KIDNEY CARE PARTNERS

August 25, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Room 445–G
Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1628-P: Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program

Dear Acting Administrator Slavitt:

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 and Quality Incentive Program" (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.

KCP supports the ESRD QIP and our members have worked diligently to help it succeed. We support many aspects of the Proposed Rule and offer a series of recommendations that we believe will improve its effectiveness. We look forward to working with your team to address these issues before the policies are finalized.

I. General Provisions

A. KCP Supports the Clarification to the "CMS Certification Number (CCN) Open Date."

KCP appreciates the clarification of the term "CCN Open Date" and agrees it should be defined as the "Medicare effective date." Once a facility is eligible to receive payment under the ESRD Prospective Payment System (PPS), it should also be eligible to participate in the ESRD QIP.

B. KCP Supports the Creation of an ESRD Measures Manual.

KCP strongly supports the proposal to create an ESRD Measures Manual. As we have indicated in multiple comment letters and meetings, it is critically important that CMS establish a transparent and open process for all quality measures, in particular any microspecifications on their implementation. We also appreciate that CMS plans to permit stakeholders to provide suggestions about technical updates to the measures. We are also supportive of the use of the JIRA system and applaud CMS for its efforts to use this system to address non- sustentative regulatory changes.

CMS indicates that the proposed manual will be released six months before the performance period begins. This timeline is appropriate only if the technical specifications and microspecifications have already been provided through the notice-and-comment rulemaking process when each measure has been adopted. Microspecifications and implementation are of equal importance to the specifications for which the Agency currently seeks comment. Thus, while the manual is an important document for aggregating technical specifications and implementation rules for all ESRD quality measures, it should not replace the notice-and-comment rulemaking that the Congress required to establish the ESRD QIP measures.

C. KCP Supports the Proposal to Allow Stakeholders to Comment on the SRR/STrR Impact Study, but Questions the Inclusion of These Measures in the QIP while the Study Is Pending.

As noted in previous comment letters, as well as in Section V.A.1. of this letter, KCP has significant concerns about the inclusion of the SRR and 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. Additionally, allowing stakeholders to comment on the methodology is an appropriate first step in implementing this study.

Despite these positive steps, the announcement of this study raises the important question of whether it is appropriate to include these measures in the ESRD QIP until the results of the study are known. 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. As we have noted previously, facilities do change their behavior based upon the measures adopted through the QIP. Therefore, consistent with our comments in Section V.A.1. of this letter, KCP recommends that CMS not include the SRR or STrR measures in the QIP until it has a better understanding of how they will impact patient care.

II. Payment Year 2016: KCP Recommends that CMS Prioritize Developing a More Targeted Measure in Consultation with the Kidney Care Community to Meet the PAMA Requirements for a Measure Specific to the Conditions Treated with Oral-Only Drugs.

We appreciate the Agency's request for suggested measures that could replace the current hypercalcemia measure. 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) Renal Standing Committee has concluded that the hypercalcemia measure is topped out and the initial recommendation is for Reserve Status because of high facility performance and minimal room for improvement. We also understand that the Agency must comply with PAMA. To this end, we encourage CMS to work closely with the kidney care community to identify a more appropriate measure to meet the statutory requirement.

To the extent CMS maintains the hypercalcemia measure for PY 2016, we urge CMS to align the ESRD QIP specifications with the revisions sent to the NQF for maintenance of a similar measure: NQF #0255, *Measurement of Serum Phosphorus*. Specifically, the specifications should state that plasma is an acceptable alternative substrate to serum.

III. Payment Year 2017

A. KCP Supports the Objective of Improving the Small Facility Adjustment (SFA), but Recommends Modification to the Proposed SFA Formula.

During the past several years, CMS has applied a small facility adjustment (SFA) to measure sample sizes between 11 and 25. The primary goal of this adjustment is to permit participation in the QIP by facilities that would otherwise be excluded due to small sample sizes. Moreover, the SFA addresses the concern that "the small sample size in these facilities puts them at risk for having one or two challenging patients dramatically alter their performance rates and ESRD QIP performance scores. The ESRD QIP, therefore applies a favorable adjustment to performance rates for facilities with 11–25 cases."[1] The current SFA[2] applies a favorable adjustment to all small facilities, regardless of their reported performance.

