



August 29, 2014

Marilyn Tavenner  
Administrator  
Centers for Medicare and Medicaid Services  
Room 445-G  
Hubert H. Humphrey Building,  
200 Independence Avenue, SW  
Washington, DC 20201

**RE: CMS-1614-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies**

Dear Administrator Tavenner:

On behalf of Kidney Care Partners (KCP), I would like to thank you for providing us with the opportunity to comment on the “Proposed Rule: End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies” (Proposed Rule). KCP is an alliance of members of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies that support the provision of high quality care for individuals with both chronic kidney disease (CKD) and End-Stage Renal Disease (ESRD). We appreciate the opportunity to provide comments on the proposals related to the End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) that are part of the Proposed Rule. We have submitted our recommendations on the ESRD Prospective Payment System (PPS) in a separate letter.

In terms of the ESRD QIP, KCP continues to be concerned that CMS has yet to establish an ESRD specific strategic quality plan. We also provide comments regarding the proposed measure changes for PY 2016, 2017, and 2018. Finally, we offer recommendations related to the proposed methodological changes for PY 2018.

**I. CMS Should Work with the Kidney Care Community to Establish a Strategic Vision for the QIP**

As you are aware, the kidney care community has been a leader in collecting and reporting quality data, as well as improving the quality of patient care for more than 20 years. Kidney care providers embraced value-based purchasing from the beginning. KCP launched the Kidney Care Quality Alliance (KCQA) to drive the development of meaningful and consensus-based measures that were proven to be

valid and reliable and that we shepherded through the National Quality Forum (NQF) endorsement process. We also recommended a structural approach for a value-based purchasing program that, among other things, acknowledged the importance of incentivizing providers not only to show improvement, but also to drive toward attainment. KCP advocated for the ESRD Quality Incentive Program (QIP) and provided valuable assistance throughout its implementation. In sum, the kidney care community understands the value of quality programs and the public reporting of quality measures in an effort to drive all providers to the highest levels of attainment.

Thus, it is disappointing to review the Proposed Rule for Payment Years (PY) 2016-18 and find no overarching strategic vision as to how Medicare identifies and implements quality metrics, benchmarks, and incentives to improve the quality of kidney care for beneficiaries during the next five to ten years. Nor does the Proposed Rule acknowledge the attempts of another silo within the Agency to enact a conflicting quality program – the Five Star Rating System.

As in past proposed rules, the Agency describes the quality AIMS, the six goals of the CMS Quality Strategy, and the foundational principles of the CMS Quality Strategy. These statements are understandably very general given the Agency's interest in applying them to all types of providers. Even so, CMS should, in consultation with the kidney care community, establish a clear set of principles and goals that are tailored to the ESRD program. Only a tailored approach will lead to meaningful improvement and attainment in quality goals.

Much of the work to establish an ESRD strategic vision for quality has already been completed. During the past several years, KCP has provided a series of recommendations as to what specific steps CMS could take, both in terms of the QIP and other quality programs more generally, to ensure that the Medicare ESRD quality programs meet the goals set forth by the Agency, as well as the Congress, MedPAC, and the community.

The development of a strategic vision for the QIP should be grounded in achieving the goals that those seeking to implement value-based purchasing in the ESRD Medicare program sought to achieve. These goals for the QIP were clearly set forth by the Medicare Payment Advisory Commission (MedPAC or Commission) and Sen. Max Baucus (D-MT). In 2003, MedPAC first recommended implementing a pay-for-performance program for dialysis facilities. In doing so, it specifically defined the goal of such a program. The Commission reiterated this goal in its June 2014 *Report to the Congress*, which stated that the program should “promot[e] clinically appropriate, coordinated, and patient-centered care at a cost that is

affordable to the program and beneficiaries.”<sup>1</sup> Senator Baucus, who introduced the Medicare Improvements for Patients and Providers Act (MIPPA) that included the QIP described the purpose of such value-based purchasing programs as “[g]iving healthcare providers a reason to make sure their service is top-notch [to] save taxpayer dollars in the long run.”<sup>2</sup> CMS also has echoed these goals:

The End Stage Renal Disease (ESRD) Quality Initiative promotes ongoing CMS strategies to improve the quality of care provided to ESRD patients. This initiative supports quality improvement efforts among providers and makes available quality information that will enable patients to participate in making health care decisions.<sup>3</sup>

Yet, the Proposed Rule is the latest example of how the QIP is not achieving these goals. It also appears that there is no systematic plan to accomplish them. Instead, the focus appears to be adding on new measures without considering whether the information available for each measure will drive actual improvement in patient care in the context of dialysis facility services. As MedPAC has noted: “The set of measures should be small to minimize the administrative burden on providers and CMS.”<sup>4</sup> The Commission also echoes the concerns KCP has raised in regard to the TEP process, as well as several QIP proposed rules, when it states: “Medicare’s quality measurement systems seem to be increasingly incompatible with the Commission’s goal of promoting clinically appropriate, coordinated, and patient-centered care at a cost that is affordable to the program and beneficiaries.”<sup>5</sup>

Understanding that federal resources are limited, the KCP has supported two efforts to establish a strategic vision for the future of kidney care quality. The first is the development and publication of “A Strategic Blueprint for Advancing Kidney Care Quality” (KCP Blueprint). As the Executive Summary states:

Despite community-wide improvements, Kidney Care Partners (KCP) felt kidney care quality would benefit from a strategic blueprint that identified the essential areas for improvement. KCP’s vision for this report is that the identification of a comprehensive, yet parsimonious, core set of strategic recommendations will help patients with kidney disease live Life to the Fullest. KCP believes care can and should be improved to:

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<sup>1</sup> Medicare Payment Advisory Committee, *Report to the Congress: Medicare and the Health Care Delivery System*, Chapter 3 “Measuring Quality of Care in Medicare” 41 (June 2014).

<sup>2</sup> Senate Finance Committee *press release* “Baucus Presses for Incentives to Improve Healthcare Quality within Medicare Programs” (June 23, 2004) *available at* <http://www.finance.senate.gov/newsroom/ranking/release/?id=58699846-a260-4564-aa59-d87a27c25bb0>.

<sup>3</sup> CMS, “End-Stage Renal Disease (ESRD) Quality Initiative” *available at* <http://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDQualityImproveInit/>.

<sup>4</sup> MedPAC, *supra*, note 1.

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

- improve survival;
- reduce hospitalizations;
- improve health-related quality of life, and
- improve patient experience with care.<sup>6</sup>

The KCP Blueprint acknowledges the important role that federal policy can play in improving the quality of care provided both in terms of quality initiatives and payment. Even so, the consensus view expressed in the KCP Blueprint highlights that federal policies must also be tailored to addressing the unique aspects of providing kidney care. There cannot be a one-size-fits-all approach if the goals for the QIP are to be realized.

Federal policy is a significant driver of health care quality in any sector, but especially for kidney care quality. KCP recommends that federal policies: support the advancement of quality in the delivery of care to patients with kidney disease, provide incentive payments as part of the QIP, encourage health information exchange and health information technology for dialysis care, incorporate a new technology adjustment that is not budget neutral, and permit dialysis facilities to be reimbursed for providing education for pre-ESRD patients.<sup>7</sup>

Thus, the KCP Blueprint specifically describes a vision for the QIP. In short, it states:

KCP has supported the overall intent of the QIP, which includes both transparency and payment components. KCP believes improving it in four areas—the measure development process, measure harmonization, inclusion of arteriovenous grafts in the measurement program, and careful deployment and improvement of ICH CAHPS—can make a marked difference in achieving the four goals.<sup>8</sup>

Additionally, the KCP Blueprint proposes a series of potential domains that could be prioritized for future measure development.

The second KCP initiative picks up where the KCP Blueprint leaves off. Through the Kidney Care Quality Alliance (KCQA), members of KCP and non-KCP organizations reviewed the potential domains identified in the KCP Blueprint in light of current federal policy objectives and clinical priorities to improve patient outcomes. By a virtually unanimous vote, the KCQA agreed that the next domain for which a measure should be developed is in the area of fluid management. It is concerning that CMS proposes several new measures for PY 2018 in the Proposed

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<sup>6</sup>Kidney Care Partners, *A Strategic Blueprint for Advancing Kidney Care Quality* i (March 2014).

<sup>7</sup>*Id.*

<sup>8</sup>*Id.*

Rule, yet not one of them addresses the top priority area that physicians, nurses, patients, dialysis facilities, and others believe is, next to removal of catheters, the most important area to improve patient outcomes, including reducing hospitalization and mortality.

