KIDNEY CARE PARTNERS

August 8, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Acting Administrator Slavitt:

Kidney Care Partners (KCP) appreciates the opportunity to provide comments on the "End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model Proposed Rule" (Proposed Rule). This letter addresses the proposals related to the ESRD QIP for Payment Years (PY) 2018-2020. We have provided our comments on the ESRD Prospective Payment Program in a separate letter.

In sum, KCP:

- Recommends that CMS work with the kidney care community to implement MedPAC's recommendation that CMS quality programs focus on fewer measures that matter more to improving patient outcomes.

- For PY 2018

    - Asks that CMS to adopt consistent criteria for establishment of the minimum data requirements and range for the Small Facility Adjuster, especially for the standardized ratio measures. We recommend that CMS set the minimum data requirement for each measure at the sample size at which the IUR reaches 0.70;

    - Asks CMS to adopt the NQF modifications to the Hypercalcemia measure and to prioritize identifying a more appropriate measure to meet the statutory requirement;

- Reiterates recommendations to adopt consistent exclusions across measures; and

- Continues to support the ICH CAHPS Measure as a Reporting Measure and reiterates our recommendation to modify the measure before it shifts to a clinical measure.

- For PY 2019

  - Remains deeply concerned that CMS would include a measure (the expanded NHSN BSI Measure) in the ESRD QIP that has been shown not to be valid;

  - Remains concerned about the use of the pooled adequacy of dialysis measure and recommends that CMS return to the previous measures for PY 2019 and future years or develop a true composite measure;

  - Continues to support the performance standards, achievement thresholds, benchmarks, and payment reductions;

  - Recommends that CMS not create the Proposed Safety Measure Domain and, therefore, recommends against modifying the total performance score and weighting recommendations associated with it; and

  - Remains concerned about the continuation of the two data validation studies.

- For PY 2020

  - Reiterates our recommendations regarding the continuation of certain measures for PY 2020;

  - Supports replacing the Mineral Metabolism Measure with the Serum Phosphorous Reporting Measure;

  - Would like to support the Standardized Hospitalization Ratio in the ESRD QIP, but cannot until its reliability has been demonstrated;

- Continues to support the inclusion of the NQF-endorsed measure *2701: Avoidance of Utilization of High Ultrafiltration Rate (≥13 ml/kg/hour)* as reviewed by NQF;

- Continues to support the inclusion of the NHSN Healthcare Personnel Influenza Vaccination Measure as a reporting measure;

- Supports setting the performance period at CY 2018, but asks that CMS align the performance period for the NHSN Healthcare Personnel Influenza Vaccination Reporting Measure with clinical and federal guidelines;

- Supports continued use of the current policies for setting the performance standards, achievement thresholds, and benchmarks, and scoring; and

- Continues to support the criteria for determining weights, with a few modifications, but remains concerned that too many measures in the ESRD QIP dilute the value of all measures.

- Recommends that CMS ensure that the ESRD QIP does not create unnecessary barriers to patient access to home dialysis.

- For Future Questions

  - Urges CMS to adopt rates to replace the standardized ratio measures with standardized rate measures for hospitalization and transfusion;

  - Supports the adoption of NQF #0226, *Influenza Immunization in the ESRD Population*, in a future payment year;

  - Recommends working with the kidney care community to address concerns about the current Standardized Mortality Ratio (SMR) measure's inclusion in the ESRD QIP;

  - Acknowledges the importance of promoting transplant options for individuals with kidney failure, but indicates that more work needs to be done before a transplant measure can be added to the ESRD QIP;

- Suggests that it is too early to determine whether an Emergency Department Measure would be appropriate to add to the ESRD QIP;

- Supports NQF #2988 *Medication Reconciliation for Patients Receiving Care at Dialysis Facilities.*

I. KCP recommends that CMS work with the kidney care community to implement MedPAC's recommendation that CMS quality programs focus on fewer measures that matter more to improving patient outcomes.

In the past, KCP has recommended that CMS adopt an ESRD-specific strategic vision based upon the Triple Aim and its quality goals. As we look toward future years of the ESRD QIP, it has become apparent that more and more measures are being added to the program with no measures being retired. MedPAC and other thought leaders have raised concerns about diluting the impact of quality programs, especially value-based purchasing programs, by incorporating too many measures.

The dilution in the ESRD space can be seen by simply looking at the chart below.

	Measure Weight as Percent of TPS PY 2018	Measure Weight as Percent of TPS PY 2019	Measure Weight as Percent of TPS PY 2020
Clinical Measures			
Adult Hemodialysis Adequacy	4.1%	14.3%	14.4%
Adult Peritoneal Dialysis Adequacy	4.1%		
Pediatric Hemodialysis Adequacy	4.1%		
Pediatric Peritoneal Dialysis Adequacy	4.1%		
VAT - Catheter	8.1%	7.1%	7.2%
VAT - Fistula	8.1%	7.1%	7.2%
Hypercalcemia	6.3%	6.0%	1.6%
STrR	6.3%	9.0%	8.8%
SRR	9.0%	12.0%	12.0%
ICH CAHPS	18.0%	19.5%	20.0%
(Clin/Safety Domain) NHSN Bloodstream Infection	18.0%	9.0%	6.0%
(Safety Domain) NHSN Dialysis Event		6.0%	4.0%
SHR			8.8%

Critically important clinical measures, such as reducing catheters, are competing for percentage points with other measures that have less clinical significance to patients. The preamble indicates that CMS too would prioritize measures that track important patient outcomes.[1] Yet, the sheer number of measures and continued proposals to add more measures to the ESRD QIP, dilute these important measures inappropriately.

Specifically, MedPAC has recommended that "[t]he set of measures should be small to minimize the administrative burden on providers and CMS."[2] MedPAC also noted that the current trajectory of value-based purchasing programs:

> creates an incentive for providers to focus resources on the exact care processes being measured, whether or not those processes address the most pressing quality concerns for that provider. As a result, providers have fewer resources available for crafting their own ways to improve the outcomes of care, such as reducing avoidable hospital admissions, emergency department visits, and readmissions and improving patients' experience of care.[3]

KCP encourages CMS to pause its current measure development efforts and instead engage with the entire kidney care community, not simply a small group of hand-selected TEP members, to identify a small set of core measures that matter. This work could identify measures that could be retired as well. KCP was one of the first organizations to embrace value-based purchasing because of the promise it held for rewarding high performers and empowering those who needed help with better tools to improve. The ESRD QIP has been successful in many ways in its efforts to achieve those original goals. Yet, it runs the risk of not longer being able to achieve them if we do not take the time to heed MedPAC's warnings and work together to create system where the measures included in the ESRD QIP are measures that matter.

II. For Payment Year 2018

A. KCP asks that CMS to adopt consistent criteria for establishment of the minimum data requirements and range for the Small Facility Adjuster, especially for the standardized ratio measures. We recommend that CMS set the minimum data requirement for each measure at the sample size at which the IUR reaches 0.70.

The Proposed Rule provides for the use of the Small Facility Adjuster (SFA) for the various QIP measures, including the standardized ratio measures. The

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[1]Proposed Rule Display Copy 99.
[2]MedPAC, *Report to the Congress*, "Chapter 3: Measuring Quality of Care in Medicare" 41 (June 2014).
[3]*Id.*

purpose of the SFA is to mitigate the risk that small facilities will be penalized by random volatility in their measure results. KCP understands this goal, and CMS' overall goal to include as many facilities in the QIP, even those with small sample sizes. However, we remain concerned (as we have expressed in previous rule-making cycles) that the inclusion of very small sample sizes means that results for many facilities will be driven more by luck than by actual performance. This is particularly exacerbated for the standardized ratio measures.

In particular, we are concerned about the sample size requirements for the standardized ratio measures. For the standardized ratio measures, CMS proposes the following thresholds for reporting and ranges for the small facility adjustment.

Measure	Minimum Data Requirements	Small Facility Adjuster
SRR	**11 index discharges**	**11 – 41 index discharges**
STrR	**10 patient-years at risk**	**10 – 21 patient-years at risk**
SHR	**5 patient-years at risk**	**5-14 patient-years at risk**

The Proposed Rule offers no rationale for these values, nor does it comport with the unit of analysis that CMS submitted to NQF. NQF considered patients as the unit of analysis for reliability testing; CMS is now proposing the use patient-years at risk for the unit of analysis in the QIP. This lack of transparency is of significant concern, as it undermines our ability to assess the proposed use of the measures. KCP believes that the values are too low, and will result in random volatility that the Small Facility Adjuster, as proposed, cannot fully offset.