In the past, KCP has expressed concern about the basic premise of small sample size adjustment. We do not believe that any adjustment can fully offset the inherent uncertainty associated with measure results for very small samples. However, we understand CMS's goal to ensure that the QIP include as many facilities as possible. We also understand that the proposed

[1] http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/ESRDQIPGlossaryofTerms.html

[2] In these comments, we use "current SFA" to refer to the SFA that CMS has used for the past several QIP annual cycles. "Proposed SFA" refers to the SFA in the CY 2016 proposed rule. "Alternative SFA" refers to the SFA that Kidney Care Partners is proposing in this letter.

SFA is intended to improve the process. In that context, we offer the following suggestions to improve the proposed SFA.

In the proposed rule, CMS suggests updating the SFA as follows:

For the i^{th} facility, suppose the original measure is p_i and the number of patients at the i^{th} facility is n_i. In cases where large values of p_i are good, we propose altering the scores for the small facilities $L \leq n_i < C$ by using the following rule.

- Let $w_i = n_i \div C$ *if* $L \leq n_i < C$. For example, L =11 and C =26 for the VAT and Hypercalcemia measures.

- The new score is: $t_i = w_i * p_i + (1 - w_i)\ P$, where P is the national mean measure.

CMS offers the following rationale for this new formula:

- The current SFA assumes a bell-shaped performance distribution. However, facility scores for some of the measures are not bell-shaped.

- It is difficult for facilities and other stakeholders to independently calculate pooled within-facility standard errors (as required by the current SFA) because doing so requires data that is not readily available.

KCP agrees with CMS on these points. The proposed SFA does not assume a bell-shaped distribution, because it does not rely on standard error as a variable in the equation. The new SFA also is easier to replicate mathematically than the current SFA.

However, there is also a policy change embedded in the new SFA formula. As quoted earlier, the stated purpose of the SFA has been to apply "a favorable adjustment to performance rates for facilities with 11–25 cases." The adjustment applies to all small facilities, because all small facilities are subject to "having one or two challenging patients dramatically alter their performance rates." Yet, the proposed SFA would only apply to facilities with performance below the national mean for a measure. Small facilities with performance rates above the national mean would not receive any adjustment. Such facilities will experience the proposed SFA as a performance reduction (when compared to the current SFA), which we believe is at odds with the purpose of the SFA.

This is an issue that will affect a large number of dialysis facilities. We analyzed the most current DFC data to identify facilities that met the following criteria for at least one measure:[3]

- The sample size is between 11 and 25, inclusive,

[3] Specifically, we analyzed the following five measures: Hemoglobin 12 g/; Kt/V Adult Hemodialysis; Kt/V Adult Peritoneal Dialysis; Fistula; and Catheter.

- The unadjusted performance rate is above the national median.

These criteria describe facilities that would have received an adjustment under the current SFA, but would not receive an adjustment under the proposed SFA. Of the 3,598 facilities with data in Dialysis Facility Compare (DFC), 480 (13.3%) meet these criteria for at least one measure. 266 facilities (7.4%) meet these criteria for two or more measures. In other words, there are many dialysis facilities that would have previously received an adjustment, and that will be negatively affected by the proposed SFA.

We also note that the average magnitude of the SFA will be reduced under the proposed SFA, when compared to the current SFA. Our analysis shows that, for the fistula measure, the current SFA adjusts performance up by an average of 2.9 percent for small facilities. The proposed new adjuster increases performance by an average of 1.1 percent. We saw similar results for the other QIP measures. (See analysis below and Appendix B.) We urge CMS to adopt an SFA formula that more closely approximates the current SFA's impact on measure scores.

To address these concerns, KCP recommends that CMS adopt a modified version of the proposed SFA. Our recommendation is based on CMS's proposed SFA, but replaces P (the national mean performance for a measure) with B (the benchmark set at the 90th percentile of national measure performance). This alternative formula is expressed a follows.