Additionally, CMS seems more inclined to add measures that have not been reviewed, let alone endorsed, by the NQF. We understand that the Congress permits the Agency to add measures that have not been endorsed by a consensus-based organization, but the exercise of that authority should be the exception rather than the rule. Coupled with this trend is the tendency of new measures extending beyond the scope of responsibility and sphere of influence of dialysis facilities. Measures such as the standardized transfusion ratio are problematic because they require facilities to obtain data that they do not have and that other providers rarely are willing to share. Such metrics also measure outcomes that other providers control. In the case of the standardized transfusion ratio, specifically, it does not differentiate among the various reasons for a blood transfusion even in terms of the underlying data. For example, the codes hospital use to record the transfusions do not distinguish between matching a patient's blood type for a potential transfusion and the actual transfusion itself. Such measure might make sense in the context of a coordinated care program, but not in Medicare fee-for-service. Measures that are disconnected from the clinical goals expressed by nephrologists, nurses, and others in the community, as well as from the ability of facilities to influence the outcomes provide neither incentives to improve care nor meaningful information to patients.

The disconnect between the work of the kidney care community and the Proposed Rule raises serious concerns about the future of the QIP and its effectiveness. While the remainder of this letter describes in detail our reaction to the Proposed Rule, KCP strongly urges CMS to refrain from adding new measures to the QIP for 2017 and 2018 and modifying the scoring methodology. Instead, in partnership with the kidney care community, CMS should consider implementing the following ESRD-specific strategic plan for the QIP. Once that plan is in place, the Agency, again working with the community, should adopt measures that clinical literature and clinical practice show actually change patient outcomes for the better in the context of the dialysis facility setting.

**Goal:** Consistent with the KCP Blueprint and the Agency's own statements about the purpose of the QIP, CMS should articulate that the goal of the QIP is to support the advancement of quality in the delivery of care to patients with kidney disease by supporting incentives to improve the quality of care and/or to attain defined quality benchmarks. The incentives arise from linking payment rates to the quality of care determined by a facility's total performance score each year.

**Strategy:** We recommend that CMS seek to achieve this goal by working closely with all members of the kidney care community to identify ESRD-specific

evidence-based measures that are actionable by dialysis facilities and have been shown to be valid and reliable through meaningful consensus-based process. The approach to develop measures must be rigorous and transparent. Additionally, CMS should maintain a consistent methodological approach to calculating the QIP's total performance scores to allow for comparisons over time.

**Tactics:** KCP recommends implementing the following tactics this year to re-align the QIP with the appropriate goals.

1. Improve the measure development process, consistent with previous KCP comments on the Technical Expert Panel process. The current process does not consider the day-to-day operations and data collection realities of dialysis facilities. The process also appears pre-determined and opposed to stimulating an open dialogue that could lead to changes in the initial proposals. The process should be completely transparent and allow for open dialogue and modification. Finally, building off of the work of the KCP Blueprint and the KCQA, we recommend that CMS work with the kidney care community to identify the most appropriate areas for measure development and establish a transparent plans and process for their development.
2. Harmonize measures used in the QIP with similar measures in other federal programs, when feasible, such as the Physician Quality Reporting System and the ESRD Seamless Care Organizations proposal.
3. Address specific critical gaps in the current QIP measures. This would require developing and including arteriovenous grafts in the measurement program and careful deployment and improvement of ICH CAHPS, consistent with previous KCP comments. It would also mean not pursuing measures that do not have a direct and evidence-based impact on patient outcomes.
4. Work with the Office of the General Counsel to identify ways to provide positive incentives, consistent with MedPAC recommendations that such programs "[r]edistribute to providers all of the funding that was set aside in accordance with their performance on the quality measures."<sup>9</sup>
5. Implement a rigorous process to ensure the integrity of the data used to develop measures and benchmarks, as well as the data being reported by facilities.

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<sup>9</sup>MedPAC, *supra* note 1, at 42.

6. Rather than change the methodology every few years, the Agency should alter the benchmarks and/or weights of the various measures to address changes in priorities. Weights should be based on the clinical importance of a measure to improving patient outcomes. The calculation of benchmarks should be based on publically available data and completely transparent. The problem of small numbers should be addressed to avoid random effects, as well as address compressed measures. While it may be appropriate to retire some measures, the Agency should also reward attainment, consistent with MIPPA and MedPAC recommendations.<sup>10</sup>
7. Communicate facility's total performance score and individual measure results in a consistent, accurate, and clear manner to empower patients and their families.

A strategic vision for the ESRD QIP would also address the inconsistencies and administrative burdens created by the various, uncoordinated Medicare quality programs that have become barriers to improving quality and empowering patients. Within the Medicare program alone, there are multiple quality initiatives (*e.g.*, ESRD QIP, Dialysis Facility Compare, Fistula First/Catheter Last, CROWNWeb, ICH-CAHPS reporting, and the new ESRD Five Star Rating System), each with its own goals, procedures, data collection systems, and data definitions. In addition, the ESRD Networks also operate their own series of quality initiatives separate and apart from the federal programs. Not only is it confusing and burdensome to facilities, physicians, nurses, and other health care professionals who must provide the data through different IT systems with different business rules, but the multiple programs with different measures and data definitions result in inconsistencies in reporting outcomes and quality performance.

A strategic vision for the QIP would help the process of aligning these various programs. A standardized data dictionary could be created; measure specifications could be aligned; redundancies among the various programs could be eliminated; there could be a single consolidated IT system; and there could be consistency in the outcomes being reported.

The streamlining could improve patient care as well. Good data drives good decisions. The current fragmentation produces inconsistent results upon which physicians and others are unlikely to rely. If they do rely upon the outcomes of inconsistent quality initiatives, the decisions they make will be suboptimal because of the flaws within the various programs. An example of this problem is the disconnect between Fistula First/Catheters Last and the ESRD QIP. Fistula

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<sup>10</sup> *Id.*

First/Catheters Last recognizes the clinical reality that not all patients can benefit from a fistula. Thus, it also incentivizes facilities to reduce catheter use and recognizes the role of grafts. Despite concerns raised by KCP over the years, the ESRD QIP continues to emphasize fistula placement and catheter removal equally. It also ignores grafts entirely. Because of these differences, there are different outcomes being reported. The inconsistencies raise questions about the validity of the programs. If facilities and physicians could trust the information being reported, the Medicare quality programs would be more likely to accomplish their goals of improving patient outcomes and reducing unnecessary hospitalizations.

Patients who want good quality information also find the various programs confusing and difficult to use as they make treatment decisions. An another example of the need for a strategic vision that aligns the various programs is the recent announcement of ESRD Five Star. As we have commented in other letters, the launch of ESRD Five Star will now result in patients being confronted with two very different sets of information. First, they will see their facilities' QIP scores, which may show a zero percent reduction. Then, if those same patients look at ESRD Five Star, they will see entirely different results. The table below describes the disconnect between the two programs.

Stars	OIP Penalty					Total
	0%	0.5%	1.0%	1.5%	2%	
<b>1</b>	468	47	21	6	9	<b>551</b>
<b>2</b>	1,019	48	17	8	9	<b>1,101</b>
<b>3</b>	2,155	38	6	0	3	<b>2,202</b>
<b>4</b>	1,091	9	0	0	0	<b>1,100</b>
<b>5</b>	552	0	0	0	0	<b>552</b>
<b>Total</b>	<b>5,285</b>	<b>142</b>	<b>44</b>	<b>14</b>	<b>21</b>	<b>5,506</b>

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We understand that there may be concerns that the ESRD QIP does not provide sufficient differentiation among facilities; however, that should not be the goal of a quality program. First, it is important to set quality goals/benchmarks and acknowledge when providers achieve them, as the ESRD QIP does. Second, it is



important to work with the community to establish the clinical metrics – when reported – provide an assessment of facility performance and can lead to changes in facility actions to improve those outcomes. Simply creating another program that relies upon a forced distribution to create differentiation that does not exist in reality is misleading.

In sum, KCP strongly encourages CMS to take a step back and re-evaluate its approach to the QIP. KCP and others in the kidney care community, as well as other interested stakeholders, would welcome the opportunity to have a constructive and meaningful dialogue to establish a system that achieves the intent of those who sought to create it.

## **II. CMS Should Validate Measures before Adding Them to the ESRD QIP**

CMS proposes two studies related to the data being reporting for the ESRD QIP. First, it proposes to continue its validation pilot, which will result in the Agency reviewing 10 records per facility from 300 facilities. The second proposal is a feasibility study for validating data reporting for the NHSN Dialysis Event Module for the NHSN Bloodstream Infection clinical measure. KCP is concerned about both of these programs.

First, the validation pilot study should be described as what it is – an audit of the data facilities are reporting for the ESRD QIP. A data validation step should have been performed prior to implementing the performance measure. While we appreciate that a pilot allows the Agency to study new programs, the validation “pilot” is not focused on testing a new payment or delivery of care model, but rather it is about confirming the accuracy of the data being reported. Under the pilot, facilities risk having two percent taken off all reimbursement amounts. This penalty is harsh, and we urge CMS to identify intermediate penalties, which would be consistent with the design of the overall QIP as well, to calibrate the penalty with the problem identified.

