particularly impact pediatric dialysis.

2. CMS should provide an ESRD PPS rate setting file to allow for a full evaluation of the impact of the proposed changes to the low-volume adjustor.

Generally speaking, KCP appreciates the Agency's clarification about the difference between the payment and eligibility years, as well as the proposed policy to clarify the process for submitting low-volume attestations to the FIs/MACs.¹⁸ These clarifications will help ensure the appropriate application of this adjustor.

However, we are concerned that CMS may have overestimated the application of the low-volume adjustor in the standardization calculation, which will lead to funds being taken out of the payment system inappropriately. As we have noted previously in this letter, it is critical for the kidney care community to have access to the data needed to estimate accurately the impact of the changes that CMS proposes.

Using the provider level impact file released with the 2011 Final Rule along with claims and cost report data, The Moran Company found that 25 pediatric facilities (>50% treatments for patients<18 years of age) were flagged as low-volume facilities, presumed eligible for the low-volume adjustor. These facilities had an average adjustor of 1.239 excluding the wage index. The Final Rule excludes pediatric facilities from eligibility for the low-volume adjustor. If these facilities and associated pediatric treatments were included with the low-volume adjustor in the standardization calculation, that calculation will be overstated, thereby decreasing the base rate below the level mandated by MIPPA.

¹⁷*Id.*

¹⁸*Id.* at 40506.

The Moran Company found other discrepant identification of low-volume facilities compared to those identified by CMS. CMS now has identified actual low-volume facilities and could re-calculate the standardization adjustment using actual data to ensure that it accurately represents the low-volume facility component of standardization. Such a procedure would be consistent with CMS's recalculation of the transition adjustor based on actual data to correct its earlier estimation based on current and accurate data.

D. CMS Should Resolve the Technical Concerns Raised in 2011, as well as Address New Concerns Raised by the Proposal to Update the Drugs and Productivity Adjustor and Training Add-On.

Another area of serious concern for KCP focuses on a series of technical issues that The Moran Company has identified in its analysis of the Proposed Rule. These include: (1) the calculation of the oral drug add-on and productivity adjustor; (2) the training add-on amount; and (3) technical concerns raised in the CY 2011 Proposed Rule that have not been addressed.

1. The proposed methodology to update the oral drug portion of the ESRD PPS bundle rate is incorrect.

KCP is concerned about the proposal to change the oral drug portion of the transition blended payments. This issue is important not only to correct the proposed adjustment, but also because we presume that CMS would adopt the same methodology when it incorporates the non-IV equivalent oral drugs into the bundle in 2014. For CY 2011, CMS used 2007 utilization data and inflated it using the national drug expenditure data to estimate the portion of the PPS bundle rate that would account for the oral drugs to be included in the bundle. In the Proposed Rule, CMS added this amount (\$0.49) to the composite rate and then applied the market basket reduced by the productivity adjustor.¹⁹

To be technically correct, however, this amount should be split with 50 percent of it paid at the market basket rates (inflated by the PPI) and 50 percent of it adjusted using the update factors. We recognize that this modification would lead to the ESRD PPS being updated differently than other payment systems, but that distinction is appropriate because of the unique nature of this program. Specifically, the factors used in the productivity adjustor, which are mostly derived from capital and labor related economic measures, are not appropriate to use to modify the market basket costs of drugs, which are consumable items. ESRD should be treated differently than other providers paid under a PPS because drugs represent such a large portion of the overall costs incurred by dialysis services.

¹⁹*Id.* at 40505.

2. CMS should finalize the technical correction to the training add-on amount, but refine how it is updated.

Generally speaking, KCP supports CMS's proposed technical correction to the training add-on amount;²⁰ however, when finalizing this proposal, CMS should update the training add-on as well. The training add-on is essential to support home dialysis. Historically, training-related payments have not been adjusted for inflation, which has meant that they have not kept pace with increasing costs, such as nursing salaries, that facilities and providers have incurred to provide these important services. KCP remains committed to promoting appropriate modalities of care for beneficiaries requiring life-sustaining dialysis services. Thus, it is important that reimbursement rates keep pace with increasing costs to ensure that the training service add-on is appropriately adjusted to reflect the costs it was designed to represent.

A separate inflationary adjustment is necessary because the training add-on is outside of the bundle base rate and, thus, would not be captured in annual market basket update methodology. KCP recommends at a minimum that CMS update the training add-on by either applying the update factor directly to it or by re-calculating the value of one hour of nursing time using the method that the Agency described in the ESRD PPS Final Rule for CY 2011. Additionally, KCP recommends a technical correction within the current claims process directions to allow for training treatments to be paid at the frequency prescribed for each patient up to the number of days currently allowed within the CMS regulations.

3. CMS should address the technical concerns highlighted in CY2011.

In previous comment letters, KCP with the assistance of The Moran Company identified a series of technical issues that resulted in a reduction in the base rate from what it should have been for CY 2011. Recognizing the challenges the Agency faced in implementing the new payment system, we deferred following up on some of these smaller, yet critical concerns. However, these issues must be addressed to avoid the impact of them multiplying as the discrepancies continue year to year.

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

²⁰*Id.* at 40516.

- Following the trims described by CMS, TMC identified 331,877 patients, compared to CMS's 328,727 patients, and absolute difference of 3,090 patients or 0.9 percent more patients.²¹
- TMC treatment counts are also 200,589 higher than CMS's (0.5 percent). TMC treatment counts do not include Method II patients. Method II payments are included in the base rate, but we know of no way to count Method II treatments and neither the proposed or final rules explained whether or how Method II treatments were counted.
- TMC calculations of payments per treatment for components of the 2007 MAP are mostly higher than those reported by CMS.²²
- TMC 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 used to calculate the 2007 MAP. Based on the 2007 SAF data, TMC 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, TMC 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. TMC 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 Final Rule. TMC 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.
- TMC used CMS values where it could not replicate payments in its SAF data. The differences between CMS and TMC values are shown in Tables 1 and 2 for 2007 and 2009 values. The TMC-calculated MAP is \$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.

²¹See Appendix B; *see also* 75 Fed. Reg. at 49068-69.

²²See Appendix B.

To move from 2009 to 2011 dollars, CMS uses a combination of inflation factors that are either in statute or based on other specific indices or data sources. CMS does not provide the component values that contribute to the 2011 unadjusted base rate, making it impossible for TMC to replicate this step in CMS's methodology. The base rate calculation would be more transparent if CMS would provide detail as to its inflation factors for each component in Table 19 in the 2011 Final Rule showing how it moves from 2009 to 2011 dollars, consistent with documentation of earlier steps in the process.

In addition to addressing these issues for CY 2012, we also request that CMS make the corrections retrospective to adhere to the requirement that the overall ESRD payments for CY 2011 should have been 98 percent of those that would have been provided if the ESRD PPS had not been implemented.²³ In addition to a meeting to discuss the overall comments, we would like to arrange a discussion between the technical team at CMS and The Moran Company to expedite the resolution of these issues.

II. CMS Should Refine the ESRD QIP PY 2013 and PY 2014 Proposals to Address Critical Flaws with the Methodology for Calculating Penalties, the Proposed Measures, the Performance Standards, and the Performance Period.

KCP strongly supports including value-based purchasing as part of the Medicare ESRD program. As you may recall, KCP led the effort working with the Congress to establish the authority for CMS to make the ESRD QIP the first value-based purchasing program in Medicare. Because of this unique position, there is a great deal of attention as to the effectiveness of this program. Its results will likely be used in further development and design of other such programs. In that regard, we have worked historically with Abt Associates, Inc., and now with Discern LLC to bring an additional level of depth and analysis to our comments that look not only at how individual facilities would fare under proposed aspects of the QIP, but also as to how effectively the proposed provisions will accomplish the overall goals of the QIP.

A. CMS Should Address the Methodological Flaws and Refine the Measures, their Definitions, and Public Reporting for PY 2013.

For PY 2013, CMS should address flaws in the proposed methodology, comply with the MIPPA prospective requirement, refine the proposed measures, ensure standardization of these measures, provide for incentive payments, and clarify the publicly reported data.

²³See 42 U.S.C. § 1395rr(b)(14)(A)(ii).

1. CMS should restructure the total performance score methodology so that it achieves the goal of incentivizing quality care and is consistent across payment years.

An area of grave concern for KCP is the proposed modifications to the methodology used to calculate the total performance score. In implementing the ESRD QIP, CMS must make sure that the methodology fairly evaluates facility and provider performance. As CMS Administrator Don Berwick has stated, one of the overarching goals of the Administration is to focus payments on how well providers are providing care.²⁴ This goal can only be met if the methodology used to calculate the performance of facilities and/or providers allows for appropriate comparison and does not skew the results by imposing penalties that are not tied to actual changes in the quality of care delivered.

While we support the continued use of a 30 point scale, calculating the performance score on each measure on a 10 point scale, subtracting two points for each percentage point below the performance standard, and the multiplier to address the reduction to two measures, the proposed penalty structure, reliance on a minimum of 11 reportable cases standard, and lack of discussion addressing between-laboratory variation are extremely problematic. After lengthy analysis, KCP is concerned that the proposed methodology for PY 2013 is structurally biased in such a manner as to make it impossible to accurately assess the quality of care being provided by dialysis facilities and providers.

a. CMS should reinstate the PY 2012 penalty structure.