> For the i^{th} facility, suppose the original measure is p_i and the number of patients at the i^{th} facility is n_i. In cases where large values of p_i are good, we propose altering the scores for the small facilities $L \le n_i < C$ by using the following rule.
>
> • Let $w_i = n_i \div C$ *if* $L \le n_i < C$. For example, L =11 and C =26 for the VAT and Hypercalcemia measures.
>
> • The new score is: $t_i = w_i * p_i + (1 - w_i) * B$, where B is the benchmark, set at the 90th percentile of national measure performance.[4]

This alternative SFA formula has the same benefits as the proposed SFA: It does not assume a bell-shaped distribution, nor does it require the calculation of pooled within-facility standard errors. It has the added benefit of providing some positive adjustment for all small facilities that may have been adversely affected[5] by one or two challenging patients. In both the proposed SFA and KCP's alternative SFA, the adjustment would be larger for worse performers and for smaller facilities. The magnitude of the adjustment under the alternative SFA would be similar to the current SFA.

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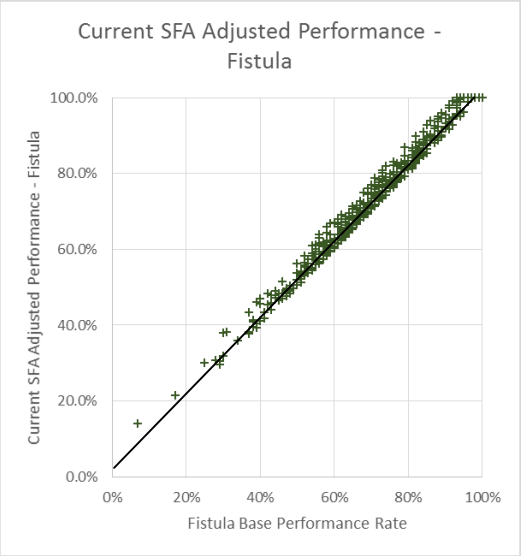
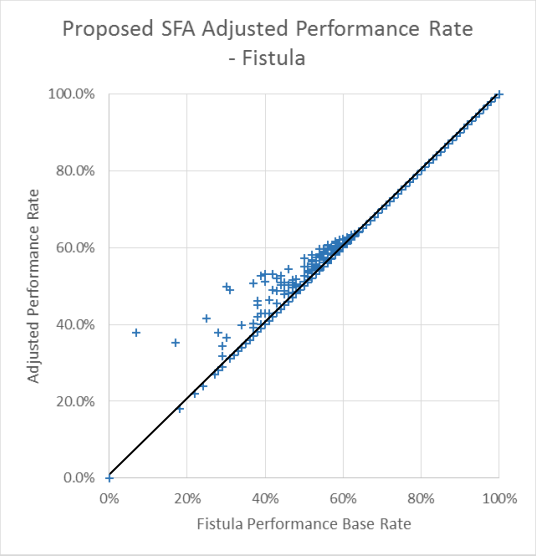
[4] As with CMS's proposed SFA, we would adjust the formula for measures where lower performance is better.

[5] The alternative SFA would not adjust performance for facilities with performance above the 90th percentile. But those facilities do not need any adjustment, since they receive a score of 10 in the QIP.

To test and compare the various options for computing the SFA, Discern Health analyzed the different approaches. For this analysis, it used the most current data set available through DFC.[6] As described below, these data are for the fistula measure, but are broadly illustrative of the other measures, as well. We have included analyses and graphs for the other measures in Appendix B.

First, Discern Health compared the outputs of the current SFA to the proposed SFA. In its analysis, the base "unadjusted" performance rate is the independent variable and the adjusted performance rate is the dependent variable.