For example, consider the Standardized Transfusion Ratio measure. When the STrR measure was considered for NQF endorsement, it was found to have very low reliability, especially for small facilities. The inter-unit reliability[4] (IUR) for facilities with sample sizes below 46 patients was about 0.4, suggesting that 60 percent of inter-facility difference was due to random noise and not underlying performance. IURs increase as a function of sample size. Therefore, smaller samples would be associated with lower IURs. Based on the NQF documentation, one would expect the vast majority of STrR variation to be due to random variation across the 10-21 patient-years at risk that CMS has proposed for the small facility adjustment for STrR. All the small facility adjustment does is raise the scores for small facilities, but it would not adequately offset the substantial effect of random variation for small sample sizes.

[4] From the NQF Measure Worksheet for STrR: A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by random noise, indicating the measure would not be a good characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real difference between facilities.

We urge CMS to adopt consistent criteria for establishment of the minimum data requirements and range for the SFA, especially for the standardized ratio measures. We recommend that CMS set the minimum data requirement for each measure at the sample size at which the IUR reaches 0.70, the value commonly used at NQF, as further noted in Adams.[5] That is, the minimum sample size would be set at the point where at least 70 percent of the observed result would be driven by actual performance. Anything below that means that too high a proportion of the observed result is simply chance. If CMS opts not to adopt this convention, we recommend that the top end of the SFA range be set at a sample adequate to achieve an IUR of 0.7. At that point, enough of the observed result is likely due to actual performance.

For discussion purposes **only**, we illustrate how adopting an IUR of 0.5 and then a subsequent SFA reliability threshold that yields an IUR of 0.7 would at least result in a more fair and meaningful representation of quality for small facilities. Based on the NQF documentation for the STrR measure, for example, we estimate that the minimum sample size required to achieve an IUR of 0.5 is about 50 patient-years.[6] We would further estimate that a sample size of about 75 patient-years would be required to achieve an SFA of 0.7. Under these parameters, the Minimum Data Requirement for the STrR measure would be 50 patient-years at risk and the SFA range would be 50-75 patient-years at risk. Again, we emphasize this is offered only as an example: We are not advocating that an initial IUR of 0.5 be used based on facility size.

CMS should apply similar logic to the SRR and SHR measures to determine the Minimum Data Requirement and SFA range. For illustrative purposes, the NQF documentation for SHR suggests a sample of about 200 patients to achieve an IUR of 0.5 and a sample of about 300 to achieve an IUR of 0.7. However, we again note that in its submission to NQF, CMS expresses these results as a function of the number of patients in a facility while CMS now proposes to set the values for the QIP using patient-years at risk. Finally, for SRR, CMS presented reliability data to NQF for which even for large facilities with >121 patients, the IUR was only 0.61. For SRR implementation, CMA proposes an adjuster of 11-41 index discharges, but this structure is even less transparent and makes it impossible to estimate an appropriate SFA range.

In summary, we urge CMS to adopt clear and transparent criteria for measure reliability to set the range for the Minimum Data Requirements and the SFA, and to update the SFA ranges for the standardized ratio measures accordingly.

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[5] J.L. Adams, "The reliability of provider profiling: A tutorial." *RAND Health* (2009).

[6] The NQF documentation only provides IUR figures for ranges of sample sizes, so we cannot calculate a precise sample size threshold for a .5 IUR.

B. KCP asks CMS to adopt the NQF modifications to the Hypercalcemia measure and to prioritize identifying a more appropriate measure to meet the statutory requirement.

In previous comment letters, KCP has raised concerns and indicated that this metric is not the best measure in the bone mineral metabolism domain to impact patient outcomes. Additionally, the National Quality Forum (NQF) has concluded that the hypercalcemia measure is topped out and placed the measure in Reserve Status because of high facility performance and minimal room for improvement. Similarly, the Measure Applications Partnership (MAP) did not support the measure in its 2016 report.

We understand that the Agency must comply with the Protecting Access to Medicare Act (PAMA). To this end, we encourage CMS to work closely with KCP and the kidney care community to identify a more appropriate measure to meet the statutory requirement. To the extent CMS maintains the hypercalcemia measure for PYs 2017-2020, we appreciate that the specifications note that plasma is an acceptable alternative substrate to serum, as recommended by KCP. Lastly, we note the exclusion "patients without at least one uncorrected serum calcium value at that facility during the 3-month study period" is present for PYs 2017 and 2019, but absent in the specifications for PYs 2018 and 2020; the latter two should be corrected to incorporate the exclusion.

C. KCP reiterates recommendations to adopt consistent exclusions across measures.

As we have noted previously, the issue of including or excluding patients from a particular measure is a critical one. Based on our experience as measure developers, we understand that many of these decisions should be made on an individual measure level, but 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. 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 recommends that CMS adopt the following global exclusions:

- Beneficiaries who die within the applicable month;
- Beneficiaries who receive fewer than 7 treatments in a month;
- 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;[7]

[7] *See, e.g.,* NQF #0255 Measurement of Serum Phosphorus Concentration (denominator exclusions include transient dialysis patients, pediatric patients, and kidney transplant recipients with a functioning graft).

- 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 that was used when the URR measure was in place, which is that the patient must have at least four eligible claim months to count towards the adequacy domain.

D. KCP continues to support the ICH CAHPS Measure as a Reporting Measure and reiterates our recommendation to modify the measure before it shifts to a clinical measure.

KCP agrees that it is critically important to evaluate patients' experiences when receiving dialysis and continues to support including the ICH CAHPS measure in the ESRD QIP. However, it is important for CMS to provide a specific list of the exclusions, and we recommend that CMS exclude homeless patients as well. We also appreciate CMS' willingness to consider expanding the ICH CAHPS survey to include peritoneal dialysis and home hemodialysis patients in future rulemaking.

KCP also reiterates that before shifting the ICH CAHPS survey to a clinical measure CMS should modify the measure to address concerns about the burden on patients and to align the specifications with those that AHRQ relied on when it tested the measure, as well as to ensure the accuracy of its fielding.

We would like to work with CMS to identify ways to address the burden and cost issues associated with administering the survey. In previous letters, we have raised concerns about patients being unable to finish the complete survey because of its length and recommended that CMS divide it into the three sections that were independently tested. Given that the Agency has not yet made this modification, we ask that CMS work with us and the patient organizations to find another alternative that promotes the completion of the survey by patients. Similarly, we have raised concerns about the requirement to administer the survey twice each year. We would like to better understand why administering the survey once each year is inadequate. In fact, the American Institutes for Research/RAND *et al.* have described in detail the difficulties in translating the results from ICH CAHPS into interventions resulting in meaningful improvement when administered more frequently than once a year.[8] We also recommend that CMS coordinate with the Networks to reduce duplication in its administration.

We also recommend that CMS ensure the accuracy of the administration of the survey. First, it is critically important to have a mechanism, which does not

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

appear to exist currently, for facilities to ensure that patients' contact information is as accurate and up-to-date as possible. Because response rates necessarily depend on accurate contact information, we recommend inclusion of 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. Similarly, CMS should review the lingual translations of the surveys to ensure that they are accurate. Several translation errors have been reported to us, and the Agency has a responsibility to ensure that the information gleaned from all foreign-language speakers is accurate and meaningful.

KCP urges CMS to adopt these recommendations to make the ICH CAHPS measure more effective and meaningful.

III. For Payment Year 2019

A. Measures

1. KCP remains deeply concerned that CMS would include a measure (the expanded NHSN BSI Measure) in the ESRD QIP that has been shown not to be valid.

As noted in our 2014 and 2015 comment letters, KCP recognizes the vital importance of reducing infections and strongly supports efforts to do so. Measures in this area have the potential to improve patient outcomes and reduce other medical costs related to treating infections. However, we are troubled by the proposal to retain the NHSN BSI Measure as a clinical measure, add the NHSN Dialysis Event Reporting Measure, and create a Safety Domain in an attempt to address the problem created by the fact that the NHSN BSI measure is not valid, as shown by the measure developer, CDC's *et al.* own research, and CMS's own data. Rather than try to jerry rig a solution, we recommend that CMS invest the time and address the problems that it has identified in the NHSN BSI measure so that it would be a valid measure. KCP would support the use of this measure, once its validity and reliability have been established. As an interim step, it may be appropriate to include the NHSN BSI measure as a reporting measure, as we have suggested in previous letters given the clinical important of monitoring bloodstream infections.