The most troubling aspects the proposed PY 2013 methodology are the narrowing of the penalty range from 0.5-2.0 in PY 2012 to 1.0-2.0²⁵ and the tightening of the rate reduction scale. Contrary to the Agency's regulatory impact analysis, Discern Consulting has concluded that this structural change will result in a significant difference in outcomes from those reported for PY 2012 that indicates an inherent flaw in the structure. If left as proposed, this flaw will make it impossible to accurately judge the quality of care and, instead, result in cuts that are unrelated to the actual care provided.

²⁴CMS, "CMS Special Open Door Forum: End Stage Renal Disease Quality Incentives Program: Notice of Proposed Rulemaking Payment Years 2013 and 2104" 3 (August 2011) *available at* <http://www.cms.gov/ESRDQualityImproveInit/Downloads/QIPODF080411.pdf>.

²⁵It is not clear why CMS decided to modify the penalty structure and sliding scale. We have considered that the Agency might view the URR as having been "topped off," meaning that it might believe there is no room for improvement above the national benchmark. If this were the case, the Agency might have tightened the penalty to create greater disincentives for those facilities and providers that do not meet the national performance standard. We can appreciate the interest in addressing behavior when a particular measure has been met prior to it being retired. However, modifying the methodology across all measures does not establish a mathematically sound way to address this problem. Instead, it should adjust the calculation of the individual measure score. We would welcome the opportunity to work with the Agency to help identify how to address this important issue on a going forward basis. We strongly recommend that CMS not modify the methodology to accommodate such a concern without going through full notice and comment rulemaking allowing for meaningful input from the kidney care community and other interested stakeholders.

In the attached analysis, Discern finds that the narrowing of the penalty range and tightening of the rate reduction sliding scale would lead to most facilities (except those cases in which a facility has a very high performance or very low performance in 2012) experiencing a payment reduction in 2013 that would be greater than it was in 2012 even if their performance had remained the same. They conclude that these differences are due entirely to the proposed structural changes and not to actual changes in facility or provider quality.

Given that the proposed structure contradicts the goals of the QIP, we strongly encourage CMS to adopt the PY 2012 penalty range and sliding scale for PY 2013. This would result in the following sliding scale:

Total QIP Performance Score	Percent Payment Reduction
30-26 points	0.0%
25-21 points	0.5%
20-16 points	1.0%
15-11 points	1.5%
10-0 points	2.0%

Retaining the PY 2012 penalty structure would not only resolve the flaws created by the proposed structure, but it would also help beneficiaries by making it easier for them to compare facilities and providers on a year-to-year basis.

In addition, the PY 2012 structure is more consistent with the recommendations of policy experts and how successful value-based purchasing programs have been structured. The Institute of Medicine (IOM) has recommended a sliding scale approach and warned about individual scoring categories including too many performance scores without adequate incentives for providers to improve performance.²⁶ In the Premier Hospital Quality Incentive Demonstration, CMS has implemented a composite performance score aggregated into ten different tiers and used a sliding scale to pay out bonuses and reductions across the deciles.²⁷ Private insurers implementing pay-for-performance programs also rely upon multiple, narrow scoring scale categories. For example, the California/IHA pay-for-performance program adjusts payments on a sliding scale across multiple, narrowly defined performance categories of percentile distribution.²⁸ Each of

²⁶ See Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century*, 92 (March 1, 2001).

²⁷ Centers for Medicare and Medicaid Services (CMS), Fact Sheet: Premier Hospital Quality Incentive Demonstration Rewarding Superior Quality Care (July 2009), *available at* <http://www.qualitycoalition.net/Data/Sites/2/media/position-statement/hqid-fact-sheet.pdf>.

²⁸ INTEGRATED HEALTHCARE ASSOCIATION, *ADVANCING QUALITY THROUGH COLLABORATION: THE CALIFORNIA PAY FOR PERFORMANCE PROGRAM, A REPORT ON THE FIRST FIVE YEARS AND A STRATEGIC PLAN FOR THE NEXT FIVE YEARS* 18 (Feb. 2006) (at the time of the five

these programs uses more than three tiers and allows for a wide range of scores. CMS should not implement the ESRD QIP in a vacuum. Rather, it should look at these programs as examples for developing the QIP.

Given the lessons learned from other value-based purchasing programs and the flaws inherent in the proposed structure, we recommend that for PY 2013 CMS should use a broader penalty range (0.5% - 2.0%) and the five-tiered penalty scale adopted for PY 2012.

b. CMS should strengthen the statistical validity of the QIP by ensuring that facilities are not penalized based upon a small number of patients.

While we appreciate the Agency's recognition that facilities with a small number of reportable cases should not be included within the QIP, we are concerned that the threshold selected by CMS is too low to mitigate statistical variance. As the attached memorandum prepared by Discern states, the reliability of the data is dependent upon sample size.²⁹ When sample sizes are small, Discern found that there "is almost no consistency in facility results over time."³⁰ When conducting a regression analysis of the 2007 and 2009 facility/provider data available through Dialysis Facility Compare, Discern found that the R-squared for fewer than 20 patients is 0.0002. This low R-squared value means that the sample size is driving the results, rather than overall quality performance. Increasing the minimum number will substantially resolve the statistical anomaly we have identified in PY 2012 when the 11 reportable cases standard is used. Therefore, we recommend that CMS increase the minimum number to at least 20 reportable cases for participation in the QIP.

c. CMS should address the problem of between-laboratory variation.

KCP remains concerned that the Proposed Rule does not address the problem of between-laboratory variability in light of the fact that there are no *absolute* values in clinical laboratory testing. This between-laboratory variation was observed in a series of studies undertaken by R. Neill Carey, Ph.D.; Gordon Kapke, Ph.D.; James O. Westgard, Ph.D.; and Sten A. Westgard, MS.³¹ Their work demonstrates that between-laboratory bias can

year report, five of six private insurers participating in the program were using a relative percentile rank and allocated quality-related payments along a sliding-scale within a pre-defined percentile range).

²⁹Discern, "Memorandum to Kidney Care Partners: Identified issues with the PY 2013 and PY 2014 ESRD QIP" (Aug. 17, 2011).

³⁰*Id.*

³¹James O. Westgard, *et al.*, "Comparability of Laboratory Tests, Westgard QC, Madison, WI, prepared for Spectra Laboratories" (2008); R. Neill Carey, *et al.*, "Study of Bias among Laboratories for Tests Used in Monitoring End Stage Renal Disease, Westgard QC, Madison, WI, prepared for Spectra Laboratories" (2009) [hereinafter "Study Bias"]; and R. Neill Carey, *et al.* "Impact of Laboratory Analytical Bias on Proportions of Patient Populations Meeting K/DOQI Targets for

dramatically affect any attempt to determine whether beneficiaries are meeting a specific metric and, in turn, whether or not a facility has achieved a specific performance standard. For example, the researchers found that the average bias and average percent bias for hemoglobin tests in its sample was 0.17 g/dL or 1.5 percent.³² The variability in laboratory testing becomes a problem when large volumes of data are compared between and among laboratories.

If between-laboratory variability is not addressed in the QIP, it will be impossible to compare facilities either to a performance standard or to each other. The problem remains even if a facility is comparing its current performance to past performance if it has changed laboratories or its laboratory has modified its practices in the intervening period. The issue has not been of significance prior to the introduction of the QIP because physicians and non-physician practitioners have the ability to adjust their prescribing behavior or other activities based upon their assessment of the laboratory upon which they rely. The QIP has no such professional judgment component built into it. Given the penalty nature of the ESRD QIP, any variation should be accounted for because – if it is not – the variation could result in a higher penalty. Patients treated in facilities that use labs with “high” values will have different outcomes than patients treated in facilities using labs with “low” values. Such variation may lead to misclassification of patients at a proportion sufficient to shift distribution curves and affect QIP performance scores. If not addressed, the QIP may penalize facilities and providers for variability rather than quality of care. Thus, even though it might be tempting to ignore between-laboratory bias in year one, the work of R. Neill Carey and his colleagues suggests that to do so would result in a quality monitoring program that lacks validity and reliability.

Because between-laboratory variation not only results in skewed total performance scores, but also could threaten beneficiary care as treatments are adjusted to conform to performance standards, we strongly urge CMS to resolve the problem by establishing an acceptable standard deviation value that would be used when comparing reported quality measure values to the performance standards. Initially, we recommend that CMS set threshold values based on the allowable range of bias allowed by CLIA standards, in order to exclude the potential for laboratory-based analytical variability as a determinative factor of the QIP scores. A group of dialysis specialty clinical laboratories with whom the community works is launching an effort to improve the CLIA standards by reducing the total allowable error under CLIA through various means of improving the precision of laboratory testing for certain analyses that are now, or will likely be, quality measures in the ESRD QIP.

Tests Used in Monitoring End Stage Renal Disease, Westgard QC, Madison, WI, prepared for the Participating Laboratories” (2009) [hereinafter “Impact of Laboratory Analytical Bias”].

³²Study Bias, *supra* note 31.