Also given that a financial penalty is attached to the program, it is important to make sure that there are adequate processes in place to address disputes that may arise. For example, Medicare payment audits include opportunities to work with the auditors and, most importantly, the ability to appeal both at the contractor and higher levels of review. Thus, we strongly urge CMS to establish such protections for the validation pilot.

A second concern is the use of the ESRD QIP to validate a measure that has already been added to this penalty-based program. A measure should be validated before it is added to the QIP. We believe that was the intent of Congress in requiring the Agency to consider measures that have been endorsed by the NQF. The NHSN

Bloodstream Infection measure has been rushed into the program without achievement benchmarks or improvement targets. Thus, we urge CMS to refrain from making the NHSN measure a clinical metric until the validation study is available for all interested parties to review. While it is true that bloodstream infections are serious clinical conditions, a validated clinical performance measure allows stakeholders to focus on the solutions to the clinical issues, rather than having also to spend time and resources to address concerns about the measure construct, internal and external validity, integrity of data collection, and understanding the baseline distribution of facility performance.

A recent example illustrating the lack of data validation has recently come to light with the CY 2013 Kt/V measure, as well. An inherent assumption that CMS has undertaken with regard to converting the measures specifications into actual QIP scores is that claims data always reflect the true performance of the facility. In reality, submitted claims are subject to local coverage decisions, billing edits, etc. Specifically for the Kt/V metric an exclusion criteria is meant to exclude patients with less than or greater than three treatments per week. However, in submitting claims, the actual number of paid treatments in a given month may be affected by claims processes. The net result is that the claims data set differs materially from the Electronic Medical Record and, in the case of Kt/V biases the results towards relative clinic underperformance. Had the data been validated prior to implementation, this problem would have been detected. Instead, the contractor processed the data, unaware of the billing nuances that impact data integrity.

### **III. KCP Supports the Extraordinary Circumstances Exceptions Proposal**

KCP appreciates the Agency's recognition that there are sometimes extraordinary circumstances that make it impossible to comply with the ESRD QIP requirements. We encourage the Agency to offer additional guidance as to the circumstances under which an exception may be granted. We agree with the examples of natural disasters identified in the Proposed Rule, but also suggest adding other events, such as fires, explosions, or other situations that are not traditionally labeled as "natural" disasters.

We also recommend that CMS allow facilities to rely upon attestations as acceptable documentation of the event. While it may seem like news clippings or other similar documents would not be difficult to obtain, there are situations that may make it difficult for a facility to be able to gather them in the 90-day timeframe. It is also possible that some events may simply not be covered in the media.

Finally, we also recommend that CMS take into account an exceptions process for short-term dialysis units. For example, some nephrologists and facilities offer "camps." These camps often occur for one week during the year and provide

patients, especially pediatric patients, with the opportunity to experience a traditional camp similar to those enjoyed by individuals who are not living with kidney failure. We would like to work with the Agency to identify an appropriate way to address this unique circumstance in light of the ESRD QIP as well.

**IV. CMS should add a “clinical importance” criterion to the decision about whether to retire measures with compressed performance measures.**

In the past, KCP has expressed concern about the impact that compressed or “topped out” measures may have on QIP scoring. We support the proposal to apply the criteria established in the CY 2013 ESRD rule to decide when a measure has become too compressed and should therefore be retired.

We further support the proposed statistical definition of when “measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made.”

Under the proposed criterion, CMS proposes to retire the Hgb>12 measure. At the same time, CMS proposes to retain the pediatric Kt/V measure, even though it meets the criteria for retirement, because “There are currently very few measures available that focus on the care furnished to pediatric patients with ESRD, and we are reticent to remove a measure that addresses the unique needs of this population.” While we understand the rationale, we think CMS should avoid bending its own rules, which could lead to future decisions and regulations inconsistent with the goals of the QIP.

Therefore we suggest modifying the criteria to retire measures as follows [our suggested language underlined]. CMS should retire or replace a measure when one of the following criteria is met:

(1) measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made; (2) performance or improvement on a measure does not result in better or the intended patient outcomes; (3) a measure no longer aligns with current clinical guidelines or practice; (4) a more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available; (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; (7) the measure does not uniquely address the needs of a specific population within the ESRD program; or (8) collection or public reporting of a measure leads to negative unintended consequences.

Adopting this modification to the criteria would allow CMS to retain the Kt/V measure while also maintaining internal consistency, and could address similar measure retirement questions in the future.

**V. KCP urges CMS not to include the proposed modifications to the NHSN Bloodstream Infection measure or designated hypercalcemia as meeting the statutory requirement for PY 2016.**

As described in detail below, we believe CMS should not finalize the proposals related to the PY 2016 measures.

**A. *KCP opposes NHSN Bloodstream Infection in Hemodialysis as a clinical measure and opposes using the Reliability-Adjusted Standardized Infection Ratio, or Adjusted Ranking Metric (ARM).***

KCP recognizes the vital importance of reducing infections and strongly supports efforts to do so. Measures in this area will improve patient outcomes and reduce other medical costs related to treating infections. However, we continue to oppose using the NHSN measure as a clinical measure for PY 2016 and continue to maintain it should be a reporting measure, given that CMS lacks the data to establish a baseline to set a standard and to provide an improvement score and so has arbitrarily proposed a 50<sup>th</sup> percentile approach. To compound this problem, CMS now proposes facility performance in PY 2016 for NQF 1460: *NHSN Bloodstream Infection in Hemodialysis* be calculated using the Reliability-Adjusted Standardized Infection Ratio, or Adjusted Ranking Metric (ARM). CMS and the Centers for Disease Control and Prevention (CDC) do not provide, however, any details about the methodology of this adjustment. KCP strongly opposes using the ARM, absent any opportunity to evaluate it.

We also note that the Proposed Rule implies that the ARM has been endorsed by NQF, when it has not been. Specifically, the Proposed Rule notes, "On April 4, 2014, in response to a measure update proposal submitted by CDC, NQF endorsed a reliability adjustment for volume of exposure and unmeasured variation across facilities to NQF #1460." In fact, although NQF #1460 remains endorsed, even with the revised specifications, we feel it important to note that an NQF Steering Committee review of the revised measure has not occurred and so independent public scrutiny and an endorsement of the ARM per se has not occurred.

As noted elsewhere, KCP does appreciate the efforts to by CMS regarding validating NHSN data. We believe the latter is particularly important because of concerns that the distribution is bimodal, which does not represent differences in reporting, but rather different levels of diligence in blood culture detection as it

relates to the comprehensiveness of data collection between all blood cultures for a patient and only those cultures from the ESRD reference lab. In that scenario the diligent get punished (by having a higher infection rate), while less diligent clinics will benefit from an artificially lower infection rate. We emphasize, however, that such validation further underscores the need to occur **before** use of NQF #1460 as a clinical measure in the QIP.

***B. KCP acknowledges the use of the hypercalcemia measure in the QIP for PY 2016, but objects to its characterization as meeting the requirement of the Protecting Access to Medicare Act of 2014 (PAMA) requirement for measures “specific to the conditions treated with oral-only drugs.”***

In our August 2013 comment, KCP supported NQF 1454: *Proportion of Patients with Hypercalcemia* as a reporting measure until CMS had collected a full year of data to support the performance standards, achievement thresholds, and benchmarks. We acknowledge, however, that CMS finalized the measure as a clinical measure for PY 2016. KCP does not concur, however, that the hypercalcemia drug meets the definition of a measure “specific to the conditions treated with oral-only drugs.” This measure is strongly influenced by parenteral vitamin D and is not an effective measure for oral-only drugs.

Finally, we remain concerned that this metric is not the best measure in the bone mineral metabolism domain to impact patient outcomes, in the absence of clinical metrics for other related mineral disturbances, such as phosphorous and PTH. We believe CMS should commit to working with the kidney care community to develop clinically meaningful measures for this area.

***VI. For PY 2017, KCP recommends that CMS modify the Vascular Access measures, the Kt/V measures, the Anemia Management and Mineral Metabolism reporting measures, and the ICH CAHPS measure; KCP opposes including the Standardized Readmissions Ratio measure until the problems with it can be addressed.***

While KCP supports the continued use of many of the measures proposed for PY 2017 with modifications, we strongly urge CMS not to include the SRR in the final rule and instead work with the kidney care community to address its flaws.

***A. KCP supports the continued use of the vascular access and adequacy of dialysis measures for PY 2017.***

KCP supports CMS’s proposal to maintain two current ESRD QIP measures for PY 2017. As noted below, however, we continue to urge the Agency to place more weight on the catheter reduction metric because of its significant impact on

patient morbidity and mortality and to focus on maximizing both AV fistulas *and* grafts.