In the preamble, CMS has states that its review of the shows that as many as 60-80 percent of dialysis events may be under-reported with the NHSN BSI measure.[9] This high under-reporting rate demonstrates that the measure is simply not valid. A lack of validity means that we cannot be certain that the measure results in accurate findings. Making sure that measures are valid in the context of public reporting and value-based purchasing is essential to the success of these

[9]Proposed Rule Display Copy 90.

programs. Providers are being incentivized to change their behavior to improve the results of the measure. If the measure is not valid, these changes may not be appropriate to implement with patients. In addition, if the measure is not producing accurate findings, it does not help patients who are trying to use measures to make informed decisions about their care.

Two recent studies have examined why the high under-reporting rate may be occurring. Both found that the reasons lie with the design of the measure and how the data are reported. One study concludes:

> A significant contributor to underreporting to [Centers for Disease Control and Prevention's National Healthcare Safety Network Dialysis Event (NHSN DE) surveillance] appears to be BSI identified from blood cultures obtained in hospitals (at the start of a hospital admission) that are not systematically captured in NHSN DE. Underreporting might occur because hospitals cannot directly report events to NHSN DE. Instead, they are expected to communicate to dialysis facilities who report these cases. Challenges in communication between hospitals and dialysis facilities are well recognized. Another factor in underreporting was incomplete antibiotic susceptibility data in NHSN; most of the *S. aureus* BSI matches did not have susceptibility data reported. Potential reasons are that either susceptibility data were not communicated to dialysis facilities or available susceptibility data were not entered into NHSN.[10]

The second study reaches a similar conclusion:

> In summary, automated surveillance for BSI performed using EHR data from outpatient dialysis centers resulted in under-ascertainment of BSI cases, largely due to the exclusion of information on blood culture drawn on day 1 or 2 of hospitalization.[11]

Dialysis facilities cannot report what they do not have. This is a fundamental flaw with the measure that should be corrected to establish its validity.

A core principle of the KCP and the Kidney Care Quality Alliance is that for quality measures must "be reliable, valid, precise, based on sound scientific

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[10]Duc B. Nguyen, Isaac See, *et al.* "Completeness of Methicillin-Resistant Staphylococcus aureus Bloodstream Infection Reporting From Outpatient Hemodialysis Facilities to the National Healthcare Safety Network, 2013" 37 *Infect. Control Hosp. Epidemiol.* 205–207 (2016).
[11]Nicola D. Thompson, Matthew Wise, "Evaluation of Manual and Automated Bloodstream Infection Surveillance in Outpatient Dialysis Centers," 37 *Infect. Control Hosp. Epidemiol.* 1-3 (2016).

evidence, and predictive of overall quality performance."[12] The National Quality Forum (NQF) also maintains as one of its core criteria for evaluating measures for endorsement demonstrating the validity and reliability of a measure.[13] A measure should be validated before it is added to the QIP.

Therefore, we ask that CMS include the NHSN BSI measure as a reporting measure for PY 2018 and 2019 and in PY 2019 neither add the NHSN Dialysis Event Reporting Measure nor the Safety Measure Domain. As we understand the preamble, the only reason CMS proposes including the NHSN Dialysis Event Reporting Measure is to try to fix the under-reporting problem due to the lack of validity of the NHSN BSI measure. Thus, if the NHSN BSI measure is included as a reporting measure, the additional NHSN Dialysis Event Reporting Measure is unnecessary. As CMS points out in the preamble, the two measures use the same data, so they are redundant despite the different calculations. Then, without the NHSN Dialysis Event Reporting Measure, the new Safety Measure Domain is also unnecessary.

The proposal to try to address the lack of validity by adding the NHSN Dialysis Event Reporting measure is not sufficient to address the validation problem and inappropriately penalizes facilities. Under the NHSN Dialysis Event Reporting measure, a facility reporting 12 months of data would receive 10 points, a facility reporting 6 to 11 would receive 2 points, and a facility reporting 0 to 5 months would receive 0 points. Under this scoring methodology, missing one month of reporting, even if for an error with the NHSN software or other unforeseen issues, would result in a substantial loss of points. The Proposed Rule would weight the measure at 40 percent of the measure topic score, which is not appropriate. We are concerned that the interaction between the scoring methodology and the weighting percentage does not appropriately distinguish among facilities. Missing one month of reporting is not same as missing 5 months. As we have recommended in the past, we think a sliding scale would be more appropriate if CMS were to include this measure.

Our goal is to work with the Agency to ensure that the ESRD QIP include valid and reliable measures that are meaningful to providers and patients. Measures that do not meet the basic requirements of measure development and endorsement should not be included in the QIP as clinical measures.

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[12] *See* Kidney Care Quality Alliance, "Guiding Principles – Phase 2" *available at http://kidneycarepartners.com/media-center/attach/60-1.pdf.*

[13] NQF, "Review and Update of Guidance for Evaluating Evidence and Measure Testing" (Oct. 2013).

2. KCP remains concerned about the use of the pooled adequacy of dialysis measure and recommends that CMS return to the previous measures for PY 2019 and future years or develop a true composite measure.

KCP continues to support the use of the individual adequacy measures and would support a well-constructed composite of such measures. However, as we noted in our comments last year, the *Kt/V Dialysis Adequacy Measure* specifications that CMS finalized for PY 2019 and subsequent years show that the measure is a *pooled* measure. This means that all patients from the four dialysis populations (adult and pediatric peritoneal and hemodialysis) will be pooled into a single denominator and scores will be calculated as would be done for a single measure. For the reasons described below, KCP asks that CMS calculate scores for the four individual measures separately and then rolling up to a single score, as is done for composites.

We understand CMS's goal is to increase the inclusion of measure of pediatric dialysis adequacy because most facilities that care for pediatric patients do not meet the minimum sample size for their pediatric population. KCP questions, however, the clinical appropriateness of reporting on the quality of the two populations in a pooled measure. Given the small numbers contribution of pediatric patients to a pooled measure, we do not believe it is appropriate to draw conclusions about quality from one group (*i.e.*, the larger adult population) to quality for the pediatric population at that facility. Important differences in performance could be masked when all populations are combined into a single denominator.

Further, while the Measure Applications Partnership (MAP) conditionally supported the measure pending NQF endorsement, the NQF Renal Standing Committee has since reviewed the measure and is recommending *against* endorsement. We note that the MAP did not review the issue of pooling, as the measure was characterized as a composite. More importantly, the NQF Renal Standing Committee did not review or question the technical construction of the measure because it did not pass NQF's "Importance" criterion (*i.e.*, it failed on performance gap), a threshold requirement for further discussion on factors such as validity and reliability.

Additionally, in its recent review of the CMS dialysis adequacy measures, the NQF Renal Standing Committee recommended that the upper Kt/V threshold exclusions be removed from the measures' specifications due to insufficient evidence supporting the selected values (<5.0 for the hemodialysis and 8.5 for the peritoneal dialysis adequacy measures). CMS indicated that the parameters were incorporated into the specifications to exclude patients with spurious Kt/V values, but the NQF Committee noted that the handling of anomalous data is more appropriately addressed by measure implementation and operationalization

guidance; our understanding is that CMS stipulated to the recommended revisions, which permitted these measure to continue through the Committee's evaluation. We note that the proposed QIP dialysis adequacy measure specifications continue to include boundaries for Kt/V values. KCP agrees with the NQF Committee that the handling of anomalous data is an implementation issue and that the evidenced-based threshold should be the only value in the specifications.

B. Structural Issues

1. KCP continues to support the performance standards, achievement thresholds, benchmarks, and payment reductions.

KCP continues to support relying upon the same basic methodology year-over-year for the ESRD QIP. Thus, we support the continuation of the previous policy of setting the Performance Standard, Achievement Threshold, and Benchmark at the 50th, 15th and 90th percentile respectively in PY 2019. We also support the continuation of the current policy for determining payment reductions, including the process for setting the minimum Total Performance Score.

2. KCP recommends that CMS not create the Proposed Safety Measure Domain and, therefore, recommends against modifying the total performance score and weighting recommendations associated with it.

KCP reiterates our support for the Agency's criteria for weighting measures. We are also pleased that CMS identifies in the preamble that:

> one of our top priorities for improving the quality of care furnished to ESRD patients includes increasing the number and significance of both outcome and patient experience of care measures because these measures track important patient outcomes, instead of focusing on the implementation and achievement of clinical processes that may not result in improved health for patients.[14]

In light of this statement, we reiterate our suggestion that CMS include three additional criteria for determining weighting.