2. CMS should revise the performance standards and performance period so that they meet the MIPPA requirements for a prospective QIP.

KCP is disappointed that CMS once again has chosen to ignore the statutory mandate that the ESRD QIP be prospective. In the Proposed Rule, the Agency indicates that it will use 2007 and 2009 data to establish the Performance Standards and 2011 as the Performance Period. This proposal is inconsistent with the plain meaning of the statute and contradicts Supreme Court doctrine that prohibits the retroactive application of regulations. It also fails to adhere to the goals of a value-based purchasing program. As such, KCP strongly recommends that CMS revise the performance standards and performance period so that they are prospective in nature.

In establishing performance standards and applying them to a performance period after it has ended, CMS has inappropriately attached new legal consequences to events occurring before the effective date of any final rule. Far from authorizing such retroactive penalties, MIPAA instead requires the Agency to establish performance standards prior to the performance period. Because such retroactive regulations are highly disfavored, the Agency may only issue them when expressly authorized by statute. Because MIPPA contains no such language, the Agency does not have authority to establish a retroactive rule.

MIPPA expressly requires a prospective application of the QIP to dialysis facilities. It provides that “the Secretary shall establish the performance standards under subparagraph (A) prior to the beginning of the performance period for the year involved.”³³ The Secretary must “establish the performance period with respect to a year. Such performance period shall occur prior to the beginning of such year.”³⁴ The plain meaning³⁵ of this provision requires that the performance standard be established before the performance period year.

The proposal for PY 2013 does not meet this clear requirement and is, thus, impermissibly retrospective. The proposed timeline for PY 2013 (which is likely to be finalized in November 2011) would have a performance standard of CY 2007 or CY 2009 and a performance period of CY 2011. Thus, the entirety or majority of the performance

³³42 U.S.C. § 1395rr(h)(4)(C).

³⁴ 42 U.S.C. § 1395rr(h)(4)(D).

³⁵See *Regions Hosp. v. Shalala*, 522 U.S. 448, 457 (1998) (noting that if “the intent of Congress is clear” as to “the precise question at issue” then “that is the end of the matter.”) (quoting *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 842 (1984)).

period will have ended prior to the establishment of the performance standards. This result is inconsistent with the requirements of the authorizing statute.

In the Final Rule for PY 2012, CMS erroneously concludes that this plain language requirement does not apply because the “Special Rule” established in subparagraph (E) trumps the requirement for the “initial period” of the ESRD QIP.³⁶ This interpretation is not supported when the entire paragraph of which subparagraph (E) is only one part is read as a whole. Rather than establishing requirements for the first year of implementation that are separate and apart from the remaining provisions in section 1881(h)(4), subparagraph (E) instead provides that, in establishing the initial performance standards for anemia management and dialysis adequacy, CMS must apply the above “Special Rule.”

The text limits the requirement of subparagraph (E) to subparagraph (A) only. Subparagraph (A) requires CMS to establish performance standards “[s]ubject to subparagraph (E).” “Subject to” means that subparagraph (E) governs subparagraph (A); not that it trumps all subparagraphs in paragraph (4).³⁷ Thus, subparagraph (C), which mandates the prospective nature of the performance period, must be given meaning independent of subparagraphs (E) and (A). Subparagraph (C) requires the Secretary to establish the performance standards under (A) “prior to the beginning of the performance period for the year involved.” If subparagraph (E) were read as being completely independent of subparagraph (A), as CMS asserts, it would not require the Secretary to “establish” any performance standards at all, nor would there be authority for a performance period. Such a reading would be absurd.

Even if MIPPA’s plain meaning were unclear, Supreme Court doctrine holds that unless Congress explicitly provides for the retroactive application of a rule, a federal agency may not apply regulations retroactively.

[A] statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms. . . . Even where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant.³⁸

³⁶ 76 *Fed. Reg.* 628, 631 (Jan. 5 2011). These “limitations suggested by commenters” were arguments that MIPPA requires a prospective QIP. The agency also asserts that it is not required to comply with Section 1881(h)(4)(B) of the Social Security Act, which requires the performance standards to “include levels of achievement and improvement,” because it “do[es] not believe that section 1881(h)(4)(E) of the Act requires that we include such levels.” *Id.* at 630.

³⁷ See *American Rivers v. FERC*, 201 F.3d 1186, 1204 (9th Cir. 2000) (quoting *Black’s Law Dictionary* to interpret the phrase “subject to” to mean “governed or affected by”).

³⁸ *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208-09 (1988) (emphasis added). In his concurrence to *Bowen*, Justice Scalia endorsed the D.C. Circuit’s holding that the Administrative Procedure Act (APA) does not authorize the issuance of any retroactive rules absent clear Congressional intent, since the APA’s definition of “rule” is “an agency statement of . . .

The presumption against retroactivity is rooted in fundamental notions of fairness, which “dictate that individuals should have an opportunity to know what the law is and to conform their conduct accordingly.”³⁹

PY 2013 as proposed would inappropriately implement payment reductions using a performance period that concluded before it was announced as final holding facilities to performance standards that were also announced after the conclusion of the performance period. Under well-established precedent, PY 2013 is retroactive because it “attaches a new disability in respect to transactions or considerations already past.”⁴⁰ The disability – payment reductions – is clearly tied to ESRD facilities’ and providers’ past performance and is based on standards that did not exist during the performance period.

Additionally, the retrospective proposal would nullify an important aspect of any quality improvement program, which is to identify standards and create incentives that encourage providers to change their practices to meet them. If providers do not know the standards until after the performance period has concluded, it is impossible for the QIP to accomplish this goal. It becomes nothing more than a retroactive penalty system. CMS’s reading of MIPPA is thus at odds with the purpose of the “quality incentives” intended by Congress.⁴¹

Thus, we strongly urge CMS in the final rule to establish for PY 2013, 2012 as the performance period and use performance standards that are consistent with the clinical practice of 2012, rather than those based on out-dated clinical protocols. A performance period of 2012 would ensure that facilities have the ability to modify their behavior based upon the standards established in the final rule.⁴² In addition, the performance standards

future effect.” *See Bowen*, 488 U.S. at 212 (Scalia, J., concurring); *Georgetown Univ. Hosp. v. Bowen*, 821 F.2d 750, 757 (D.C. Cir. 1987) (“[T]he APA requires that legislative rules be given future effect only.”). Subsequent D.C. Circuit cases involving retroactive rulemaking have adhered to this precedent. *See, e.g., Health Insurance Ass’n of Am. v. Shalala*, 23 F.3d 412, 423 (D.C. Cir. 1994).

³⁹*Landgraf v. USI Film Products*, 511 U.S. 244, 265 (1994).

⁴⁰*Health Ins. Ass’n of Am. v. Shalala*, 23 F.3d 412, 422 (D.C. Cir. 1994) (citations omitted).

⁴¹ *See United States Nat’l Bank of Oregon v. Indep. Insur. Agents*, 508 U.S. 439, 455 (1993) (“In 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.”) (quoting *United States v. Heirs of Boisdore*, 49 U.S. (8 How.) 113, 122 (1849)).

⁴²We recognize that CMS may consider it impossible to use 2012 as a performance period for PY 2013 because it will not obtain the December 2012 (and perhaps even October and November) data until the beginning of 2013. The authorizing statute does not require CMS to implement payment reductions on January 1 of any particular year. *See* 42 U.S.C. § 1395rr(h)(1)(A). Thus, it could collect the penalty at any time during the year. While CMS must provide facilities with the opportunity to review their data, this review process could take place in a sequential manner. For example, it could provide facilities with an opportunity to review the first 6 or 9 months of data and then institute a follow-up review process. The community would welcome the opportunity to work with CMS to avoid significant delays in PY 2013. Of course, the going forward solution is to provide for an earlier rulemaking process, as the Agency is attempting to do with PY 2014.

must be based upon years that reflect clinical practice in the performance period more closely to measure quality performance accurately. CMS should ensure that its performance standards take account of such changes by using 2011 as the year of data used to establish the performance standards.⁴³

3. CMS should continue to track hemoglobin levels.

KCP understands that the hemoglobin less than 10 g/dL measures may not be an appropriate payment measure within the QIP at the current time. There have been a series of changes during the past several years, such as the FDA Black Box Warning, culminating in a label change for ESAs that make it impossible to rely upon historic data to evaluate the quality performance of dialysis facilities and providers. National benchmarks that are 5 or more years old coupled with performance periods that are 2-3 years old do not reflect the actual quality of care being provided nor present an accurate picture of current practice patterns. Thus, we agree that until an appropriate metric is available, there should not be a lower hemoglobin measure tied to payment. At the same time, as soon as an appropriate, clinically relevant hemoglobin measure is available, KCP would strongly support inclusion of such a measure in the QIP for payment. KCP also is interested in discussing the feasibility of including the hemoglobin less than 10 g/dL measure for reporting in the QIP.

It is important that CMS and the kidney care community monitor changes in both upper and lower hemoglobin of patients to ensure that patient care is not adversely affected. In the interim, KCP strongly supports continued tracking of the lower range of hemoglobin levels. Low hemoglobin is clinically important to monitor, and continuing to track the lower range is critical to assessing the impact of the recent practice changes. It is equally important to make sure that patients are aware of how their facilities and providers are performing in this area as well. The information is only meaningful, however, if it is based upon recent data.