***1. KCP supports the continued use of the vascular access measures for PY 2017.***

KCP continues to strongly support the inclusion of vascular access measures in the ESRD QIP. Reducing catheters in favor of a permanent access (ideally an AV fistula, but in some instances, an AV graft when clinically appropriate) is arguably the most important factor in improving patient outcomes. However, we note that the Agency has not addressed our previous comments on this issue and again express our concern in regards to the potentially significant negative clinical impact of having fistula and catheter measures in the absence of a graft measure. The failure to include a graft measure in the vascular access type composite disincentivizes the use of what is frequently the most clinically appropriate access, selected with and in the best interest of a patient.

We again strongly encourage the Agency to adjust the weighting of the catheter measure as an interim way to address the concern and to work with the kidney care community to develop a graft measure over the long-term. Specifically, we suggest that CMS weight the catheter minimization measure two-thirds compared to one-third for the maximizing of AV fistulas.

***2. KCP continues to support Kt/V as the measure for adequacy of dialysis, but again urges CMS to establish a consistent set of minimum exclusions that apply to all measures.***

KCP continues to support the use of Kt/V as the measure for adequacy of dialysis for in the QIP. As we have previously commented, the clinical literature demonstrates that Kt/V is the outcome metric upon which practitioners primarily rely when making treatment decisions related to adequacy. However, we note that the adult and pediatric hemodialysis adequacy measures exclude patients treated at the facility fewer than two times during the claim month. We reiterate our concern about the minimum number of treatments a beneficiary must receive to be included in a measure. CMS has recognized previously that there are instances during which a facility may not be able to draw a beneficiary's blood because the beneficiary is not present for other treatments during the month.<sup>11</sup> As health professionals well know, consistent interaction is necessary to monitor patient conditions, modify treatment protocols, and evaluate the impact of such changes. Just as CMS recognized that transient patients—*i.e.*, beneficiaries who receive fewer than 7 treatments in a month—should be excluded from the reporting measures, so should this exclusion be applied to the clinical measures.

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<sup>11</sup>See 77 Fed. Reg. 40952, 40968 (July 11, 2012).

KCP, thus, recommends that CMS revise this exclusion to “patients treated at the facility fewer than 7 times during the claim month” and again urges the Agency to establish a consistent set of minimum exclusions that apply to all measures. As we have noted historically, the issue of including or excluding patients from a particular measure is a critical one. While our experience as measure developers teaches us that many of these decisions should be made on an individual measure level, it is also true that there should be a global set of exclusions that would apply consistently to all measures related to the treatment of ESRD patients. Thus, we again urge CMS to adopt a set of minimum global exclusions that would be automatically applied to all measures, unless there is a specific clinical or operational reason they should not be. To this end, KCP has recommended that CMS adopt the following global exclusions:

- Beneficiaries who die within the applicable month;
- Beneficiaries who receive fewer than 7 treatments in a month;<sup>12</sup>
- Beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented good faith effort to have them participate in such a visit during the applicable month;
- Transient dialysis patients;<sup>13</sup>
- Pediatric patients (unless the measure is specific to pediatric patients);
- Kidney transplant recipients with a functioning graft.

In addition, beneficiaries must have treatment for at least 60 days to be assigned to a facility or alternatively, CMS should reinstate the prior rule for URR that the patient must have at least 4 eligible claim months to count towards the adequacy domain.

***B. KCP supports the use of the anemia management and mineral metabolism reporting measures in the QIP, but reiterates the need for important and immediate modifications for PY 2017.***

KCP supports CMS’s proposal to maintain these two QIP measures for PY 2017; however, as described below, we continue to urge the Agency to appropriately address reporting thresholds and small numbers for these measures. KCP is pleased that CMS will revise the mineral metabolism measure to include plasma as an acceptable substrate for PY 2018, but is puzzled as to why “feasibility”

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<sup>12</sup>See CMS, Transmittal 2311, “Implementation of the MIPPA 153c End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and Other Requirements for ESRD Claims” 50.9 (Sept. 23, 2011).

<sup>13</sup>See, e.g., NQF #0261 Measurement of Serum Calcium Concentration (denominator exclusions include transient dialysis patients, pediatric patients, and kidney transplant recipients with a functioning graft).

issues prevent this from being deployed for PY 2017; we urge CMS to adopt plasma for PY 2017.

KCP agrees that it is important to continue monitoring Medicare ESRD patient mineral metabolism and hemoglobin levels. We are pleased that CMS has now standardized the exclusions for both reporting measures. However, KCP reiterates our significant concerns about the reporting thresholds and small numbers described in Section VIII of this letter. As we have previously noted, these concerns are exacerbated with the reporting measures, which apply to n=2 to 10 patients (with room for only one missing value), whereas previously the threshold that was used across the QIP was less than n=11. Despite the significant concerns we have expressed about the <11 threshold in the past and evidence that we have presented on how it can unfairly penalize facilities that may legitimately miss a few patients' values, CMS continues to maintain the unreasonably low threshold of requiring facilities treating <11 eligible patients to submit data for all but one patient for the reporting measures. We urge CMS to address the small numbers problem and apply a consistent minimum number of cases (26) to all QIP measures, including these reporting measures.

Additionally, we recommend that the mineral metabolism reporting measure specifications be modified to indicate that plasma is an acceptable substrate in addition to serum. In 2013-2014, KCP requested an NQF ad hoc review to consider this issue. The NQF Panel concurred with KCP's position; however, CMS proposes that these changes should not be adopted until PY 2018. KCP instead urges the Agency to incorporate these revisions into the measure specifications for PY 2017.

***C. Before using the Standardized Readmission Ratio (SRR) in the QIP, CMS should modify it***

KCP recognizes the importance of measuring readmission rates in the context of assessing quality of care. However, KCP does not support use of the SRR, as currently specified, for PY 2017. As described below, we offer alternative solutions to address the identified concerns.

First, as currently constructed, the SRR reflect readmissions for all causes and does not distinguish ESRD-related admissions: KCP believes that the measure should be appropriate to the sphere of influence. KCP recommended in our May 2013 comment letter to Arbor Research and CMS when the measure was under development that the measure be limited to those readmissions that are related to or actionable to ESRD, rather than the all-cause readmissions promulgated in the current specifications. We believe admissions and readmissions are of great importance and can be a valuable indicator of the quality of care provided, but believe the dialysis unit has limited ability to impact those outcomes for all causes. A review of 2011 Medicare Claims data indicates that ESRD patients had an



admission rate of 1.88 per patient. The percentage of those admissions attributable to diagnoses related to dialysis and/or ESRD and its sequelae were low—five percent for vascular access infection and 27 percent for all cardiovascular disease, including fluid overload, CAD, and AMI. Thus a significant majority of admissions, and presumably, readmissions—nearly 70 percent—are due to other manifestations.

KCP continues to believe that the measure should account for this issue by limiting readmissions to those related to ESRD. However, given the inherent complexity of the disease and the significant number of serious comorbidities that oftentimes afflict dialysis patients, we acknowledge that precisely elucidating which readmissions are truly a result of an ESRD-related condition can be a daunting task. We, thus, suggest that CMS could alternatively account for this issue with appropriate statistical modeling and case-mix adjustments. We urge the Agency, short of limiting the measure to readmissions related to or actionable to ESRD, to consider this approach so as to develop a stronger, more actionable measure that has the potential to meaningfully impact renal care.

Additionally, KCP notes that the measure as currently constructed offers a skewed and inaccurate picture of readmissions that we urge CMS address prior to incorporation in the QIP. Specifically, as currently specified, the SRR is a misleading measure—a fact that could be remedied by revising the denominator to include all patients within a given facility, rather than just hospital discharges.

We emphasize that use of the SRR as currently constructed will speciously damage facilities' performance scores. If, for example, a dialysis facility has low overall readmission rates but cares for one or two patients who require repeated rehospitalizations, the facility's SRR performance will appear—falsely—to be poor. Expanding the SRR denominator beyond hospital discharges to include all patients treated within a facility would serve to present readmission data in a broader and more genuine context. We urge the Agency to recognize a misleading and patently inaccurate portrait of quality that its proposal to use the current SRR measure will create, and to revise the denominator appropriately prior to its use in the QIP.