- **Strength of Evidence**. This criterion goes beyond the current CMS criteria by taking into account the extent to which a measure is supported by either suggestive clinical or epidemiological studies or theoretical rationale. Endorsement by the NQF could factor into this criterion. We believe that

[14]Proposed Rule Display Copy 99.

measures with stronger evidence should be weighted more than those with less.

- **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 variation. 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.** We recommend that CMS refine the term "clinical priorities" by clarifying that it focuses on the number of patients affected by measure compliance and the impact that measure compliance has on patient outcomes. Measures that significantly affect outcomes for large numbers of patients would receive a higher weight.

In applying these criteria, we urge CMS to work closely with the kidney care community, especially physicians and other health care professionals, in determining the clinical significance of potential measures. KCP would like to work with CMS to improve upon the current criteria to ensure that the weighting of measures reflects these aspects as well.

As noted above in the discussion of NHSN BSI measure, the lack of validity of the NHSN BSI measure demonstrated by CMS and independent researchers does not support its inclusion as a clinical measure. Therefore, we ask that CMS not finalize the Patient Safety Measure Domain at this time and retain the weight the NHSN BSI measure as part of the reporting measures until modifications can be made to the measure to ensure its validity and reliability.

C. KCP remains concerned about the continuation of the two data validation studies.

KCP remains concerned that CMS has not validated data collection through CROWNWeb or data collected via the NHSN Dialysis Event Module for the NHSN Bloodstream Infection Clinical Measure. We also remain concerned that the timeframes and penalties attached to these studies do not provide due process to dialysis facilities required to participate in them.

While we appreciate that CMS may wish to audit quality data submissions to ensure their accuracy at the individual facility level, the Proposed Rule for PY 2019 and previous preambles to proposed rules indicate that the effort is a "validation study" of CROWNWeb data submissions and the NHSN Bloodstream Infection Clinical Measure, not an audit. Given this description, KCP is concerned that CMS is conducting the study because (1) the yet-to-be-released validation study of

CROWNWeb showed the data collection tool is not reliable or valid and (2) the NHSN Bloodstream Infection Measure has not been appropriately validated.

Regarding the first, KCP has formally and informally requested the CROWNWeb validation study, including submitting a FOIA request, but so far CMS has not released this study. If CROWNWeb is not validated, then CMS should refrain from using it as part of the ESRD QIP until such validation has been established. Regarding the second, and as we have noted in previous letters with regard to the NHSN Bloodstream Infection Clinical Measure, validation testing should take place before a measure is incorporated into a quality program and participating facilities should not be penalized if the results of the study show the data submission process is not reliable and/or valid. As CMS notes in the preamble, there are serious questions about the validity of this measure: "our thorough review of data reported for the PY 2015 NHSN Dialysis Event Reporting Measure and results from the PY 2014 NHSN data validation feasibility study, suggest that as many as 60-80 percent of dialysis events are under-reported." A measure that is valid and reliable would not lead to such a high percentage of under-reported events. Thus, we reiterate our request that CMS first establish validity and reliability for this measure before it is incorporated in to the ESRD QIP and the Total Performance Score.

If, despite the label, CMS truly seeks to audit dialysis facilities to ensure their adherence to reporting the required data, it should provide appropriate due process that includes the right to appeal adverse decisions. In particular, we are disappointed that CMS has proposed to reduce the response period for the NHSN Bloodstream Infection Clinical Measure from 60 days, which applied in previous payment years, to 30 days for PY 2019. The preamble indicates that the reduced response time is to allow contractors to have more time to review the materials, yet there is no recognition that facilities may require more than 30 days to obtain the specific records requested. It would seem more appropriate to adjust the contractor's timeline, which is substantial when compared to that of the facilities, than to reduce the time facilities have to identify, locate, and transmit the number of positive blood cultures demanded by the contractor. As noted in previous comment letters, as well, KCP remains deeply troubled that the timeframe is inadequate and the penalty for failing to comply with it is disproportionately several when compared to the problem being identified. While this "study" is taking place, CMS should not reduce a facility's QIP total performance score since the purpose of the study is to assess future policies to ensure the accuracy of NHSN data.

KCP would welcome the opportunity to work with CMS to ensure the validity and reliability of the data being submitted, but these "validation studies" are not the appropriate way to address concerns the Agency might have. Therefore, we ask CMS to clearly state in the final rule the reason such studies are necessary and if the purpose is to audit facilities, CMS should provide appropriate due process.

IV. For Payment Year 2020

A. Measures

1. KCP reiterates our recommendations regarding the continuation of certain measures for PY 2020.

KCP reiterates our concerns about continuing to include some of the measures in the ESRD QIP as currently specified. We support the continued inclusion of the vascular access measures, but as noted in our discussion of weighting, suggest placing greater emphasis on removing catheters. As noted above, we recommend that CMS use a composite measure for dialysis adequacy rather than a pooled measure. We also request that CMS make the recommended modifications to the ICH CAHPS measure, which are described above as well. Our concerns about the hypercalcemia measure and NHSN BSI measure also apply for PY 2020.

KCP continues to have significant concerns about the inclusion of the Standardize Readmissions Ratio (SRR) and Standardized Transfusion Ratio (STrR) measures in the ESRD QIP. We are pleased that CMS has decided to evaluate the impact of these measures on access to care. We also recommend evaluating their effectiveness in measuring the actual care provided in dialysis facilities. Despite this positive step, the question of whether it is appropriate to include these measures in the ESRD QIP until the results of the study are known remains. If CMS is unclear about whether these measures will have a positive or negative impact on dialysis patients and the care they receive, the Agency should not use these measures until it has such clarity.

Most importantly, we reiterate that rather than continuing to add more measures to the ESRD QIP, CMS should focus on a few core measure that matter, as described in the first section of this letter.

2. KCP supports replacing the Mineral Metabolism Measure with the Serum Phosphorous Reporting Measure.

KCP supports replacing the Serum Phosphorus Reporting Measure for the Mineral Metabolism Reporting Measure. We note that, based on the information provided recently for NQF 0255, measurement in this area is topped out and so not the best indicator of quality. NQF 0255 is in Reserve Status because of high facility performance and minimal room for improvement. We understand the Agency must comply with the Protecting Access to Medicare Act (PAMA). To this end, we encourage CMS to work closely with the kidney care community to identify more appropriate measures to meet the statutory requirement.

KCP also notes that plasma as an acceptable substrate is absent from both the measure title and specifications, although it is mentioned in "Additional Information." To more clearly and accurately convey the measure specifications, we recommend the title be modified to clearly denote plasma is an acceptable substrate and that the specifications specifically note this, not just be described under "Additional Information."

Finally, we note the exclusions between the new Serum Phosphorus Reporting Measure and the Mineral Metabolism Reporting Measure differ. For example, the previous exclusion of "in-center HD patients treated at facility <7 times during the claim month" has been replaced with "transient dialysis patients (in unit <30 days)." A further exclusion expanding on this also is provided: "Patients not at the facility for the entire month ("Admit Date" > the first day of the month and "Discharge Date" < the last day of the month)." We do not disagree with the exclusions, but again recommend that CMS examine its measures and standardize the exclusions. Changing exclusions from iteration to iteration without clear justification creates confusion.

3. KCP would like to support the Standardized Hospitalization Ratio in the ESRD QIP, but cannot until its reliability has been demonstrated.

KCP concurs that hospitalization is an important quality domain, and we appreciate and approve that the SHR now accounts for prevalent co-morbidities. We would like to support a hospitalization measure, but we do not support incorporation of the SHR until its reliability at the proposed facility size is demonstrated. Specifically, we are concerned that only facilities with <5 patient-years at risk during the performance period are not eligible for the measure.

First, as we have noted elsewhere, KCP believes the standardized ratio measures should be harmonized—currently the SHR uses a <5 patient-years at risk threshold, but the standardized mortality ratio and standardized transfusion ratio use <10 patient-years at risk.

Second, and more importantly, CMS's own data, recently submitted to NQF, points out the significant issues of reliability with the one-year SHR.