Therefore, we also recommend that CMS continue to collect lower level hemoglobin data, as it currently does through the claims. The Agency should post data from the most recent six months (from the date of the posting) showing the distribution of lower level hemoglobin ranges (*e.g.*, percentage of patients with hemoglobin levels 9-10 g/dL, 8-9 g/dL, etc.) on Dialysis Facility Compare, as well as the national average. It should also provide individual facility/provider certificates containing the distribution range for that facility/provider and the national average. Facilities and providers would be required to

⁴³Even if CMS were to use more contemporary data to establish the performance standards, CMS would not have to rely upon 42 U.S.C. §1395rr(h)(4)(E) to provide for the option of applying either a national benchmark or an individual benchmark. While it is true that subparagraph (E) requires CMS to use this bifurcated approach for the “initial” year of the QIP and, in doing so, to rely on 2007, 2008, or 2009 data for the individual facility benchmark, there is sufficient general authority as to the establishment of benchmarks that would allow the Agency to continue apply an individual and/or national benchmark as the performance standard for PY 2013 or in future years, such as when new measures are incorporated into the program. The text of MIPPA only requires that the Agency establish the performance standards and does not require that they be tied to any specific year (with the exception that they be established prior to the performance period) after the initial year of the program’s implementation.

post these certificates, which would be updated by CMS every six months. The data should include the hemoglobin levels of all dialysis patients, regardless of whether or not they are receiving ESA therapy. This data would be similar to that which is part of the Networks eLab project. We would welcome the opportunity to work with the Agency to determine the appropriate way of presenting this information so that it is easily understandable and clear.

4. CMS should develop a clear, transparent, and timely process for developing and publishing standardized measure specifications and definitions, as well as data submission requirements.

In implementing the ESRD QIP, CMS not only has to make sure that the methodology fairly evaluates facility and provider performance, it must also adopt measures that consistently measure performance among different facilities and providers and that can be collected in an identical fashion across facilities and providers. Unfortunately, the current specifications and data collection requirements do not provide clear, standard definitions for all measures and data elements.

A central tenant of the QIP is to allow CMS and beneficiaries to compare the results from one facility to another. To accomplish this goal, the data collection and reporting processes must ensure that there is a consistent understanding of the parameters for the data elements being collected and reported. As we have noted on previous occasions, many of the specifications remain open to more than one interpretation. Because of this fact, it is likely that facilities will reach different conclusions as to what they should be collecting and reporting. Unless CMS provides more specific guidance, the goal Congress set for the QIP cannot be met. For the QIP to succeed, facilities and providers must be held to the same standards. The only way to accomplish this goal is to provide clear, consistent, standardized definitions and collection methods. We urge CMS to provide for a standard process in guidance immediately.

5. CMS should provide incentive payments under the QIP.

While we appreciate that MIPPA requires CMS to include payment reductions in the ESRD QIP,⁴⁴ KCP continues to urge the Agency to establish incentive bonus payments for facilities or providers that demonstrate attainment and/or substantial improvement. Even if the Agency does not believe the text of MIPPA provides sufficient flexibility to allow it to provide for such payments, there is sufficient demonstration authority to allow for testing and ultimately implementing such a program. Because MIPPA does not require CMS to use the funds collected through the penalty in a specific manner, the Agency could use them to support incentive rewards so that there is no cost to the Medicare program overall.

⁴⁴ By contrast, the Hospital VBP program includes incentive payments to hospitals that meet or exceed performance standards. 42 U.S.C. § 1395ww(o)(6).

Even though MIPPA does not expressly authorize incentive reward payments, it does not expressly prohibit them either. Under the *Chevron* doctrine, because Congress has not “spoken directly to the issue” of what CMS should do with funds resulting from these reductions, CMS may “fill the gap” by providing incentive payments for high-performing facilities or providers (those that attain the performance standards and/or demonstrate substantial improvement).⁴⁵ Such payments would increase the incentives to attain performance standards and improve quality, while ensuring that there is adequate funding to the program as a whole.

Implementing an incentive reward payment would be consistent with the views of policy experts, such as MedPAC and the IOM. These organizations have explicitly stated that quality programs linking payment to performance should not be used to obtain program savings.⁴⁶

Even if CMS were not comfortable exercising gap-filling authority, it has ample authority under SSA § 402(a) to conduct demonstration programs to test methods of payment that have the potential to increase the efficiency and economy of Medicare.⁴⁷ There is precedent for this approach in other Medicare value-based purchasing programs.⁴⁸

Adopting such payments would not require additional funding because it could be funded from the payment reductions required by MIPPA. These incentives would ensure that ESRD beneficiaries continue to receive the highest standard of care as facilities adapt to the new PPS and the payment reductions that have already been implemented in the base rate.

6. CMS should provide clarifying language for the public reporting requirement.

In addition to linking payment to quality performance, MIPPA also establishes a public reporting requirement that provides greater transparency and allows beneficiaries to have access to the performance of their facilities and providers. While KCP continues to strongly support public reporting, it is important that the information shared is meaningful and clear. For example, if CMS does not modify the PY 2013 performance year and performance standards to comply with the prospective requirements of MIPPA as

⁴⁵ “Where Congress has entrusted an agency to administer a statute or program the agency has the latitude to formulate policy and make rules necessary ‘to fill any gap left, implicitly or explicitly, by Congress.’” *Chevron*, 467 U.S. at 844 (quoting *Morton v. Ruiz*, 415 U.S. 199, 231 (1974)); see also *Methodist Hosp.*, 38 F.3d at 1229 (recognizing heightened deference to the Secretary’s interpretation of the Medicare program).

⁴⁶ MedPAC, “Strategies to improve care: Pay for performance and information technology,” *Report to the Congress: Medicare Payment Policy* 184, 187 (March 2005); See, e.g., Institute of Medicine, *Crossing the Quality Chasm*, *supra* note 26.

⁴⁷ See 42 U.S.C. § 1395b-1(a)(1)(A)).

⁴⁸ See M.T. Rapp, “Outcome Measures and Value Based Purchasing,” at Slide 5 (presented at the AHRQ 2009 Annual Conference), available at <http://www.ahrq.gov/about/annualconf09/rapp.htm>.

discussed earlier in this section, the data will be inconsistent with the current medical practice of the facilities and providers. Beneficiaries need to understand this in order to make informed choices. In addition, facilities and providers should not be represented as providing or not providing quality of care in a particular year without the details as to how that conclusion was made being clear and understandable. Thus, we strongly recommend that CMS include language on the certificate that makes the following points:

- The date of the Performance Period;
- The date of the Performance Standards; and
- A statement that the data may not reflect current medical standards or facility/provider performance.

An example could be: “The data represented on this certificate are based upon care provided in 2011 [the performance period] and are compared to national and/or facility performance in 2007 or 2009 [the performance standard years]. They may not reflect current medical practice or the current performance of this facility.”

Such language is especially important to beneficiaries. Information that is provided without context or explanation may not only create confusion, but also lead to poor decision-making. We would welcome the opportunity to work with you on the precise wording of such a clarification.

B. CMS Should Resolve Methodological Flaws and Adopt Only Some of the Proposed Measures for PY 2014.

KCP encourages CMS to revise the proposed measures, ensure standardization of their definitions and reporting, and refine the weighting of the measures. We support the proposed performance period, so long as the performance standards are published prior to its beginning. Finally, CMS should address flaws within the proposed methodology.

1. CMS should revise the proposed measures for PY 2014.

Overall, KCP supports the Agency’s expansion of the number of measures included in the QIP for PY 2014. However, we are concerned that in some instances the measures selected are not defined precisely enough, not supported by sufficient evidence to be payment measures, or operationally impossible to implement. Thus, we strongly encourage CMS to: (1) maintain the hemoglobin greater than 12 g/dL; (2) maintain the peritoneal dialysis Kt/V measure; maintain, but modify, the hemodialysis Kt/V at least 1.2 clarifying that residual renal function (RRF) is removed; and retire the URR measure; (3) not include the arteriovenous fistula (AVF) measure as a payment measure, but maintain the reduction in catheters measure; (4) not include the vascular access infection measure tied to the V8/V9 HCPCS modifiers; (5) not include the standardized hospitalization ratio (SHR); (6) maintain the National Healthcare Safety Network (NHSN) bloodstream infection measure, but permit an alternative data stream mechanism that

provides equivalent data; (8) maintain, but modify the CAHPS In-Center hemodialysis survey to allow facilities and providers to divide the administration of the survey into three distinct domain-cores; and (9) maintain the structural bone mineral metabolism measure.

a. CMS should maintain the hemoglobin greater than 12 g/dL as a payment measure.

KCP continues to support the inclusion of the hemoglobin greater than 12 g/dL in the PY 2014 QIP. The appropriate management of anemia is a critical component of helping patients maintain a high quality of life and directly impacts patient satisfaction. Thus, we support this measure.

b. CMS should maintain the adequacy of dialysis measures, but modify the hemodialysis measure to remove RRF and retire the URR measure.