KCP's most significant concern with the SRR relates to the lack of an exclusion for patients readmitted before being seen by the dialysis unit. In our May 2013 comment letter to CMS, KCP recommended that patients readmitted in the first 1-3 days after discharge be excluded from the measure. 2011 Medicare claims data indicate that 17 percent of hospitalized ESRD patients had a readmission within three days following discharge, meaning that the dialysis unit would frequently not have had the opportunity to intervene and affect care. Data from two KCP member organizations confirm this finding—among their patients who were rehospitalized within 30 days of the initial hospitalization in 2011, 11-17 percent were readmitted within the first 1-3 days post-discharge—often before the first outpatient dialysis encounter. Specifically, for one KCP member, 17 percent of

patients were readmitted within three days post discharge, among whom only 35 percent of patients had been seen by the dialysis unit prior to the readmission. In other words, by an approximately 2:1 margin, rehospitalized dialysis patients had not been seen by the dialysis facility before readmission. Penalizing facilities for such situations is patently unreasonable. Further in this regard, during the first 8 days after discharge, up to 40 percent of patients were readmitted—again the dialysis center had had a limited number of encounters to intervene/affect quality of care.<sup>14</sup> Additionally, not all discharges are to home and a significant number of patients are readmitted before they receive care from a dialysis facility.

Information provided to a KCP member from the University of Michigan Kidney Epidemiology and Cost Center following the SRR dry run stated, “Approximately 0.8 percent of dialysis facilities were classified as “As Expected” when early readmissions were included and “Worse than Expected” when early readmissions were removed; 0.7 percent of dialysis facilities moved in the other direction. These changes are relatively small but significant for the affected facilities.” Indeed, given facilities may be facing a penalty under the QIP, KCP concurs about the significance and believes these data reinforce the need to adjust the specifications to exclude early readmissions.

For CMS to be aware of this information and not act to fairly treat facilities is troubling. Penalties under the QIP operate on the facility-level performance and CMS’s measures should be deployed to assess facilities with a scientifically valid construct, not one for measure “simplicity.” Again, KCP strongly recommends that the measure exclude readmissions occurring in the first 1-3 days following hospital discharge.

Among the additional concerns KCP has raised with the SRR, we note that as specified, the SRR is inconsistent with CMS’s *Dialysis Facility Standardized Mortality Ratio (SMR)* and *Standardized Hospitalization Ratio (SHR)* measures. Specifically, these measures only include patients who have had ESRD for 90 days or more, and the proposed SRR measure does not appear to be harmonized in this respect. In our May 2013 comment letter to Arbor Research and CMS when the measures were under development; KCP requested clarification on why this difference is present and asked CMS to provide the data analysis on the implications of the difference. To date, these details have not been provided for stakeholder review. We stress that harmonization is of particular importance with the SHR, given the SRR and SHR are likely to be used in conjunction to obtain a complete picture of a facility’s hospitalization use.

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<sup>14</sup> See Chan KE, Lazarus JM, et al. Association between repeat hospitalization and early intervention in dialysis patients following hospital discharge. *Kidney Internat’l*. 2009;76:331-43.

The SRR measure specifications submitted to NQF's Measure Applications Partnership (MAP) in November, 2013 had an exclusion for index hospitalizations that occur after a patient's 6th readmission in the calendar year, which has now been revised to those that "occur after a patient's 12th readmission in the calendar year." In particular, we are concerned about the impact of the revision on low-volume facilities, and believe it is imperative for CMS to report on the underlying distribution that led to the change in order to understand its implications as compared to the version submitted to the MAP.

CMS's *Hospital-Wide All-Cause Unplanned 30-Day Readmission Ratio* (NQF #1789) excludes patients who have incomplete claims history from the past year, but the proposed dialysis facility SRR does not. In May 2013, we asked for CMS to provide the data on readmission rates for patients who have a full year of claims versus those who do not, as well as data on the impact of such an exclusion on the sample size and performance gap. While this information has not to date been provided, we believe such data and analyses are necessary in order to understand why the dialysis measure is not and/or should not be harmonized with the hospital measure.

CMS has incorporated numerous comorbidities into the SRR risk model, but KCP has recommended that in addition to sickle cell anemia, sickle cell trait also be included—as well as angiodysplasia, myelodysplasia, diverticular bleeding, and asthma. Likewise, we have suggested that the risk model also adjust for nursing home status, and have requested clarification on whether "poisoning by nonmedical substances" encompasses ongoing/chronic alcohol or drug abuse and not just acute events.

KCP believes the measure's risk model fails to adequately account for hospital-specific patterns and fails to adjust at all for physician-level admitting patterns—a particular concern because the decision to admit or readmit a patient is a physician decision. We note that geographic variability in this regard is well documented in other areas, and maintain that there is no reason to believe the situation is different for ESRD patients. Specifically, merely adjusting for the hospital as a random effects variable is insufficient. Recent research indicates that beyond a simple hospital ranking, broader regional and geographic variability persists and must be accounted for. Local practices and regional conditions may dictate why hospitalization rates may vary between markets such as Los Angeles, Anchorage, New Orleans, Syracuse, or Miami.

CMS should provide data to demonstrate there is no bias of the SRR between rural and urban facilities; this is not simply adjusted for by the hospital as a random effect variable. We note that the distance of a patient's home relative to the outpatient facility and to the hospital likely influences their choices for care, and it likely further influences their utilization of care, particularly if there are symptoms

that occur on non-dialysis days. The co-pay for transportation also may influence health utilization behavior. It is important for CMS to evaluate the impact of these factors on readmission rates for patients with ESRD and report why such factors should or should not be incorporated. We posit that billing data may shed light on how to evaluate these factors, yet they were not even considered.

Finally, before adopting this measure for the QIP, KCP strongly believes data upon which facilities can take action must be made available to facilities in a timely fashion. We have previously noted an inability for facilities to access accurate, timely discharge and other data from hospitals. Such data are important for facilities to make timely strides in reducing readmissions.

We believe that these technical flaws could be addressed and would work with the Agency to validate the measure. However, at this time given the specification of the proposed measure, KCP does not believe this measure should be included in the QIP. CMS has the data to address a number of these issues—specifically the ability to understand the types of readmissions that dialysis patients experience, the length of time post-discharge when readmissions occur in relationship to when outpatient dialysis unit care resumes, the sites of service that patients are discharged to, and claims data related to physician admission/readmission for purposes of adjusting the model for this factor. Further, KCP is concerned with the approach and assumptions for the predictive model, which posits to reveal an actual versus predicted rate when the basis for the ratio comes from claims data and not EMR data. We strongly recommend a more evidence-based approach to this measure and reiterate our opposition to its advancement, as well as our recommendations on how it can be improved.

***D. KCP continues to recommend important modifications to the proposed ICH CAHPS measure, described below, before it is added to the QIP.***

KCP recognizes the importance of evaluating patients' experiences when receiving dialysis. However, we reiterate our concerns about the burden of ICH CAHPS on patients and providers. We also have several concerns about the administrative specifications that depart from the Agency for Healthcare Research and Quality's (ARHQ) tested approach.

First, CMS requires that patients complete at least 50 percent of the CAHPS Survey's 58 core items to be considered complete. As previously noted, we maintain that patients will find it difficult to complete such a lengthy survey. Many KCP members have developed their own patient satisfaction tools and understand the difficulty patients have in completing them. Often patients require assistance from caregivers or family members to complete these forms. While monitoring patients' experiences is important, it should not be done in a way that burdens patients and is

likely to result in incomplete surveys that benefit no one. To address this issue of “survey fatigue,” we again propose that CMS allow the vendor to divide the survey into AHRQ’s three independently verified domains when administering it. Under this option, one-third of a facility’s patient population would receive one of the three domains plus the core demographic questions. In this manner, a facility would be assessed for all three domains to provide a complete picture of patient experience, but the burden on patients of a lengthy survey would be significantly reduced, thereby resulting in higher completion rates and a valid assessment of performance on this measure. CMS may review and consider whether a staged implementation of the survey will be more successful and could focus its utility.

Second, CMS requires that the ICH CAHPS survey be administered twice yearly. In addition to creating significant and additional risk for survey fatigue with patients, the costs associated with fielding the survey twice are not trivial. Moreover, CMS has not demonstrated why administering the survey twice yearly is advantageous, or how it adds value to patient care or improves outcomes. Additionally, we note that at least one ESRD Network has begun using the survey and are, in the case of Network 16, administering the survey (or portions thereof) as frequently as on a monthly basis. Thus, KCP strongly urges CMS to reduce the fielding requirement to once yearly, as in PY 2015, and to coordinate administration of the survey with the ESRD Networks. Doing so would allow for more meaningful and reliable information to be collected from patients who are not overwhelmed with frequent and lengthy surveys, and would strike the appropriate balance between gathering important information while not overwhelming patients and caregivers. An annual survey would permit facilities to develop a more thoughtful approach to improve patient experience with care in light of the American Institutes for Research/RAND et al. study’s conclusions about the difficulties in translating the results from ICH CAHPS into interventions resulting in meaningful improvement.<sup>15</sup>

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

Fourth, because CMS will identify the patients who will complete the survey and a third-party vendor will administer the survey, there is no apparent mechanism for facilities to ensure that patients’ contact information is as accurate

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

and up-to-date as possible. As response rates necessarily depend on accurate contact information, we object to CMS's proposal that facilities be held accountable for low response rates from such populations for which CMS's contact information may be inaccurate and/or out of date. There will undoubtedly be instances where the contact information is out of date due to the time lag in drawing the sample, providing the information to vendors, and administering the survey. We believe it is important for the CMS administrative specifications to provide an opportunity for facilities to ensure that the primary survey and/or any follow-up is delivered to the most current contact (phone or mail) given the penalty that applies for non-responsiveness.