IUR for One-year SHR, Overall and by Facility Size, 2010-2013

	2010		2011		2012		2013	
Facility Size (Number of patients)	**IUR**	**N**	**IUR**	**N**	**IUR**	**N**	**IUR**	**N**
All	0.72	5407	0.71	5583	0.70	5709	0.70	5864
Small (<=50)	0.54	1864	0.51	1921	0.48	1977	0.46	2028
Medium (51–87)	0.65	1702	0.63	1785	0.58	1825	0.57	1930
Large (>=88)	0.81	1841	0.81	1877	0.81	1907	0.82	1906

Although the overall reliability statistic for 2013 (and previous years) is 0.7, a level generally considered the minimum by NQF, the reliability statistics for medium and small facilities fall significantly short of the 0.7 threshold. CMS's own data indicate that for facilities <=50 patients, more than half a facility's score (54%) is due to random noise and not a signal of quality. Even for medium facilities, the IUR is significantly below the 0.7 threshold, with 43% of a facility's score attributable to random noise and not signal. Penalizing facilities for performance due to random chance is not appropriate.

We recognize that the proposed implementation is cast in patient-years, and not patient numbers, and support that construct. However, even under a scenario of a small facility of 50 patients, where all 50 contribute 12 months to the denominator (600 patient-months, thereby reaching the 60-patient months/5-patient years minimum), the CMS data indicate the performance score will be more random noise than actual performance. Clearly even smaller facilities (or facilities on the upper end with less than 100% contribution by all patients) will have reliability that's even lower—arguably completely unreliable. Accordingly, KCP does not support inclusion of the SHR at the proposed data implementation threshold (i.e., only those facilities with <5 patient-years of risk are not eligible). We further believe the Agency must publicly release the reliability statistics (as it did for the NQF submission) using the patient-years at risk construction, so a transparent and informed analysis can be drawn on the measure's reliability.

Additionally, CMS proposes both the SHR and SRR be used in the QIP beginning in PY 2020. Based on the SHR specifications, a readmission occurring within 30 days of the index discharge will be captured as a hospitalization by the SHR and a readmission by the SRR, such that a facility would be penalized twice for each such readmission. We believe this "double penalty" for a single occurrence is inappropriate and urge CMS to modify the SHR specifications to incorporate an exclusion for hospitalizations that occur within 29 days (i.e., <30 days) of the index discharge; doing so results in the SHR and SRR appropriately measuring two different types of events.

Finally, KCP also made numerous comments to improve the measure during it's comments in February 2016 to KECC, and so appends the letter to KECC for completeness because they still apply as CMS considers maintenance of the SHR.

4. KCP continues to support the inclusion of the NQF-endorsed measure *2701: Avoidance of Utilization of High Ultrafiltration Rate (≥13 ml/kg/hour)* as reviewed by NQF.

KCP believes fluid management is an important quality area, which is why it funded the Kidney Care Quality Alliance (KCQA) to undertake such measure development. We commend CMS for using KCQA's NQF-endorsed measure, *2701: Avoidance of Utilization of High Ultrafiltration Rate (≥13 ml/kg/hour).* CMS indicates the measure is "based on" 2701, however, and so we have a few concerns and questions.

First, CMS is proposing facilities with <11 patients be excluded from qualifying patients, rather than the <=25 specified by KCQA. KCP has concerns about the impact on small facilities with this change.

Additionally, while "number of HD session delivered during the month" is included among the data elements that must be reported, patients with <7 treatments are not explicitly excluded from the qualifying patients description—i.e., it appears that the transient exclusion is not addressed in the reporting measure. As we have advocated previously, we believe it is important for transient patients to be excluded, and we believe this exclusion should be standardized. We strongly recommend the measure incorporate a standard specification for transient patients: The Mineral Metabolism Measure had been patients with <7 treatments (for which KCP advocated), the the Serum Phosphorus Reporting Measure defines transient patients as "in unit < 30 days," and now the UFR Reporting Measure seems to lack this exclusion, although present in the original specifications.

KCP also notes that CMS does not indicate that reporting the number of hemodialysis (HD) sessions delivered during the Kt/V week will be required for the reporting measure. NQF 2701 excludes patients regularly prescribed >3 sessions/week. We believe the revised construct may be a CROWNWeb data collection issue, but ask for confirmation that the intent is to ultimately implement this measure as specified for those patients receiving thrice weekly HD. Finally, the UFR Reporting Measure excludes patients on dialysis <90 days at the beginning of reporting month, which is not present in the KCQA measure. We seek clarification as to whether this is a data collection issue or, if not, justification for this approach.

5. KCP continues to support the inclusion of the NHSN Healthcare Personnel Influenza Vaccination Measure as a reporting measure.

KCP believes that influenza vaccination of healthcare personnel, the focus of this measure, is an important public health concept. KCP supported including NHSN Healthcare Personnel Influenza Vaccination as a reporting measure, but as noted below we continue to have significant concerns about the performance period and believe it should be modified. The measure needs to accurately and validly capture all vaccinations that occur in accordance with CDC's guidelines.

Second, we supported eliminating the requirement for written documentation, but continue to 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.

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

B. Structural Issues

1. KCP supports setting the performance period at CY 2018, but asks that CMS align the performance period for the NHSN Healthcare Personnel Influenza Vaccination Reporting Measure with clinical and federal guidelines.

KCP supports setting CY 2018 as the Performance Period for PY 2020. However, we remain concerned that CMS proposes the performance period for the NHSN Healthcare Personnel Influenza Vaccination Reporting Measure as October 1 through March 31. KCP strongly objects to these parameters and instead asks that the Agency comport with the NHSN protocol upon which the measure is based, as well as with NQF's standardized influenza immunization specifications. Both define the acceptable immunization period as commencing on "October 1 or when the vaccine became available." Penalizing providers when practicing according to established clinical guidelines will place patients at increased risk early in the influenza season. Per the CDC, approximately two weeks are required after vaccination for sufficient antibody production to protect against infection; early vaccination is recommended to protect patients before the virus begins spreading through the community. Vaccine shipments typically begin in August, and we believe the measure should be specified to allow for this fact.

2. KCP supports continued use of the current policies for setting the performance standards, achievement thresholds, and benchmarks, and scoring.

KCP believes it is important to use the same basic methodology year-over-year. As we have noted in the past, this approach allows patients to be able to compare changes over time. Thus, KCP supports the continuation of the previous policy of setting the Performance Standard, Achievement Threshold, and Benchmark at the 50th, 15th and 90th percentile respectively in PY 2020. We also support the continuation of the current policy for determining payment reductions, including the process for setting the minimum Total Performance Score.

3. KCP continues to support the criteria for determining weights, with a few modifications, but remains concerned that too many measures in the ESRD QIP dilute the value of all measures.

As noted previously, KCP is pleased that CMS has implemented specific criteria to determine the weights of the individual measures within Domains and the Domains themselves. We continue to recommend that CMS also take into account the strength of evidence, the opportunity for improvement, and the clinical significance of measures when setting the weights.

To that point, we also again reiterate our concern that CMS weights the reduction in catheters at the same percentage as the number of AV fistulas. In previous letters, we have highlighted the fact that the equal weighting and lack of a graft measure has lead to patients having to endure the attempts to place AV fistulas, which it would otherwise be clinically inappropriate to attempt to do so. We appreciate that the recent technical expert panel modified the specifications for these measures, but once again urge CMS to weight the reduction in catheters more than the placement of AV fistulas to address this ongoing problem.

Additionally, we reiterate the concern noted at the opening of this letter. The weighting of the measures demonstrates that the number of measures is diluting the impact of the most important clinical and patient experience measures. We encourage CMS to work with KCP and others in the kidney care community to create a small core set of measures that would eliminate the problem of dilution.

Finally, we note that there appears to be errors in the Reporting Domain scoring methodology. Figure 7 on page 139 indicates that each of the six measures within the Reporting Domain shall be weighted at 14.0 percent of the domain score. Based on our analysis, each measure within the Reporting Domain would need to be weighted as 16.67 percent rather than 14.0 percent in order to equal 100 percent, given that 14 percent * 6 measures = 84 percent.

The other potential error relates to the Vascular Access Type measure weight as a percent of TPS in PY 2020. Table 10 on page 135 states that the Vascular Access Type measure topic will be weighted as 18.8 percent of TPS in PY 2020. However, both Table 10 and Figure 6 on page 138 indicate the combined VAT measure will be weighted as 18.0 percent of the Clinical Measure Domain. Our analysis found that the 18.0 percent combined VAT Weight and the 80 percent Clinical Domain weight results in a combined VAT measure that would comprise 14.4 percent of the TPS rather than 18.8 percent.

CMS should ensure that any weights or other parameters included in the final QIP are accurate and sum up to the required amounts.

V. KCP recommends that CMS ensure that the ESRD QIP does not create unnecessary barriers to patient access to home dialysis.