Consistent with our previous comments, KCP is pleased that CMS proposes transitioning from URR to Kt/V as the measure for adequacy of dialysis. As the clinical literature demonstrates, Kt/V is the outcome metric upon which physicians primarily rely when making treatment decisions related to adequacy. We are also pleased that CMS recognizes the importance of home dialysis by including a peritoneal dialysis measure. In line with clinical literature, we recommend that CMS remove RRF from the hemodialysis measure.⁴⁹ Including RRF presents operational challenges. It requires patients to collect urine during a 48-hour period and must be repeated at least every three months. Often it does not affect the Kt/V calculation, but if included could result in patients being under dialyzed. Thus, for clinical and operational reasons, we urge CMS to modify the measure's specification so that RRF is excluded from the hemodialysis Kt/V measure.

Additionally, the formula used to calculate adequacy should be representative of the actual number of treatments delivered. The Kt/V specifications should acknowledge that the Daugirdas II or UKM formulas are based upon thrice weekly hemodialysis care, which would greatly understate the adequacy delivered for patients dialyzing more frequently.

c. CMS should modify the vascular access measures to remove the AVF measure, but maintain the reduction in catheter measure.

⁴⁹Frans J. Hoek, et al., *Estimation of residual glomerular filtration rate in dialysis patients from the plasma cystatin C level* 22 NEPHROL. DIAL. TRANSPLANT 1633-1638 (2007).

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.⁵⁰ KCP strongly supports inclusion of a measure to reduce catheters.

We are concerned 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.⁵¹ Even so, not everyone is eligible for one. For example, some patients have small veins or other conditions that do not support the growth of an AV fistula. 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.⁵² This historic emphasis, as evidenced by the Fistula First Initiative, grew in part out of the fact that graft placement outnumbered 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 evolution in thinking that the focus should be on permanent access—fistulas or grafts—and catheters last.

Thus, while we believe it continues to be important to incentivize the use of fistulas, it is equally important to make sure that patients receive the vascular access that is most appropriate for them. Including a maximizing AV fistula measure without similarly recognizing graft placement will likely inappropriately drive some patients who would do better with a graft to a fistula. We suggest that CMS not include the AV fistula measure in the QIP.

If CMS were to maintain both measures, however, we do not support weighting them equally within the composite measure. Rather, we strongly recommend that CMS weight the catheter reduction measures at two-thirds for purposes of calculating the composite result.

d. CMS should not include the vascular access infection measure tied to the V8/V9 HCPCS modifiers.

Given the importance of preventing infections, we understand why CMS has been monitoring vascular access infections through the claims data. KCP is concerned about

⁵⁰ 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)).

⁵¹ See Arteriovenous Fistula First, *History of the Fistula First Project*, <http://fistula.memberpath.com/AboutAVFistulaFirst/History.aspx>.

⁵² See American Association of Kidney Patients (AAKP), *Understanding Your Hemodialysis Access Options*, <http://fistula.memberpath.com/LinkClick.aspx?fileticket=ds2HSHjdV4U%3d&tabid=202>.

incorporating these data elements into a performance measure in the QIP for several reasons. First, this measure was rejected by NQF, which has endorsed the NHSN bloodstream infection measure in this domain (NQF #1460). Second, the measure lacks clear definition. In fact, because CMS has not issued specific guidance, there is no uniformity in reporting the V8/V9 HCPCS modifiers. Even if CMS were to resolve this problem in the short-term, the previous data collected and upon which performance standards have been identified remain flawed.

Thus, KCP recommends not including this measure in PY 2014 and instead urges that CMS work with the Centers for Disease Control and Prevention (CDC) and the community to monitor the continued use of the NHSN bloodstream infection measure so that, when appropriate, it could be adopted as an outcome measure to monitor vascular access infections. In the short-term because catheters are the primary source of vascular access infections, the emphasis on greater weighting of the reduction in catheters measure would create the necessary incentives to reduce infections as well.

e. CMS should not include the SHR measure.

KCP agrees that reducing hospitalizations is an important goal. But, we cannot support including the SHR measure at this time. Even though NQF has endorsed it, the measure should not be incorporated in a quality payment program because the information upon which it is based is not specific to dialysis facilities. However, as designed, the SHR measure will not incentivize reductions in hospitalizations in the dialysis context. The SHR relies upon hospital diagnostic related groups (DRGs) and is not limited to DRGs related to fluid management and vascular access infection. This fact means that dialysis facilities and providers would inappropriately be held responsible for admissions not related to the care they provide. Additionally, the methodology used to calculate the SHR is not transparent. Until such time as the community can work with the Agency to develop a transparent and tailored measure related to hospitalizations, CMS should not include such a measure generally and the SHR specifically in the QIP.

f. CMS should maintain the NHSN bloodstream infection measure.

KCP recognizes the high morbidity and mortality associated with infections and supports NQF endorsement of the NHSN bloodstream infection measures (NQF #1460). We further support the inclusion of the NQF #1460 as a structural measure in PY 2014. 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. We agree with the proposal to focus on reporting for three consecutive months to achieve maximum credit.

Based on the NQF's criteria, KCP believes that the NHSN measure is important, has reliable and valid specifications (scientifically acceptable), and provides performance results that can be useful to all stakeholders; as just noted, we supported it for endorsement. KCP has always had concerns, however, about the manner in which data must be transmitted to CDC/NHSN.

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 error due to human error. We are especially concerned about the problems that can arise with 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.

Thus, in addition to CMS's proposed structural measure for NHSN reporting (enrollment/training/reporting), we request the CMS arrange an alternative mechanism, no later than third quarter of 2012, so that compliance with the structural measure can be attained by either the NHSN manual registration/training/manual submission OR via a direct electronic data download mechanism of data consistent with NHSN requirements. Specifically, we ask that CMS provide a means for facilities to directly download data from facility electronic records into the NHSN system or via an alternative path—but not both. Direct electronic submission will not only reduce burden on staff, permitting them to focus on patient care, but also will supply CMS/CDC more accurate data.

g. CMS should modify the CAHPS survey so that it is permissible to divide the administration of the survey into three distinct domains.

KCP recognizes the importance of monitoring patients' experiences when receiving dialysis. However, we have serious concerns with the incorporation of the CAHPS survey measure in the QIP as proposed. 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 they require help from caregivers or family members. While monitoring patients' experiences is important, it should not be done in a way that burdens patients and is likely to result in incomplete surveys that benefit no one.

Thus, we propose that, rather than mandate the completion of the entire survey, CMS allow facilities and providers to break the survey into its three independently verified domains when administering it. We propose that one-third of a facility's patient population receive one of the three domains plus the core 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.

KCP remains concerned that CROWNWeb will not provide an adequate reporting system. Some KCP members have participated in the pilot and found serious data submission and entry problems. Additionally, CROWNWeb does not yet permit all dialysis facilities and providers to batch submit their data. Manual entry or paper submission of such information will be time consuming and burdensome. We also continue to be very concerned about the validity of performance results when two different methods of data collection are used for a measure; manual and electronic submission for the same measure are not equivalent and have not been demonstrated to yield equivalent results that permit equitable comparisons. 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 of providing beneficiaries with easy access to the data.

h. CMS should maintain the bone/mineral structural measure.

KCP supports maintaining the bone/mineral structural measure to attest to phosphorous and calcium monitoring. It is based upon two currently NQF-endorsed measures (NQF #0255 and #0570). While KCP strongly supports monitoring of phosphorous and calcium, we do recommend that these two measures be moved to NQF's reserve status in their current Renal Endorsement Maintenance project because they have topped out. Nevertheless, we agree that at this time the proposed structural measure will provide an important incentive to continue monitoring that will become even more important when CMS incorporates ESRD-related oral drugs without an IV equivalent form into the PPS bundle.

As described in our comments on the CAHPS survey, CROWNWeb is not at a stage that allows it to be used effectively. However, paper submissions will be overly burdensome and prone to error. We reiterate our recommendation that CMS continue to work with the kidney care community to establish an appropriate electronic data collection system.

2. CMS should develop a clear, transparent, and timely process for developing and publishing standardized measure specifications and definitions, as well as data submission requirements.

In implementing the ESRD QIP, CMS not only has to ensure that the methodology fairly evaluates facility and provider performance, it must also adopt metrics that consistently measure performance among different facilities and providers and that can be collected in an identical fashion across facilities and providers. Unfortunately, the current specifications and data collection requirements do not provide clear, standard definitions for all measures and data elements. For example, CMS should clearly state the definition of

UKM and Daugirdas II for calculating Kt/V; establish that testing for hemoglobin levels should be performed prior to the beginning of dialysis; and indicate that the current reporting rules related to counting catheters should be used for purposes of reporting the reductions in catheter measure.

A central tenant of the QIP is to allow CMS and beneficiaries to compare the results from one facility to another. To accomplish this goal, the data collection and reporting processes must ensure that there is a consistent understanding of the parameters for the data elements being collected and reported. As we have noted on previous occasions, many of the specifications remain open to more than one interpretation. Because of this fact, it is likely that facilities will reach different conclusions as to what they should be collecting and reporting. Unless CMS provides more specific guidance, the goal Congress set for the QIP cannot be met. We look forward to working with the Agency to ensure the standardization of measure specifications and data collection requirements.