Fifth, KCP member organizations have noted that the survey's lingual translations are flawed. For instance, one member has identified numerous translation errors in the Chinese version of the survey, even indicating that native speakers have commented that the translation oftentimes does not make sense. We thus urge the Agency to validate its translations of the ICH CAHPS survey to ensure that the information gleaned from foreign-language speakers is accurate and meaningful.

Finally, we are concerned that the CAHPS survey is designed to monitor the experience of patients who receive dialysis in-center and does not account for experience of care for patients on other modalities. CMS should assess the experience of all patients, not just those whose treatments are in-center.

In sum, KCP strongly urges CMS to address these concerns prior to continued use of the ICH CAHPS survey in the QIP.

**VII. KCP supports some of the proposed measures for PY 2018, but urges CMS to modify the ICH CAHPS and NSHN Influenza Vaccination measures and to refrain from adding the Standardized Transfusion Ratio measure, Depression Screening and Follow up, and the Pain Assessment measures.**

KCP supports maintaining those measures from previous years of the ESRD QIP in PY 2018, with the exception of those metrics we have previously indicated are not appropriate. We recommend that CMS modify the ICH CAHPS and NSHN Influenza Vaccination measures. We strongly oppose adding the Standardized Transfusion Ratio measure, Depression Screening and Follow up, and the Pain Assessment measures.

**A. KCP supports the use of the measure Pediatric Peritoneal Dialysis Adequacy for PY 2018.**

KCP believes including pediatric patients in the scope of the QIP is important and supports use of *Pediatric Peritoneal Dialysis Adequacy* for PY 2018.

**B. KCP strongly opposes use of the Standardized Transfusion Ratio (STrR) for PY 2018.**

KCP has several significant concerns about the Standardized Transfusion Ratio (STrR) and strongly opposes its use in the QIP for PY 2018. As with the SRR, the STrR does not adjust for hospital- or physician-related factors. The literature notes that both hospital and physician factors impact transfusion rates in other care settings; there is no reason to think transfusions related to ESRD patients are any different. The risk model should account for these variables. Absent this, the burden is on the developer to conduct the analyses and show that accounting for hospital-level and physician-level factors is not important in this area. Such details are particularly important because facilities do not have access to transfusion data. Furthermore, transfusions related to non-actionable conditions such as non-surgical chronic GI bleeding or motor vehicle accidents/homicide may be clinically appropriate and should be excluded.

Regarding our concern about hospital-level factors, KCP has significant concerns about the validity of the hospital transfusion data central to this measure. In 2011-2012, short-term, critical access, and long-term hospitals administered 98.5% of transfusions in the inpatient setting and 82.9% of transfusions in the outpatient setting. Transfusions are coded by hospitals and coding varies nationwide and even within hospitals—specifically, coding is inconsistent between type and screens (i.e., preparing for a transfusion) and actual transfusions. Some coding variations potentially overestimate the number of transfusions, which would inappropriately penalize facilities in those areas. CMS should ensure data integrity through an audit of transfusion data before deploying the STrR.

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

KCP notes that transfusions do not occur in the dialysis unit and, as with our comments on other measures, we believe measures should assess matters within facilities' sphere of control in a real-time, actionable manner.

Last, but not least, the measure has not been endorsed by NQF. In addition to our concerns about the specifications, KCP remains concerned about the lack of transparency in the development of this measure and its scientific acceptability—i.e., validity and reliability. We strongly object to its inclusion in the PY 2018 QIP.

***C. KCP Opposes Shifting ICH CAHPS to a Clinical Measure Until the Underlying Problems Are Resolved.***

Consistent with our comments in Section VI, KCP continues to have concerns about the burden on patients, and costs to facilities, of twice yearly administration of ICH CAHPS. Additionally, we have significant concern that only the experiences of patients on in-center hemodialysis are measured.

***D. KCP does not support use of the measure Clinical Depression Screening and Follow-Up, based on NQF 0418, as a reporting measure for PY 2018.***

KCP is acutely sensitive to the importance of clinical depression in ESRD patients.<sup>16</sup> When we evaluated the measures as part of the MAP in January 2014, KCP opposed use of this measure as a reporting measure for the PY 2018 QIP because, among several reasons, it was endorsed by NQF as a clinician-level measure; the follow-up component of the measure necessarily requires action (e.g., referral) by the nephrologist—not the facility. This is again borne out by NQF endorsement at the clinician level. In fact, recognizing this, KCP supported this measure in the broader context of the Comprehensive ESRD Care (CEC Initiative), which includes physician participants. We do not believe, however, that it is appropriate for inclusion in the QIP as a facility-only measure. As defined in Section SSA § 1881(h), the QIP specifically pertains to “renal dialysis services” provided by dialysis facilities.

KCP also has concerns about the impact of “check-box” measures such as this one, as well as the lack of a specific tool for ESRD and effective interventions. Specifically with regard to the latter, limited data exist on the pharmacotherapeutic treatment of depression in patients with ESRD, and even less data to support the role of cognitive behavioral therapy and social support group interventions.<sup>17</sup> Prior to implementing such a measure in the dialysis facility setting, KCP believes that larger randomized, controlled clinical trials aimed at the treatment of depression in

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<sup>16</sup> Weisbord, SD, Mor, MK, Sevvick MA, et al. Associations of Depressive Symptoms and Pain with Dialysis Adherence, Health Resource Utilization, and Mortality in Patients Receiving Chronic Hemodialysis. *CJASN*. 2014; published ahead of print July 31, 2014.

<sup>17</sup> Kimmel P, Cohen S, Peterson R. Depression in patients with chronic renal disease: where are we going? *J Ren Nutr*. 2008;18(1):99-103.



patients with ESRD are needed.<sup>18</sup> A study in the general population that implemented a more aggressive strategy to improve recognition and therapy of depression found increased use of antidepressants without clinical improvement of depression.<sup>19</sup>

Finally, we note that the KDQOL, required by the Conditions for Coverage, includes a mental health assessment component. We believe that dialysis facility social workers are already attuned to the need for assessing patients for depression. Combined with the required use of KDQOL, KCP member facilities suggest that depression assessment already occurs to a significant degree within dialysis facilities.

***E. KCP does not support use of the measure Pain Assessment and Follow-up, based on NQF 0420, as a reporting measure for PY 2018.***

KCP recognizes that pain assessment should be part of the evaluation of every patient, however KCP does not support incorporating the measure *Pain Assessment and Follow-up* as a reporting measure for PY 2018.

First, we note that the proposed measure upon which this was based (NQF #0420) was endorsed as a clinician-level measure; we believe it is not appropriate for use in dialysis facilities. Pain is a particularly complex issue in the dialysis setting, in which chronic and acute pain oftentimes coexist. While the dialysis facility must respond immediately to pain related to the dialysis procedure itself, the measure does not address this issue. Rather, the measure focuses on the strict monitoring by the dialysis facility of broader pain management regimens that can only be appropriately addressed by the physician; KCP believes that chronic pain must be addressed by the physician and that use of this measure at the facility level is inappropriate, as reflected by NQF's endorsement of this measure at the clinician level. Further, KCP is perplexed by the application of a generic pain management measure given that there's not significant pain associated with dialysis treatment—and, again, any acute pain related to the dialysis procedure is and must be responded to immediately.

KCP also has concerns about the impact of “check-box” measures such as this one, as well as the lack of a validated tool for ESRD. KCP believes that until a dialysis-specific measure has been developed and tested, any pain assessment

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<sup>18</sup> Weisbord, SD, Mor, MK, Sevvick MA, et al. Associations of Depressive Symptoms and Pain with Dialysis Adherence, Health Resource Utilization, and Mortality in Patients Receiving Chronic Hemodialysis. *CJASN*. 2014; published ahead of print July 31, 2014.

<sup>19</sup>Kravitz, R.L, Franks, P., et al., “Patient Engagement Programs for Recognition and Initial Treatment of Depression in Primary Care: A Randomized Trial” 310 JAMA 1818-28 (2013).

measure is most appropriate through an internal quality improvement approach, but not for the QIP.