KCP has identified an overarching issue with the QIP methodology that could be perceived as a barrier to home dialysis. As you know, the UFR measure relies on treatment-level information the week the Kt/V is provided and, additionally, the QIP includes Kt/V measures. Further, implementation of other measures—e.g., the hypercalcemia measure—are affected. We believe the situation could be addressed through exclusions that addresses patients who switch from hemodialysis to home dialysis. This change would level the methodology for home and in-center patients, as we illustrate further, below.

Specifically for Kt/V-related measurements, if a patient was on HD for more than 90 days and then switched to PD, the patient will be included in the QIP calculation as soon as patient has a PD-related Medicare claim. If existing patients switched to PD, started training, and no Kt/V was performed during the month of training, then this patient-month will be counted as deficient; this is in contrast to an incident patient starting dialysis with PD who has a 90 day grace period.

To avoid being deficient, the only recourse is for a facility to perform a Kt/V on PD patients during training. Clinically this does not make good sense, since in many cases the training period is a process of "breaking in" the exit site/membrane and determining the best prescription. In addition, until training is complete, it is unsafe to have the patient do nighttime exchanges, if needed. The next month, just out of training, is when most providers work on obtaining Peritoneal Equilibration Test (PET) results to see what type of membrane transport the patient has and from these results tailor the PD prescription. So, once again, to avoid being counted as deficient, some clinics are performing a PD Kt/V again because the training KT/V is going to be inadequate. By not accounting for this, the QIP methodology could be perceived as a barrier to home dialysis or, at the very least, as driving inappropriate testing for this subset of patients. The solution to this would be to change the

exclusion criteria from "patients on dialysis for less than 90 days" to "patients on the PD modality for less than 90 days."

A similar issue arises for the hypercalcemia and phosphorus measures. Once again, as soon as a home patient has a related Medicare claim, there needs to be a lab result (as opposed to in-center patients, which have a 6-treatment grace period). Moreover, if a home patient gets a treatment on the 1st month and then goes to the hospital for the rest of the month, the patient-month will be counted as deficient. A solution for the hypercalcemia and phosphorus measures would be to edit the exclusion criteria to: "Home dialysis patients for whom a facility does not submit a claim during the claim month or PD patients with fewer than 15 billable days or home HD patients with fewer than 7 treatments during claim month." This change would level the methodology for home and in-center patients. As facilities analyze why their scores are low and realize their home patients are bringing down their scores, they may become more insistent about home patients getting clinically unnecessary labs (as noted above during the training period) or lose their enthusiasm for home dialysis because the ESRD QIP methodology for home patients brings their scores down.

VI. Future Questions

A. KCP strongly urges CMS to adopt rates to replace the standardized ratio measures with standardized rate measures for hospitalization and transfusion.

KCP is pleased that CMS is considering using the rates rather than the ratios for the SRR and STrR measures. We have consistently supported using risk standardized rates instead of ratios not only because they are easier to understand, as CMS points out in the preamble, but also because the current ratio measures have a wide range of uncertainty that does not provide an accurate view of a facility's performance when the ratio is reduced to a single number. (Elsewhere in this letter, we comment on the lack of reliability for the standardized ratio measures, especially with small sample sizes.) Rather than continue to use a confusing set of measures, KCP reiterates our recommendation that CMS in the short-term use the year-over-year difference between normalized (per 100 patient years) rates (e.g., for hospitalization) currently available from Dialysis Facility Reports data until they can be replaced by risk standardized rate measures.

Moving to rates, while an important step forward, also creates its own set of issues and CMS should carefully choose the methodology it uses to convert ratios to rates. For example, the use of the national median rate as the conversion factor for ratios may be misleading in regions of the country where typical performance varies significantly from the national rate. The goal of using rates instead of ratios is to make the measure results more meaningful to patients, providers, and other

stakeholders by expressing measure results in terms that have intrinsic meaning (rather than the abstract meaning expressed by ratios).

The Proposed Rule does not describe whether CMS considered any alternative methods for converting ratios to rates, or the criteria used to select the proposed method. While KCP supports the transition to rates, we request that CMS engage in additional review before finalizing the specific method to be used. KCP and its members would welcome the opportunity to engage CMS in such a dialogue before any final methods are selected.

KCP has also reviewed the suggestion in the Proposed Rule that CMS is considering reporting national performance standards and individual facility performance as rates, as opposed to ratios. Similarly, CMS is considering the use of rates for calculating improvement scores as well. Discern Health performed two simulations of these proposals. First, it used the median rate to convert the ratio to a rate (as CMS suggests in the Proposed Rule); second, it used the mean rate to convert the ratio to a rate. The QIP scores remain identical – dialysis facilities will receive the same score regardless of the ratio or rate methodology. Therefore, KCP would likely support this change in future iterations of the Proposed Rule, but we would need to see the complete proposal before finalizing this support.

B. KCP appreciates the opportunity to provide comments on potential measures for inclusion in future iterations of the ESRD QIP.

While KCP appreciates having the opportunity to provide comments on potential measures for future iterations of the ESRD QIP, we recommend that CMS provide more detail when making these suggestions so it is clear what measures are being proposed. In some instances, we recognize that the Agency may be seeking to determine whether further measure development should be undertaken in regard to a specific domain rather than proposing a specific measure. Providing clarity as to this intent would be useful as well. However, we again strongly encourage CMS to work with KCP and others in the kidney care community to implement MedPAC's recommendation to focus on a few measures that matter. Taking this approach would mean that new measures would not need to added during each rulemaking cycle.

1. KCP supports the adoption of NQF #0226, *Influenza Immunization in the ESRD Population*, in a future payment year.

KCP agrees that influenza immunization is a critical aspect of ESRD care that should be addressed by performance measurement and that a flu vaccination measure should be included in the QIP. As we have noted in previous letters, we

support the adoption in future payment years of the current NQF-endorsed measure #0226 *Influenza Immunization in the ESRD Population*, developed by the KCQA, which fully aligns with NQF's standardized specifications for influenza vaccinations.

We continue to have serious concerns about the ESRD Vaccination—Full-Season Influenza Vaccination" (MUC #XDEFM), which the NQF's Measure Applications Partnership did not recommend earlier this year, favoring instead NQF #0226. First, # XDEFM does not follow the NQF standardized specifications for a measurement timeframe of "October 1 through March 31 or when the vaccine became available." We have significant concerns about this omission. Given that vaccine is often available in late July or early August, omitting patients who were vaccinated before October 1 is both unfair and a potentially unwise disincentive to early and thorough vaccination of a vulnerable patient population.

Second, NQF #0226 is superior to MUC #XDEFM, because it has been fully tested and specified. As we have noted elsewhere to CMS[15], KCP is particularly troubled by this assertion that reliability and/or validity testing is not applicable or necessary because the measures are "reporting measures." "Scientific Acceptability" is an essential component of a measure's properties. Measure developers must show that data elements can be *reliably* reported, not simply that the can be reported. NQF measure testing guidance notes that even if data elements can be reliably reported, it does not necessarily follow that they are indicative of, or have an impact on, health care quality— *i.e.*, that they are valid. CMS has not made available for NQF or other public review any testing data for MUC #XDEFM.

CMS and the kidney care community are best and most efficiently served if CMS conforms to existing NQF processes to address full-season influenza vaccination performance measurement. Specifically, if CMS believes the evidence supports the changes its specifications encompass, it should work with KCQA, and use the NQF endorsement maintenance process to request that NQF 0226 deviate from the standardized specifications or that the standard specifications themselves be updated.

While KCP remains concerned with aspects of CROWNWeb, we believe collecting patient-level influenza immunization clinical measure data is preferable to collecting it through the NHSN. KCQA specified and tested this measure using facility data with the intention such data be submitted through CROWNWeb, so there is no question that the information can be reliably collected. In addition, CROWNWeb is supposed to be the hub for collecting this type of data. Using NHSN only introduces another factor that would require reliability and validity testing, as

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[15] Kidney Care Partners. *August 19, 2013 Letter to CMS on Proposed TEP Measures.* http://kidneycarepartners.com/files/2013-08- tep-comments.pdf. Last accessed December 20, 2013.

well as increasing the burden on dialysis facilities because of manual entry issues. Therefore, we strongly recommend that if CMS decides to add a patient-level influenza immunization clinical measure, that it add NQF #0226 unchanged and collect the data through CROWNWeb as indicated by this measure's specifications.

2. KCP recommends working with the kidney care community to address concerns about the current Standardized Mortality Ratio (SMR) measure's inclusion in the ESRD QIP.