3. CMS should not weight all measures within the outcomes categories equally.

As described in more detail in our comments on future measures, KCP recommends that CMS adopt a more predictable process for adopting measures and applying weights. KCP agrees that for PY 2014 the clinical outcomes-based measures should be weighted at 90 percent of the total performance score and the structural measures at 10 percent. However, within the clinical measures category, we strongly recommend that CMS assign a greater weight to the catheter measure. This weighting is warranted because published literature supports that the reduction of catheters will help to reduce infections and mortality.⁵³ There is also evidence of a performance gap.⁵⁴ Specifically, we propose the following weights (based upon our recommendations above that the AV fistula and vascular access infection measures not be included in the QIP).

	Weight within Clinical Outcomes Category
Adequacy	25%

⁵³K. R. Polkinghorne, *et al.*, *Vascular Access and All-Cause Mortality: A Propensity Score Analysis*, 15 J. AM. SOC NEPHROLOGY 477, 479-80 (2004).

⁵⁴CMS highlights the ongoing performance gap in its submission for measure endorsement to NQF, stating:

“Based upon the most recent data from the CMS Fistula First Breakthrough Initiative (FFBI), a gradual trend towards lower catheter use has been observed among prevalent maintenance HD patients in the US, declining from approximately 28% in 2006 to approximately 24% by May 2007. Furthermore, the percentage of maintenance HD patients using a catheter for >90 days has declined as well over this time period from nearly 12% to 9.5-10%. Continued monitoring of chronic catheter use is needed to sustain this trend.”

CMS, National Quality Forum Measure Submission and Evaluation Worksheet 5.0 for NQF #0256 Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access.

Hemoglobin	25%
Catheter Reduction	50%

KCP agrees that the structural measures (*i.e.*, what CMS refers to as “reporting measures”) should represent only 10 percent of the total performance score. Specifically, we recommend the following weighting be applied given the greater clinical impact of bloodstream infections and monitoring mineral metabolism, assuming that the measure built on V8/V9 HCPCS modifiers is not adopted and the alternative data submission for NHSN is in place.

NHSN	40%
CAHPS	20%
Mineral Metabolism	40%

4. CMS should maintain 2012 as the performance period, as long as the agency finalizes the actual performance standard before that year begins.

As noted in our comments on PY 2013, MIPPA requires CMS to implement the QIP in a prospective manner. Thus, we are pleased that CMS included PY 2014 in the Proposed Rule. Assuming the Agency can finalize the rule in the timely manner, this would allow for the first prospective application of the QIP. However, we caution the Agency that in order for the QIP to be prospective not only must the performance period occur in a future year, but the performance standards must be established prior to the beginning of the performance period.⁵⁵ Therefore, and as described in more detail below, CMS must provide notice of and an opportunity to comment on the actual performance standards for PY 2014. If it does not, then it should not begin the performance period on January 1, 2012.

5. CMS should refine and clarify its approach to the PY 2014 performance standards.

Performance standards establish the backbone of the QIP; yet, the Proposed Rule does not provide the actual values for PY 2014. We support the proposed baseline years and appreciate the difficulty of proposing standards when some of the data used to establish them has only just been collected. Even so, it is impossible to truly evaluate the entire PY 2014 proposal without knowing these standards. It is particularly problematic when trying to analyze the total performance score methodology. In addition, we are concerned that the Agency has not addressed the between-laboratory variation problem that we highlighted in our comments for PY 2012 as well. Finally, we oppose using

⁵⁵42 U.S.C. § 1395rr(h)(4)(C).

performance goals as the performance standards in future years given that the QIP is a penalty-based system and that CMS has thus far not been prospective in setting the performance standards.

a. CMS should maintain as proposed the baseline years for the performance standards.

KCP supports the baseline periods as proposed. Given the challenges rulemaking poses, we believe that using data from part of 2010 and 2011 is appropriate because it is likely as close as the Agency can come to performance period of 2012 and still publish actual performance standards before the beginning of the performance period. Again, we emphasize that it is important that there be as little time between the performance period and baseline years for the performance period so that there is less of a risk that clinical practice has changed in the interim; this also provides patients with a more accurate picture of quality. As CMS improves its data collection processes, we encourage the Agency to try to shorten the distance between the baseline performance standard years and the performance period year even more.

b. CMS should provide for a transparent process for adopting the actual performance standards for PY 2014 and finalize them before the beginning of the performance period to maintain a prospective QIP.

KCP appreciates that CMS proposes PY 2014 in a manner that seeks to address our concerns about the retroactive nature of PY 2012 and 2013. We also understand that in doing so, the Agency finds itself in a position of having to propose performance standards before it has the data to state exactly what those standards will be. Thus, while we support the proposed years from which the performance rates data will be collected, we strongly urge the Agency to publish and obtain comment on the actual standards before they are finalized and to do so prior to the beginning of the performance period.

To accomplish this goal, we recognize that the timeline will be tight. However, KCP recommends that the Agency publish through guidance with comment or an interim final rule with comment the proposed performance standards in early October, provide for a 30-day comment period, and finalize the actual standards in November. This would provide approximately a month for facilities and providers to determine what is expected of them for the performance year 2012. In the future, we encourage CMS to provide for a similar process, but ideally provide the performance standards in late summer or early fall.

c. CMS should address the problem of between-laboratory variation.

As we noted in our comments on PY 2013, given that there are no absolute values in clinical laboratories, KCP remains concerned that the Proposed Rule does not address the

problem of between-laboratory variability. We previously described the problems associated with failing to address this issue directly, which include penalizing facilities for laboratory variation rather than quality performance, not being able to compare outcomes accurately among facilities, and potential harm to patients. Thus, we reiterate our recommendation that CMS initially set threshold values for a standard deviation based on the allowable range of bias allowed by the CLIA standards. This amount would be used when comparing reported measure values against the performance standards. As laboratories work to reduce the variability, this amount should be narrowed.

d. CMS should set performance standards that reflect the national median of the actual performance of facilities and providers.

KCP strongly supports the aspirational performance goals widely embraced by the kidney care community. In fact, through the Performance Excellence and Accountability in Kidney Care (PEAK) program, KCP has been a leader in trying to reduce patient mortality. This voluntary quality improvement campaign seeks to reduce mortality among first-year dialysis patients by 20 percent by the end of 2012 – an effort to extend, even save, 10,000 lives – a real goal for real change.⁵⁶ Using current data from CMS and the USRDS methodology, the PEAK campaign is reporting progress toward reaching its goal of improving patient survival of reducing first-year mortality by 20 percent by the end of 2012.⁵⁷

As important as performance goals similar to those of PEAK are, the design of the QIP does not warrant their inclusion. Unlike other value-based purchasing programs and contrary to the recommendations of organizations such as MedPAC and the IOM, CMS has implemented the QIP as a payment reduction program. It is one thing to establish performance standards based upon goals that a community should reach at some point in the future in a system that rewards providers for quality improvement, but entirely another to use these standards when a facility or provider is being penalized. Therefore, we strongly discourage CMS from using anything other than 35 percent below the median performance.

6. CMS should refine the total performance score methodology and allow for additional comments when performance standards are established before finalizing the methodology.

Given that the Agency does not provide the actual performance standards for PY 2014, it has been impossible to evaluate the total performance score methodology. We strongly urge CMS to allow for another review of the methodology once the Agency

⁵⁶See <http://kidneycarepartners.com/>

⁵⁷See <http://www.kidneycarequality.com/CampProg.htm>.

proposes the actual performance standards. Even with our limited ability to assess the methodology for PY 2014, we recommend that CMS: (1) adopt the PY 2012 penalty range and five-tier rate reduction scale (as we did for PY 2013); (2) address the problem of variable types of distributions in the attainment threshold methodology; (3) increase the minimum number of reportable cases to 20; (4) adopt a modifier to address a problem with the improvement methodology; and (5) resolve a technical issue with the formula.

a. *CMS should maintain the PY 2012 penalty structure for PY 2014 and subsequent years.*

As we described in detail in our comments on PY 2013, we believe CMS should maintain a 0.5 – 2.0 percent reduction penalty range and have at least five tiers in the rate reduction scale. In addition to allowing comparisons between years, a five-tier rate reduction scale is more consistent with the literature supporting value-based purchasing programs, recommendations of the IOM, and the design of other such programs in both the private and public sector.⁵⁸

b. *CMS should revise the attainment threshold methodology to address the problem of variable types of distributions.*

KCP supports the Agency's effort to establish a clear methodology that could be applied year-to-year for setting the attainment threshold. However, the Agency's proposal to use one standard deviation below the national performance rate presents a serious problem that we strongly encourage CMS to correct. The use of a relative reference point such as standard deviation will lead to unpredictable results. It incorrectly presumes that that range of dialysis facility and provider performance is normally distributed, statistically speaking. In examining this question, Discern found that distributions are likely to be skewed.⁵⁹

Discern provides the following example: If the distribution is normally distributed around a mean of 92 percent and has a standard deviation of 6.5 percent, the achievement threshold would be 85.3 percent. If the distribution is skewed because, for example, a large number of facilities is near the top performance range, with the same mean, the standard deviation is 1.0 percent. In this instance, the achievement threshold would be 91 percent.⁶⁰

⁵⁸See Institute of Medicine, *Crossing the Quality Chasm*, *supra* note 26, at 92; Centers for Medicare and Medicaid Services (CMS), Fact Sheet, *supra* note 27; INTEGRATED HEALTHCARE ASSOCIATION, *supra* note 28, at 18 (at the time of the five year report, five of six private insurers participating in the program were using a relative percentile rank and allocated quality-related payments along a sliding-scale within a pre-defined percentile range).