***F. KCP supports in principle the measure NHSN Healthcare Personnel Influenza Vaccination, based on NQF 0431, as a reporting measure for PY 2018, but has concerns about the specifications as presented and believes they should be modified before implementation including specific provisions for batch data transmission.***

KCP believes that influenza vaccination of health care personnel, the focus of this measure, is an important public health concept. KCP supports including *NHSN Healthcare Personnel Influenza Vaccination* as a reporting measure for PY 2018 if the specifications can be modified before implementation. We support eliminating the requirement for written documentation, but have concerns about implementation and feasibility of the requirements related to the third part of the denominator—i.e., adult students/trainees and volunteers. Facilities often have such individuals on a very short-term basis and to document influenza vaccination status would be difficult to capture, highly burdensome, and divert resources from clinical care.

Additionally, KCP notes that batch submission to NHSN for this measure is currently not feasible. KCP believes the lack of this approach is problematic.

**VIII. KCP opposes the proposed methodological changes for PY 2018 and recommends modifications to the assignment of weights and small sample size adjustor.**

KCP continues to believe that CMS should maintain a consistent payment methodology from year to year of the QIP. We agree that it is important to recognize change in quality performance and to drive for continued improvement. That goal is best accomplished through the addition of new measures, modifications to the weights assigned to measures, and updating benchmarks and thresholds. We also offer recommendations related to assigning weights for measure sub-domains and individual measures, as well as an alternative to addressing the problems with the small sample size adjustment.

- A. CMS should adopt the second of the two options it presents for the PY 2018 QIP scoring. KCP opposes the adoption of the first option until CMS has had more time to develop the model and ensure it will achieve the goals of the QIP and not be unduly disruptive to payments under the program.**

In the proposed rule, CMS offers two options for scoring for PY 2018 and beyond.

- The first scoring option<sup>20</sup> would group the measures into new sub-domains and apply new weighting criteria at the sub-domain and measure level (see Issue 2, below). CMS would first score a facility on its clinical measure performance, and then subtract points for non-compliance or partial compliance with the reporting measures. For purposes of this comment letter, we refer to this method as “Option 1.”
- The alternative scoring option<sup>21</sup> would be to retain the existing scoring methodology (with the addition of new measures), and weight the clinical measures at 90 percent and the reporting measures at 10 percent of the total score. For purposes of this comment letter, we refer to this method as “Option 2.”

CMS has asked for comment on which method is preferred. We strongly prefer Option 2 (in which the clinical and reporting measures are weighted 90 percent and 10 percent respectively), for the reasons explained below.

**Disruption to Payment Mix.** In the Proposed Rule, CMS includes a table that estimates the distribution of the QIP payment reductions under Option 1 compared to PY 2016. The table is reproduced below.

Payment Reduction	PY 2016		PY 2018, Proposed	
	Number of Facilities	Percent	Number of Facilities	Percent
0.0%	4828	79.4%	4606	75.7%
0.5%	884	14.5%	739	12.2%
1.0%	242	4.0%	306	5.0%
1.5%	69	1.1%	108	1.8%
2.0%	59	1.0%	323	5.3%

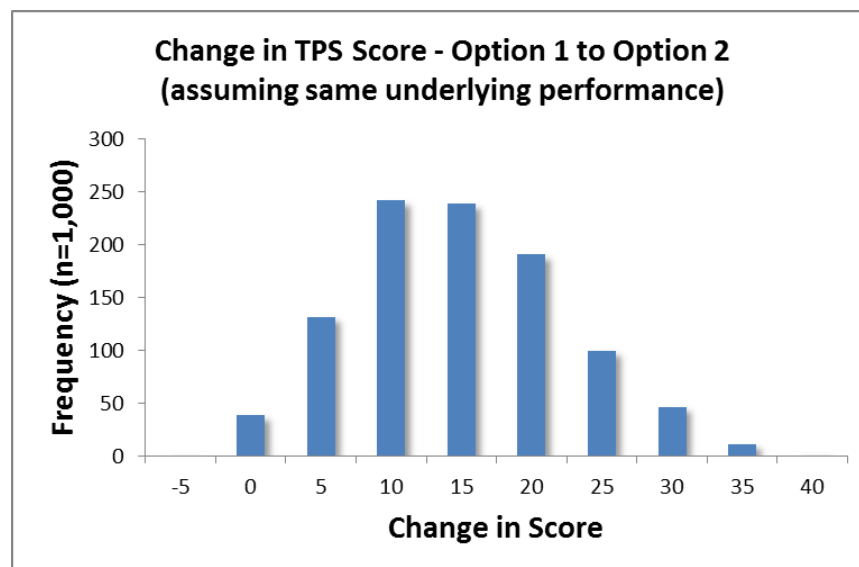
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<sup>20</sup>Display copy at 198-208.

<sup>21</sup>*Id.* at 208-209.

There is a five-fold increase in the number of facilities who would receive the full 2 percent reduction under the proposed 2018 methodology. The weighted average payment reduction under the proposed Option 1 method for PY 2018 is .24 percent, compared to a weighted average reduction of .15 percent under the PY 2016 model. These are very substantial changes in the payment reductions under the QIP. Such changes should not occur as a by-product (intentional or not) of a new scoring model.

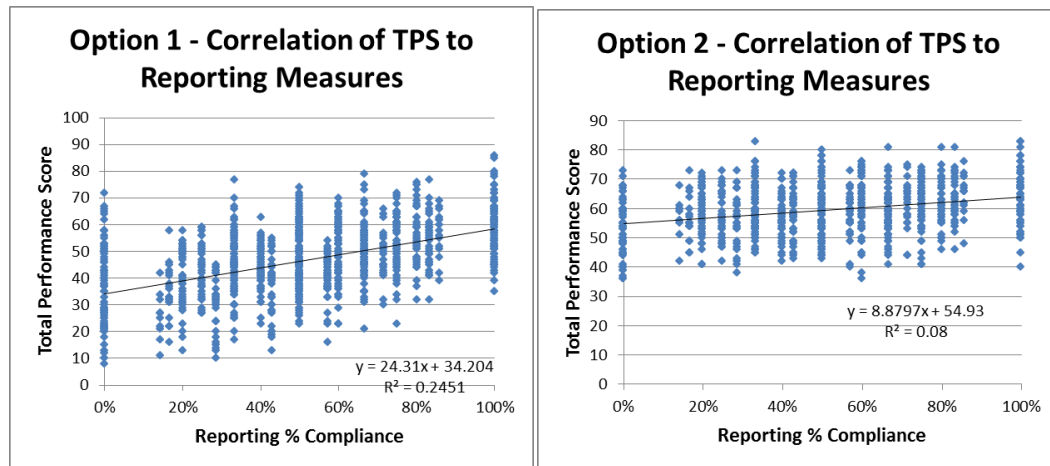
**Disruption to Score Distribution.** To compare Option 1 to Option 2, we built a model in which we compared the Total Performance Score (TPS) for a facility under the two models, given the same set of performance inputs. We then ran a simulation of 1,000 facilities to assess how much, on average, the Option 1 model might alter the TPS compared to Option 2. Our results suggest that there is significant volatility associated with the implementation of Option 1. Given the same set of performance inputs for the clinical and reporting measures, a facility might see its TPS score reduced by as many as 39 points under Option 1 compared to Option 2. However, the maximum observed increase in a score from Option 1 to Option 2 is only 6 points. Overall, the average TPS score decrease under Option 1 (when compared to Option 2) is 8 points (which helps to explain why the overall payment reduction distribution would shift down). The graph below illustrates, in our simulation of 1,000 facilities, the range of changes to Total Performance Score that results from using Option 2 vs. Option 1. (A positive value means that a facility scores higher under Option 2.)



What this analysis shows is that, given equal performance on the QIP measures, most ESRD facilities would see a reduction in their TPS, making trends in the TPS over time less meaningful. Again, this is very substantial change in the QIP,

and should not be made unintentionally as a by-product of changing the scoring model.

**Overemphasis on the Reporting Measures.** Options 2 suggests that CMS is aiming for a 90/10 split in the relative importance of the clinical and reporting measures. Whether Option 1 hits this target is hard to estimate, since in Option 1 the calculation and point deduction for the reporting measures is separate, and is not assigned a weight that is directly comparable to the weight of the clinical measures. However, our simulation suggests that the proposed Option 1 methodology (which subtracts points for reporting after calculating the clinical score) is much more sensitive to reporting measure performance than Option 2 (which has a defined 90/10 weighting split between clinical and reporting measures). In the graphs below, each blue dot represents one facility in our simulation of 1,000 facilities. We compared their reporting measure performance to their overall TPS score.



The correlation of TPS is much stronger to the reporting measures under option 1 (r-squared = .25) compared to Option 2 (r-squared = .08). In other words, in Option 1 the reporting measures account for 25 percent of the variation in the TPS. This 75/25 split of relative weight between clinical and reporting measures does not seem intentional, and KCP believe more emphasis on the clinical measures is appropriate.