KCP has on several occasions expressed concern about the current SMR. We appreciate the Agency's recognition in 2013 that CMS needed to "properly take into account the effect that comorbidities have on hospitalization and mortality rates in the ESRD population,"[16] as well as its movement away from exclusively relying on the 2728 data as noted above and have commented separately on the new specifications. We agree with patients that mortality is an important measure, but it is critically important that the measure be tailored to the actions of the dialysis facility. For example, it does not help patients or consumers to have mortality from automobile accidents included with mortality due to infection. We note that even the revised measure (*i.e.*, including prevalent co-morbidities) was not recommended by the NQF Renal Standing Committee in its recent review. Therefore, we recommend that CMS work more closely with the kidney care community to establish an appropriate morality rate measure that focuses on year-over-year, facility-specific improvement before considering its addition to the ESRD QIP.

3. While KCP acknowledges the importance of promoting transplant options for individuals with kidney failure, more work needs to be done before a transplant measure can be added to the ESRD QIP.

It is unclear from the preamble of the Proposed Rule what specific measure(s) examining kidney transplants in patients with ESRD CMS may be considering for future addition to the ESRD QIP. KCP has noted in previous comment letters that it is important to encourage referrals and patient education about transplant. We would welcome the opportunity to work with CMS on such measures.

Unfortunately, the two transplant-related wait list measures proposed by a recent technical expert panel (TEP) (Percentage of Prevalent Patients Waitlisted (PPPW) Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis

[16] "End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Proposed Rule" 78 *Fed. Reg.* 40836, 40861 (July 8, 2013).

Patients (SWR)) are not appropriate for the ESRD QIP based upon the most recent specifications CMS has shared with the kidney care community. KCP agrees that it is tremendously important to improve transplantation rates for patients with ESRD, but we cannot support attributing the success of being waitlisted to dialysis facilities because, as patient organizations and others have noted, the decision to include a patient on a transplant waitlist rests with the transplant center. KCP recommends instead that efforts focus on developing measures for dialysis facilities that would relate to patient education, referral to a transplant center, initiation of the waitlist evaluation process, or completion of the waitlist evaluation process (with which a facility can often provide assistance). In addition, CMS could explore a care coordination measure with mutual facility-transplant center responsibilities. A completion of the waitlist process measure and a waitlisting measure should be developed for transplant centers. Transplantation is a multi-party process: To optimally drive improvement, measurement of all parties should be deployed.

In our response to the measures proposed by the TEP, KCP provided detailed comments raising concerns about the proposed specifications. To the extent that CMS is considering adopting either or both of these measures, we reiterate these measures for the record as well.

1. ***PPPW and SWR: Facility attribution.*** As just noted, KCP strongly objects to attributing successful/unsuccessful placement on a transplant waitlist to dialysis facilities. The transplant center decides whether a patient is placed on a waitlist, not the dialysis facility. One KCP member who is a transplant recipient noted there were many obstacles and delays in the evaluation process with multiple parties that had nothing to do with the dialysis facility—*e.g.,* his private pay insurance changed the locations where he could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a facility each month through the PPW and SWR for these or other delays is inappropriate. Again, KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued.
2. ***PPPW and SWR: Age as the only risk variable.*** KCP strongly believes age as the only risk variable is insufficient. We believe other biological and demographic variables are important, and not accounting for them is a significant threat to the validity of both measures.

   Geography, for instance, should be examined, since regional variation in transplantation access is significant. For example, regional differences in waitlist times differ, which ultimately will change the percentage of patients on the waitlist and impact a performance measure score. That is, facilities in a region with long wait times will "look" better than those in a region with shorter wait times where patients come off the list more rapidly—even if both are referring at the same rate.

Additionally, criteria indicating a patient is "not eligible" for transplantation can differ by location—one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply them differently or have addition/different criteria. The degree to which these biological factors influence waitlist placement must be accounted for in any model for the measure to be a valid representation of waitlisting. Moreover, transplant centers assess a myriad of demographic factors—e.g., family support, ability to adhere to medication regimens, capacity for follow-up, insurance-related issues, etc. Given transplant centers consider these types of sociodemographic factors, any waitlisting measure risk model should adjust for them. Of note, KCP does not support, as the TEP did not support, adjustment for waitlisting based on economic factors or by race or ethnicity.

3. ***SWR only: Rate vs. ratio.*** The proposed specifications for the SWR indicate the measure can be calculated as a rate. Notwithstanding our many concerns regarding attribution and risk adjustment of this measure, consistent with our comments on other standardized ratio measures (e.g., SHR, SMR), KCP prefers normalized rates or year-over-year improvement in rates instead of a standardized ratio. We believe comprehension, transparency, and utility to all stakeholders is superior with a scientifically valid *rate* methodology.

4. KCP suggests that it is too early to determine whether an Emergency Department Measure would be appropriate to add to the ESRD QIP.

KCP acknowledges that while emergency department utilization may be an important area to measure, but we also notes it would be a complex measure that would require careful construction and risk modeling to account for many factors (*e.g.*, patient, geographic, etc.) Without detailed specifications on the measure that CMS envisions, we cannot support it at this time. As we note elsewhere, like MedPAC, we believe the QIP should focus on a parsimonious set of measures and any new additions should be examined against a strategic framework to achieve this.

5. KCP supports NQF #2988 *Medication Reconciliation for Patients Receiving Care at Dialysis Facilities*.

Similarly, the Agency indicates it is contemplating inclusion of a medication reconciliation measure. KCP believes medication reconciliation is an important patient safety process for patients with ESRD, most of whom have multiple prescriptions. Through the Kidney Care Quality Alliance, KCP supported the development and testing of *NQF #2988: Medication Reconciliation for Patients*

Receiving Care at Dialysis Facilities. NQF #2988 is supported by KCP and is currently under evaluation by the NQF Patient Safety Standing Committee. If CMS were to adopt such a measure for the QIP, it should adopt NQF #2988.

VII. Conclusion

KCP appreciates the opportunity to provide comments on the ESRD QIP. We look forward to working with CMS on addressing the concerns in this letter as well as implementing the final rule. While we have scheduled a meeting to discuss some of the key points outlined in this letter, please do not hesitate to contact Kathy Lester at (202) 534-1773 or klester@lesterhealthlaw.com if you have any questions.

Sincerely,

Frank Maddux, M.D.
Chairman
Kidney Care Partners

Appendix A: KCP Members

AbbVie
Akebia Therapeutics, Inc
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
AstraZeneca
Baxter Gambro Renal
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners Inc.
Dialysis Clinic, Inc.
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medicare Care Renal Therapies Group
Greenfield Health Systems
Hospira
Keryx Biopharmaceuticals, Inc.
Kidney Care Council
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical, Inc.
Renal Physicians Association
Renal Support Network
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KIDNEY CARE PARTNERS

TO: Joel Andress, PhD
Centers for Medicare and Medicaid Services

University of Michigan Epidemiology and Cost Center
dialysisdata@umich.edu

DA: February 24, 2016

RE: Public Comment on Standardized Mortality Ratio (SMR) and Standardized Hospitalization Ratio (SHR)

Kidney Care Partners (KCP) is a coalition of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care—patient advocates, health care professionals, dialysis providers, researchers, and manufacturers and suppliers—organized to advance policies that improve the quality of care for individuals with chronic kidney disease and end stage renal disease (ESRD). We appreciate the opportunity to comment on the draft specifications for the SMR and SHR developed under a CMS contract by the University of Michigan Kidney Epidemiology and Cost Center and posted on February 8, 2016.

Because the measures share much in common, we have organized the comments in five areas; when a comment pertains only to one of the measures, we specifically note this. The six areas are:

1. Specifications
2. Co-Morbidities
3. Risk Model Fit
4. Reliability and Validity Testing
5. Ratio vs. Rate Measures

1. SPECIFICATIONS

KCP offers several comments on the specifications

- **SMR Measurement Period**. The SMR specifications for the time period state "at least one year." As a principle, KCP believes specifications should be unambiguous—i.e., the construction is imprecise. We believe the time period should be an exact period, and we further believe the 1-year period is inappropriate based on the testing data. We recommend, at minimum, a 4-year period.

  CMS's reliability testing for the 1-year SMR yielded IURs of 0.26-0.32 for each of 2010, 2011, 2012, and 2013—a low degree of reliability, where only about 30% of the variation in a score can be attributed to between-facility differences. Using the 4-year SMR yielded an IUR of 0.66 (2009-2012)—i.e., about 60% of the variation can be attributed to between-facility differences; for 2010-2013 data, the IUR was only 0.59. We further note

a reliability statistic of 0.70 is often considered as "good" reliability,[1] though the characterization also depends on the analytic method. The overall reliability, even for the 4-year SMR, falls short in this regard.