⁵⁹Discern, Memorandum to Kidney Care Partners, *supra* note 29.

⁶⁰*Id.*

Discern concludes that given the unpredictability of the standard deviation method for setting the achievement threshold, CMS should set specific thresholds prospectively.⁶¹ Therefore, we recommend that CMS adjust this methodology to correct for this statistical problem and instead adopt an attainment threshold set at 35 percent below the median performance. This methodology would be the same as that proposed by CMS, except that it would address the problem of distribution variance. In addition to modifying the methodology, CMS would need to refine its definition of the national performance rate to conform to the use of the median rather than the mean.

- c. CMS should strengthen the statistical validity of the QIP by ensuring that facilities and providers are not penalized because of the outcomes a small number of patients.***

As we described in our comments on PY 2013, KCP remains concerned that the proposed threshold of 11 reportable cases is too low to mitigate random variance. We recommend that CMS adopt 20 as the minimum number of reportable cases. As the attached memorandum prepared by Discern indicates, the reliability of the data is dependent upon sample size.⁶² When sample sizes are small, Discern found that there “is almost no consistency in facility results over time.”⁶³ Increasing the minimum number will substantially resolve the statistical issues we have identified in PY 2012 when the 11 reportable cases standard is used. Therefore, we recommend that CMS increase the minimum number to at least 20 reportable cases for participation in the QIP.

- d. CMS should include an adjustment in the achievement and improvement calculation to address an anomaly that will result in some facilities and providers being penalized, even though their quality is better than others.***

KCP is pleased that CMS proposes incorporating improvement into the QIP. Generally, we agree with the proposed methodology. However, we encourage CMS to include an adjustment to address an unintended consequence. As designed, facilities and providers that are not high performers or low performers, but in the middle, will find that they are penalized greater in the long run even though they performed better than the bottom tier of performers in the early years of the QIP. The chart below demonstrates how this problem could occur.

⁶¹*Id.*

⁶²*Id.*

⁶³*Id.*

	Facility A	Facility B
Facility Baseline Period Score	70%	20%
Facility Performance Period Score	80%	70%
Benchmark	85%	85%
Achievement Threshold	75%	75%
Achievement Score	5	0
Improvement Score	6	7
Applicable (Greater) Score	6	7

The QIP should not result in facilities and providers that perform consistently being penalized. We recommend that CMS establish a multiplier derived from the maximum allowable improvement when compared to the maximum allowable improvement in the middle tier. Such an adjustment would allow for a fair system, which is critically important when facilities and providers are being penalized, rather than rewarded for quality performance.

e. CMS should resolve a technical issue with the formula.

Finally, KCP recommends that CMS address a technical issue we uncovered in attempting to model the proposed methodology. The Proposed Rule does not address the possibility that some facilities will have a facility performance rate that is exactly the same during the performance period and the baseline periods. In this instance, the numerator for the improvement score would equal zero and the formula would require that 0.5 would be subtracted from it, which would lead to a negative score. CMS should clarify that facilities with the same or lower performance score compared to their prior score in the baseline period will have an improvement score of zero.

III. KCP Supports Continued Efforts to Develop Additional Quality Metrics for Future Payment Years.

KCP supports considering additional measures derived from the proposed domains and suggests a few others. As CMS moves forward with expanding measures, we also encourage CMS to set forth in the final rule its criteria for adopting new measures and weighting them, as well as the process for integrating new measures into the QIP.

A. KCP supports the proposed domains and encourages CMS to consider additional ones as well.

KCP supports ongoing efforts to develop measures in additional domains that could eventually be used in the ESRD QIP. We agree that CMS should begin considering the domains of: (1) serum calcium concentration; (2) serum phosphorous concentration; and (3) assessment of iron stores. Each of these domains addresses two critically important aspects of patient care, namely mineral metabolism and anemia management. In addition,

KCP encourage CMS to consider other domains, such as immunization, albumin, fluid management, and bone and mineral metabolism. We look forward to working with the Agency to pursue the development of measures in these domains.

The pediatric nephrology component of the community is eager to participate in the ESRD QIP. The QIP as currently structured does not allow them to do so. KCP encourages CMS to take into account the unique needs of this part of the kidney care community and work with them to develop appropriate measure specifications and performance standards that would permit their full participation in the program.

B. CMS should establish a transparent framework for adopting and updating measures for the QIP.

For both PY 2012 and 2013, CMS has picked measures without providing insight into the criteria it has used to do so. KCP is troubled by this approach and recommends that in the final rule, CMS state its criteria clearly. Congress clearly favored including measures endorsed by a consensus-based organization.⁶⁴ 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) be in the public domain; (2) 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 (3) 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 ground in evidence supporting the relationship of the outcome to a process or structure of care **(Impact, Opportunity and Evidence)**;
- Containing data elements that produce the same results a high proportion of the time when assessed in the same population in the same time period; having specifications that are consistent with the evidence to support the focus of the measure; having been the subject of testing validating that the data elements and measure scoring are correct; containing necessary exclusions supported by clinical evidence or sufficient observation; for outcomes-based measures, including a specified evidence-based risk-adjustment strategy; demonstrating that methods for scoring and analysis are statistically significant; and allowing for identification of disparities if identified through stratification of results **(Reliability and Validity)**;

⁶⁴42 U.S.C. § 1395rr(h)(2)(B)(i).

- 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**).⁶⁵

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 the full transparency and provides all interested parties with the opportunity to provide comments.

Finally, we also urge CMS to establish a phased-in process for incorporating new measures into the QIP. First, a measure should be reported outside of the QIP for at least one year to establish a clear baseline for establishing performance standards. Then, when added, facilities should be judged by the lesser of the facility's performance or one based on the national performance rates for at least the initial year. Congress recognized the need to allow facilities to adjust to the new QIP by establishing the Special Rule;⁶⁶ a similar adjustment period should be used to allow them to adjust to new measures, especially as the measures extend beyond those traditional reporting through previous initiatives.

⁶⁵For a complete description of the NQF measure evaluation criteria, *see* http://www.qualityforum.org/docs/measures_evaluation_criteria.aspx.

⁶⁶*See* 42 U.S.C. § 1395rr(h)(4)(E).

C. CMS should establish a transparent framework for adopting measure weights for the QIP.

Specifically for weighting measures, we recommend that CMS set forth in the final rule the methodology it will use for establishing measure weights. First, measures endorsed by NQF should be weighted greater than those that have not been endorsed. Second, measures that focus on aspects of care over which dialysis facilities and providers have direct control should be weighted greater than those focused on areas over which they do not. Third, if a measure is not NQF-endorsed, the following criteria should be used to determine the weight: (1) does the metric measure the root cause of a problem or a causal pathway; (2) does the measure center on an indicator that has a demonstrated impact on patient morbidity or mortality; or (3) is there strong evidence of a performance gap. Measures that are not NQF-endorsed but that meet one of these criteria should be weighted greater than those that do not.

KCP also reiterates our recommendation from earlier letters that CMS should rely upon the MAP for identifying measures and weights, as well as the rulemaking process. This process will allow for public and transparent consensus-based decision-making and include multi-stakeholder groups. We continue to support rulemaking for the actual adoption of measures and weights for the QIP, but the MAP will provide CMS with consensus-based recommendations from the full spectrum of experts.

IV. Conclusion

KCP appreciates the opportunity to provide comments on the PPS CY 2012 and QIP PY 2013 and PY 2014 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 detail.

Sincerely,



Ronald Kuerbitz
Chairman
Kidney Care Partners



Appendix A: Kidney Care Partners Members

Abbott Laboratories
Affymax
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Diagnostic and Interventional Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
California Dialysis Council
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
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
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.