**Option 1 adds complexity without adding value.** Option 1 adds significant complexity to the scoring algorithm for the QIP, especially for clinical and administrative staff who are familiar with the current QIP rules (which are similar to Option 2).

CMS offers the following rationale for Option 1: “we do not believe that the current scoring methodology provides the program with enough flexibility to strengthen incentives for quality improvement in areas where quality gaps continue

to exist.” However, our analysis shows that Option 1 would actually decrease emphasis on clinical performance.

We believe that the current scoring methodology does provide a framework in which CMS can emphasize quality improvement and align the QIP with overall health system goals. By adjusting the relative weights of the clinical and reporting measure categories, and of the individual weights within those categories, CMS can use the Option 2 scoring model to signal its priorities and expectations for ESRD facility performance.

***B. CMS should adopt more detailed criteria for assigning weights to measure sub-domains and individual measures, including adding criteria for strength of evidence and opportunity for improvement.***

In previous QIP Payment Years, the weights assigned to the various measures have been somewhat arbitrary, assigned equally to all measures within a topic area, without regard to clinical impact or experience with the measure. The result was that single measures could potentially have an impact on QIP results out proportion to their clinical relevance. KCP has argued for a more refined approach to weighting the measures.

In the current Proposed Rule, CMS proposes new criteria for assigning weights to the measures. The new proposed criteria (which apply both to the “subdomain” and the measure level) are: “(1) the number of measures and measure topics in a proposed subdomain; (2) how much experience facilities have had with the measures and measure topics in a proposed subdomain; and (3) how well the measures align with CMS’s highest priorities for quality improvement for patients with ESRD.”

KCP supports these proposed criteria. However, we suggest there are additional criteria that would help to better align the QIP with clinical priorities and performance improvement. These additional weighting criteria, which have been used in other quality improvement programs to generate composite measures of performance, include:

- **Strength of Evidence.** The extent to which a measure is supported by either clinical or epidemiological studies or theoretical rationale, especially related to the connection between the measure and patient outcomes. Endorsement by the National Quality Forum could factor into this criterion.
- **Opportunity for Improvement.** The actual variation between excellent and poor performers on a measure. The coefficient of variation (Standard Deviation / Mean) is one method to measure such variation, and could be

used to adjust the relative weights of measures. Using such a weighting criterion would have the advantage of reducing weight gradually as measures become more topped-out, making the decision to retire such measures less disruptive to overall scores.

- **Clinical Significance.** This criterion could add detail those suggested in the proposed rule. Clinical significance could be defined as both the number of patients affected by measure compliance, and the impact that measure compliance has on patient outcomes (i.e., measures that have a strong impact on patient morbidity/mortality would have a higher weight). Measures that significantly affect outcomes for large numbers of patients (i.e., measure with relatively large denominators) would also receive a higher weight. This is similar to the third criterion proposed by CMS, but could help to better define what CMS means by “clinical priorities.”

In summary, KCP supports the adoption of more defined criteria to determine measure weights, and we think CMS can improve on the criteria included in the proposed rule. We note that such criteria could be implemented with the “Option 2” scoring method,<sup>22</sup> which is KCP’s preference.

***C. CMS Should Increase the Minimum Sample Size to 26 to Address Problems with the Random Effect Created by the Current Small Numbers Adjustment***

KCP recommends that CMS adopt a minimum sample size of 26 patients for reporting and exclude the small numbers adjustment. Using sample sizes as small as 11 is inconsistent with measurement best practice, and exposes the QIP results to random results that are not fully compensated by the small sample size adjustment.

We note that one of CMS’s goals for the ESRD QIP is to align with the National Quality Strategy. Principle 6 of the NQS states that “National standards for health care quality and consistent approaches to measuring quality are essential components of the National Quality Strategy.” [our emphasis] We do not believe that including small sample sizes and trying to then compensate for their inevitable random effects – a process which is, to our knowledge, unique to the QIP – is consistent with the goals of the NQS, and we urge CMS to raise the minimum sample size.

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<sup>22</sup>*Id.* at 208-209 (description of Option 2).

While the small sample size adjustment is intended to mitigate the impact of random variation, it is itself subject to random effects. KCP has replicated the small sample size adjustment for all the clinical measures for which CMS has released the necessary standard error values. Our analysis finds that the small sample size adjustment has “choppy” results, with some facilities getting a positive adjustment, and other very similar facilities receiving no adjustment. The table at right illustrates these results for the Adult

Sensitivity Analysis: Achievement Scores With and Without Small Sample Adj													
Adult PD - Effect of Sample Size Adj													
		"Missed" Patients											
		0	1	2	3	4	5	6	7	8	9	10	11
Sample Size	11	0	2	2	2	1	0	0	0	0	0	0	0
	12	0	2	1	1	2	0	0	0	0	0	0	0
	13	0	1	1	1	1	0	0	0	0	0	0	0
	14	0	1	2	1	1	0	0	0	0	0	0	0
	15	0	1	1	1	1	1	0	0	0	0	0	0
	16	0	1	1	1	1	1	0	0	0	0	0	0
	17	0	1	1	1	1	1	0	0	0	0	0	0
	18	0	1	0	0	1	1	1	0	0	0	0	0
	19	0	1	0	1	1	1	0	0	0	0	0	0
	20	0	0	0	1	0	0	1	0	0	0	0	0
	21	0	0	0	1	0	1	0	1	0	0	0	0
	22	0	0	1	0	0	0	0	0	0	0	0	0
	23	0	0	1	0	1	0	0	0	0	0	0	0
	24	0	0	1	0	0	0	0	0	0	0	0	0
	25	0	0	0	0	0	0	0	0	0	0	0	0

Peritoneal Dialysis Adequacy measure. A facility with 18 adult patients and which misses the PD measure for 3 patients would receive no adjustment to its QIP score. However, a facility with 17 patients that misses compliance for 3 would get a positive adjustment of point, as would a facility with 19 patients and 3 missed. In other words, a facility with 18 cases would be unlucky and get no adjustment, but one more or one fewer patient and the facility would get an adjustment. This result does not seem reasonable or intended. KCP’s analysis shows similar results across all the QIP measures (we can share the full analysis with CMS on request).

Our analysis further shows that these results are due to rounding a facility’s QIP score before applying the small sample size adjustment. Therefore, a method to smooth the results is to round the facility’s QIP score after applying the adjustment. This method would result in the distribution of small sample size adjustments illustrated in the chart below. (Again, KCP has performed analysis for all the QIP measures and found similar results.)



WITH SMOOTHING													
Adult PD Measure - Effect of Sample Size Adj													
Sample Size	"Missed" Patients												
	0	1	2	3	4	5	6	7	8	9	10	11	
	11	0	2	2	2	0	0	0	0	0	0	0	0
	12	0	2	2	2	1	0	0	0	0	0	0	0
	13	0	2	1	1	1	0	0	0	0	0	0	0
	14	0	2	1	1	1	0	0	0	0	0	0	0
	15	0	1	1	1	1	0	0	0	0	0	0	0
	16	0	1	1	1	1	1	0	0	0	0	0	0
	17	0	1	1	1	1	1	0	0	0	0	0	0
	18	0	1	1	1	1	1	0	0	0	0	0	0
	19	0	1	1	1	1	1	0	0	0	0	0	0
	20	0	1	1	1	1	1	1	0	0	0	0	0
	21	0	1	0	0	0	0	0	0	0	0	0	0
	22	0	1	0	0	0	0	0	0	0	0	0	0
	23	0	1	0	0	0	0	0	0	0	0	0	0
	24	0	0	0	0	0	0	0	0	0	0	0	0
	25	0	0	0	0	0	0	0	0	0	0	0	0

## IX. Stratifying ESRD QIP Measures for Dual-Eligible Beneficiaries

KCP notes that the Agency seeks comments on the feasibility and advisability of stratifying ESRD QIP measures based on whether the beneficiaries are Medicare-Medicaid status—*i.e.*, specifically whether stratification of dual-eligible beneficiaries should be reported publicly and/or if/how this should be incorporated into the scoring methodology. We believe that stratifying measures is an interesting idea that should be explored. However, we recognize that this is a highly complex, nuanced matter and strongly encourage the Agency to actively engage in dialogue with the community as it considers stratification (for either public reporting or payment) based on dual eligibility status.

## X. Conclusion

KCP appreciates the opportunity to provide comments on the ESRD QIP Proposed Rule. We look forward to working with CMS to resolve our concerns. Please do not hesitate to contact Kathy Lester at 202-534-1773 or at [klester@lesterhealthlaw.com](mailto:klester@lesterhealthlaw.com) if you have any questions.

Sincerely,



Edward R. Jones, M.D.  
Chairman  
Kidney Care Partners

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