Not surprisingly, reliability depends on facility size. Even with the 4-year SMR, the testing results still indicate poor reliability for small (IUR=0.30) and medium (IUR=0.45) facilities—i.e., only large facilities have a reasonable IUR of 0.73 for 2010-2013 data. Given these results, we also believe it is incumbent on CMS to address the lack of reliability and use an adjuster or otherwise account the poor reliability in small and medium facilities before the measure is implemented.

- **SHR Measurement Period**. The SHR specifications for the time period also state "at least one year." Again, as a principle, KCP believes specifications should be unambiguous. We believe the time period should be an exact period. Further, based on the results from the reliability testing, we have significant concerns about the reliability of the 1-year SHR for small and medium facilities (IUR range of 0.46-0.65, depending on the year. Given there are a significant number of facilities that have fewer than 87 patients, KCP requests that CMS reanalyze the data and set the time period so the reliability/IUR is satisfactory, even for small facilities.
- **SMR and SHR Denominator**. KCP supports limiting the denominator to Medicare patients. As you know, KCP has long advocated that the measures should account for more current co-morbidity data, and we understand and support the trade-off to now limit the denominator population due to claims data availability.
- **SMR Exclusion for Incident Hospice Patients**. The NQF Measure Applications Partnership (MAP) recently did not support the SMR in part because the measure did not exclude patients who are already in hospice when they initiate dialysis. During the MAP deliberations, it was noted that occasionally incident patients begin dialysis treatments while in hospice, but then choose to discontinue them after a period of time. KCP supports MAP's recommendation that patients who initiate dialysis while also in hospice be excluded from the SMR. As currently constructed, such patients are attributed to the facility providing the dialysis.

2. CO-MORBIDITIES

We strongly support the use of prevalent co-morbidities in the risk models for the SMR and SHR, and commend CMS for moving to incorporate prevalent co-morbidities in the proposed specifications—an approach for which KCP has long advocated. We also encourage CMS to review co-morbidities as they relate to the ESRD population under the age of 18 years, since these measures include all ESRD patients. We comment separately on the approaches for incident vs. prevalent co-morbidities.

- **Incident Co-morbidities**. Incident co-morbidities will continue to be derived from the 2728, but the new model proposes adjustments for each incident comorbidity separately instead of using a "comorbidity index." Diabetes also is proposed as a single comorbidity, whereas before the model used four separate indicators. KCP supports treating each incident comorbidity separately, including diabetes. As we have noted before, however, we continue to be concerned about the validity of the 2728 as a data source. We urge CMS to work with the community to assess this matter.

[1] Adams, JL. The Reliability of Provider Profiling: A Tutorial. Santa Monica, California:RAND Corporation. TR-653-NCQA, 2009.

- **Prevalent Co-morbidities**. KCP supports the inclusion of prevalent co-morbidities derived from Medicare claims data, but the review time does not permit us to comment specifically on the 555 co-morbidities originally considered, nor the 210 ultimately included. While we may in the future (e.g., during NQF review) comment on specific items, we note the face validity of some co-morbidities that have been included in the model is puzzling (e.g., "urinostomy status not elsewhere classified [NEC]", "sacroiliitis NEC"). One approach might be to assess posterior probability. In sum, while we appreciate the details provided in the TEP report, we believe there are anomalies among the 210 co-morbidities and suggest a transparent process to refine the list.

  Further, in reviewing the approach used to identify appropriate prevalent co-morbidities, the TEP report indicates an initial assessment was applied to the ESRD Hierarchical Comorbidity Conditions (HCCs) with a prevalence of at least 0.1% in the patient population in order to identify those with a statistically significant relationship to mortality and/or hospitalization ($p<0.05$). However, we note that many of the co-morbidities included in the final model appear to have p-values significantly greater than 0.05 (e.g., paralytic ileus [p=0.5007], episodic mood disorder NOS [p=0.8254]) and so are puzzled as to the rationale for their inclusion. We seek clarification on this apparent discrepancy between the described approach to co-morbidity selection and the end-product.

- **Determination of Co-morbidities**. The determination that a prevalent co-morbidity exists requires at least two outpatient claims or one inpatient claim. No TEP justification or empirical analyses were offered to justify this algorithm. KCP requests the underlying rationale for the approach.

3. RISK MODEL

KCP is pleased the model incorporates prevalent co-morbidities, but we have a few concerns related to the model's details.

- **Model Fit**. Testing yields a c-statistic for the SMR of 0.724, and a c-statistic for the SHR of 0.65. We are concerned the model will not adequately discriminate performance—particularly that smaller units, including pediatric units, might look worse than reality. We believe a minimum c-statistic of 0.8 is a more appropriate indicator of the model's goodness of fit and validity to represent meaningful differences among facilities, and seek an ongoing commitment from CMS to improve the model.

- **Nursing Home Status:** The Measure Information Form (MIF) indicates patient characteristics included in the stage 1 model as covariates include "Nursing home status in *previous* year." It is unclear to us if this means that patients moving into a nursing home for the first time *during* the measurement year would not be adjusted for "nursing home status". KCP seeks clarification as to whether the look-back is *one year prior to the given event* (inclusive of the data year) or if this verbiage means the look-back is *in the previous calendar year* (not inclusive of the data year); we recommend the current reporting year be included, not just the previous one.

- **Age:** The age groups for the SMR (n=3) differ from those for the SHR (n=6). No TEP justification or empirical analyses were offered to justify this difference. KCP requests the underlying rationale and empirical justification for the approach, given the general principle that specifications should be harmonized when appropriate and possible.

- **Duration of ESRD**. Similarly, the number of groups for ESRD duration for the SMR (n=4) differs from that for the SHR (n=6). No TEP justification or empirical analyses

were offered to justify this difference. KCP requests the underlying rationale for the approach and empirical justification, given the general principle that specifications should be harmonized when appropriate and possible.

4. RELIABILITY AND VALIDITY

As we noted under Item 1, Specifications, we have significant concerns about the reliability of both the SMR and SHR and make recommendations on the specifications.

We noted the Spearman's correlation coefficients for SHR-SMR ranged from 0.27-0.30; SHR-SRR = 0.48-0.54; SHR-AVF = -0.15 to -0.12; SHR-catheter = 0.16-0.21; SHR- Kt/V>=1.2 = -0.13 to -0.10. Again, these correlations are directionally as expected. However, KCP believes the Measure Justification Form (MJF) overstates these correlations, concluding, "the SHR correlates strongly with outcomes, processes of care, and causes of hospitalization that are commonly thought to be potentially related to poor quality of care." By convention, Spearman's rho of 0-0.19 appears to be considered "very weak" and must be 0.60-0.79 to be considered "strong."[2] We request the results be more accurately characterized, as they were for SMR—i.e., that the correlations were directionally as expected.

Additionally, for the facility minimum data requirements, the MJF notes at least 3 expected deaths must occur for inclusion in the SMR calculations. No TEP justification or empirical analyses were offered to justify this threshold. KCP requests information on the underlying analysis—e.g., how many clinics were excluded using this approach and what is the impact on scoring because of the exclusion? Similarly, for SHR the minimum requirement is 5 patient-years at risk. KCP notes the STrR uses 10 patient-years at risk. No TEP justification or empirical analyses are offered to justify this difference. KCP again requests the underlying rationale for the approach and empirical justification, given the general principle that specifications should be harmonized when appropriate and possible.

5. RATIO VS. RATE MEASURES

The proposed specifications for the SMR and SHR indicate the measures can be calculated as rates. KCP prefers normalized rates or year-over-year improvement in rates instead of a standardized ratio. We believe comprehension, transparency, and utility to all stakeholders is superior with a scientifically valid *rate* methodology. We note that MAP also did not support the SMR because, in addition to the lack of a hospice exclusion, as previously noted, MAP felt "mortality rates would be more meaningful to consumers and actionable for facilities."

KCP again thanks you for the opportunity to comment on this important work. If you have any questions, please do not hesitate to contact Lisa McGonigal, MD, MPH (lmcgon@msn.com or 203.298.0567).

Sincerely,

AbbVie
Akebia
American Kidney Fund
American Nephrology Nurses Association
American Renal Associates
American Society of Nephrology
American Society of Pediatric Nephrology

[2] Stats Tutor, *Spearman's Correlation*. Available at www.statstutor.ac.uk. Last accessed February 2016.

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