**Appendix B: Technical Appendix: Comparison of the Inflated Moran Company
Replication to the Inflated CMS Reported 2009 Payments**

From "Table 19. Average Medicare Allowable Payments (MAP) for composite rate and separately billable services, 2007, with adjustment for price inflation to 2009", pgs 224 -225 of the Display Copy, 2011 Final ESRD Rule	CMS Reported (Rptd.) Values in Table 19		CMS Rptd. Inflation Factors: 2007 to 2009	INFLATED TMC Replicated Values Using 2007 SAF		Difference Between CMS Reported Total Values & TMC Replicated Total Values		Difference Between CMS Reported AVG MAP Values & TMC Replicated AVG MAP Values	
	Total	Avg. MAP per Treatment		Total	Avg. MAP per Treatment	Absolute Difference	Percent Difference	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	\$8,947,882,675	\$243.65		\$ 9,054,131,877	\$ 245.20	\$ 106,249,202	1.2%	\$ 1.55	0.6%
Total for Part B services	\$8,936,542,191	\$243.19		\$ 9,042,791,393	\$ 244.74	\$ 106,249,202	1.2%	\$ 1.55	0.6%
Composite rate services	\$5,792,196,328	\$157.62	1.3%	\$ 5,858,120,922	\$ 158.55	\$ 65,924,594	1.1%	\$ 0.93	0.6%
Separately billable services (Part B)									
EPO	\$1,937,063,301	\$52.71	3.2%	\$ 1,968,912,907	\$ 53.29	\$ 31,849,606	1.6%	\$ 0.58	1.1%
Darbepoetin	\$150,925,735	\$4.11	-10.1%	\$ 153,548,803	\$ 4.16	\$ 2,623,068	1.7%	\$ 0.05	1.1%
Calcitriol	\$2,645,644	\$0.07	-15.4%	\$ 2,665,242	\$ 0.07	\$ 19,598	0.7%	\$ 0.00	3.0%
Doxercalciferol	\$89,814,291	\$2.44	16.8%	\$ 90,477,710	\$ 2.45	\$ 663,419	0.7%	\$ 0.01	0.4%
Paricalcitol	\$313,002,443	\$8.52	-3.1%	\$ 314,972,873	\$ 8.52	\$ 1,970,430	0.6%	\$ 0.00	0.1%
Iron sucrose	\$172,625,432	\$4.70	3.9%	\$ 173,948,071	\$ 4.71	\$ 1,322,639	0.8%	\$ 0.01	0.2%
Sodium ferric gluconate	\$67,575,376	\$1.84	-0.8%	\$ 68,049,845	\$ 1.84	\$ 474,469	0.7%	\$ 0.00	0.1%
Levocarnitine	\$4,021,810	\$0.11	-20.0%	\$ 4,067,291	\$ 0.11	\$ 45,481	1.1%	\$ 0.00	0.1%
Alteplase	\$27,960,906	\$0.76	4.7%	\$ 28,176,610	\$ 0.76	\$ 215,704	0.8%	\$ 0.00	0.3%
Vancomycin	\$3,176,525	\$0.09	-11.4%	\$ 3,208,420	\$ 0.09	\$ 31,895	1.0%	\$ (0.00)	-3.5%
Daptomycin	\$1,429,021	\$0.04	15.8%	\$ 1,436,083	\$ 0.04	\$ 7,062	0.5%	\$ (0.00)	-2.8%
Other injectables	\$5,038,108	\$0.14	1.7%	\$ 5,050,994	\$ 0.14	\$ 12,886	0.3%	\$ (0.00)	-2.4%
Laboratory tests	\$308,732,410	\$8.40	4.4%	\$ 309,737,916	\$ 8.38	\$ 1,005,506	0.3%	\$ (0.02)	-0.2%
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	0.0%	\$ 1,530,328	\$ 0.04	\$ 82,844	5.7%	\$ 0.00	3.5%
Dialysis patients with Part D	221,154	--		221,154	--				
HD-equivalent dialysis treatments for patients with	24,737,326	--		24,737,326	--				
MAP for Part D services	\$11,340,484	\$0.46		\$ 11,340,484	\$0.46				
Calcitriol (oral)	\$2,839,032	\$0.11		\$ 2,839,032	\$0.11				
Doxercalciferol (oral)	\$5,262,356	\$0.21		\$ 5,262,356	\$0.21				
Paricalcitol (oral)	\$3,188,606	\$0.13		\$ 3,188,606	\$0.13				
Levocarnitine (oral)	\$50,490	<\$0.01		\$ 50,490	<\$0.01				

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

TMC reverse-engineered the composite rate inflation factor using the totals for the uninflated composite rate services.

The listed inflation factor for "Other Injectables" is 1.7% yet when we double-check what CMS used, the inflation factor is 1.905%.

Appendix B: Technical Appendix: Comparison Moran Company Replication of Inflation of 2009 Payments to 2011 to CMS' Published Analysis

	CMS Reported (Rptd.) Values		CMS Reported Inflation Factors: 2007 to 2011	INFLATED TMC Replicated Values to 2011		Difference Between CMS Reported Total Values & TMC Replicated Total Values		Difference Between CMS Rptd AVG MAP Values & TMC Replicated AVG MAP Values	
	Total	Avg. MAP per Tx		Total	Avg. MAP per Tx	Absolute Difference	Percent Difference	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	\$9,200,352,360	\$250.53		\$ 9,310,233,735	\$ 252.14	\$ 109,881,374	1.2%	\$ 1.62	0.6%
Total for Part B services	\$9,188,271,966	\$250.04		\$ 9,298,153,341	\$ 251.65	\$ 109,881,374	1.2%	\$ 1.62	0.6%
Composite rate services	\$5,971,322,776	\$162.50	4.40%	\$ 6,039,286,119	\$ 163.45	\$ 67,963,344	1.1%	\$ 0.96	0.6%
Separately billable services (Part B)									
EPO	\$2,008,311,433	\$54.65	7.0%	\$ 2,041,411,639	\$ 55.25	\$ 33,100,205	1.6%	\$ 0.60	1.1%
Darbepoetin	\$152,821,733	\$4.16	-9.0%	\$ 155,427,598	\$ 4.21	\$ 2,605,865	1.7%	\$ 0.05	1.2%
Calcitriol	\$2,303,577	\$0.06	-26.3%	\$ 2,321,848	\$ 0.06	\$ 18,271	0.8%	\$ 0.00	0.2%
Doxercalciferol	\$89,667,409	\$2.44	16.6%	\$ 90,322,782	\$ 2.44	\$ 655,373	0.7%	\$ 0.00	0.2%
Paricalcitol	\$312,518,169	\$8.50	-3.2%	\$ 314,647,823	\$ 8.52	\$ 2,129,654	0.7%	\$ 0.01	0.1%
Iron sucrose	\$170,541,042	\$4.64	2.6%	\$ 171,771,628	\$ 4.65	\$ 1,230,586	0.7%	\$ 0.01	0.2%
Sodium ferric gluconate	\$67,950,534	\$1.85	-0.2%	\$ 68,461,437	\$ 1.85	\$ 510,904	0.8%	\$ 0.00	0.2%
Levocarnitine	\$3,895,496	\$0.11	-22.5%	\$ 3,940,188	\$ 0.11	\$ 44,693	1.1%	\$ 0.00	0.6%
Alteplase	\$31,209,168	\$0.85	16.9%	\$ 31,459,844	\$ 0.85	\$ 250,676	0.8%	\$ 0.00	0.3%
Vancomycin	\$3,472,415	\$0.09	-3.1%	\$ 3,508,983	\$ 0.09	\$ 36,568	1.1%	\$ 0.00	0.5%
Daptomycin	\$1,605,961	\$0.04	30.1%	\$ 1,613,423	\$ 0.04	\$ 7,462	0.5%	\$ (0.00)	-0.1%
Other injectables	\$5,171,355	\$0.14	4.6%	\$ 5,195,025	\$ 0.14	\$ 23,670	0.5%	\$ (0.00)	-0.1%
Laboratory tests	\$307,033,237	\$8.36	3.9%	\$ 308,254,497	\$ 8.34	\$ 1,221,260	0.4%	\$ (0.01)	-0.1%
Ultrafiltration	\$2,676,457	\$0.07	4.4%	\$ 2,676,457					
Dialysis facility supplies and IV fluids	\$38,263,239	\$1.04		\$ 38,263,239					
Durable medical equipment and supplies (method II)	\$18,060,483	\$0.49		\$ 18,060,483					
Dialysis support services (method II)	\$1,447,484	\$0.04	0.0%	\$ 1,530,328	\$ 0.04	\$ 82,844	5.7%	\$ 0.00	5.1%
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	\$ 12,080,394	\$ 0.49		\$ 12,080,394					
Calcitriol (oral)	\$ 3,024,265	\$ 0.12	12.9%	\$ 3,024,265					
Doxercalciferol (oral)	\$ 5,605,698	\$ 0.23	12.9%	\$ 5,605,698					
Paricalcitol (oral)	\$ 3,396,646	\$ 0.14	12.9%	\$ 3,396,646					
Levocarnitine (oral)	\$ 53,784	\$ 0.00	12.9%	\$ 53,784					

NOTE: The CMS reported value for its Final ESRD PPS Base Rate is \$251.60.

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

We did update the Ultrafiltration but we believe it should be considered a fourth treatment.

We are unable to precisely replicate CMS' updated of the composite rate, which also affects ultrafiltration.

Appendix B: Technical Appendix: TMC replication of Laboratory Test Payments

Source	Treatment Units	Total Lab Payments (\$)	Lab Payments Carrier File 5% SAF (\$)	Lab Payments 72x from 5% OP SAF (\$)
CMS Reported Values, Table 9 (Page 206 – 207 of the ESRD PPS Final Rule Display Copy)	36,747,662	\$ 295,508,409		
Per Treatment		\$ 8.04		
TMC Estimated Values Using CMS' Methodology as Reported in ESRD PPS Final Rule	1,844,253		\$ 14,834,191	\$ 809,948
Per Treatment			\$ 8.04	\$ 0.44