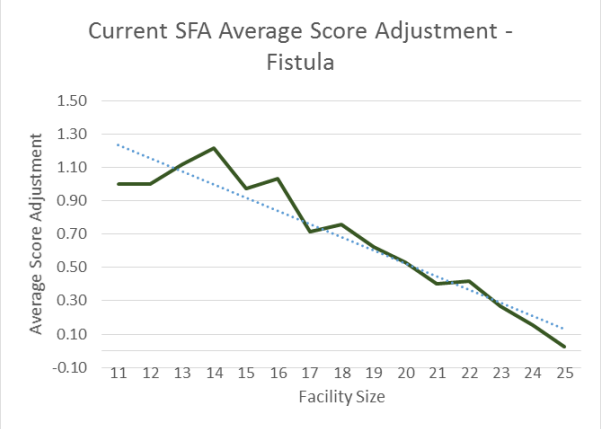


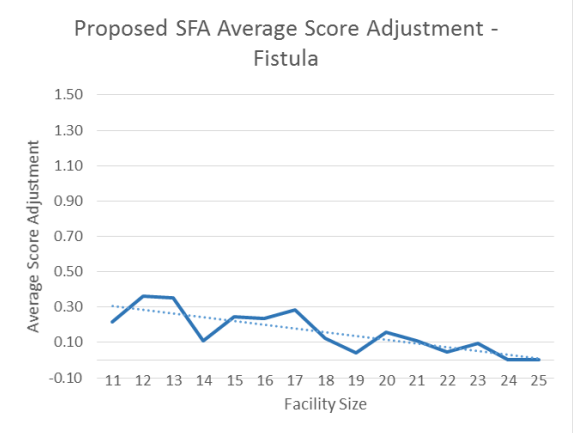


As the illustrations above demonstrate, the behavior of the two methods is quite different. The current SFA provides some adjustment across the entire range of performance. The proposed SFA only adjusts below-average performers. In the proposed SFA, the adjustments get larger as performance goes down, while the current SFA makes similar adjustments across the performance range.

Discern Health then analyzed the adjustment as a function of sample size. Both the current SFA and proposed SFA are designed to provide a larger adjustment as sample size decreases. In the analysis, it calculated the adjusted and unadjusted achievement score for each facility on the DFC data set. It then calculated the average adjustment for each sample size between 11 and 25.

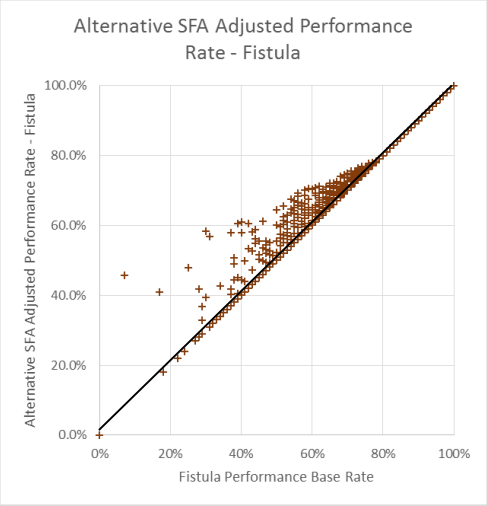
[6] Please note that the standardized ratio measure data are not yet available.

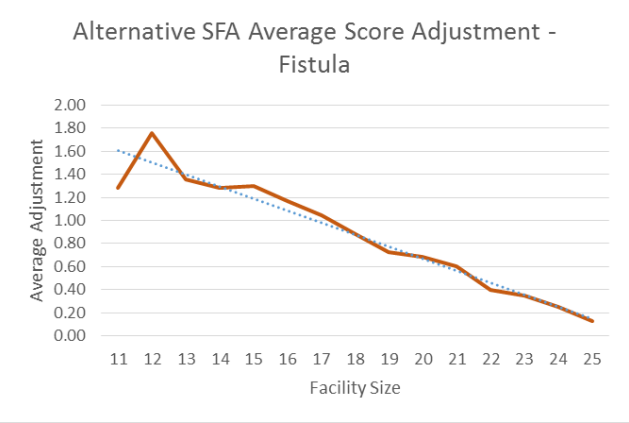




As the charts make clear, the magnitude of the adjustment for small facilities is very different when comparing the current SFA to the proposed SFA.

As a final step in our analysis, we conducted similar analyses for KCP's alternative SFA.





Compared to the proposed SFA, KCP's alternative SFA provides positive adjustment for a broader range of performance, which KCP believes is more consistent with CMS' original intent for the SFA. In addition, the magnitude of the adjustment is similar to the current SFA. KCP's alternative SFA would adjust average performance up by 3.1 percent, which is very similar to the average 2.9 percent adjustment in the current SFA. By contrast, the proposed SFA increases performance only by an average of 1.1 percent, which we submit is an unintended consequence of the proposed SFA.

Appendix B to this letter includes the analysis of the different SFA options for other QIP measures for which DFC data is currently available. These results support KCP's suggestion for an alternative SFA that is consistent with the QIP's goals and history. We also urge CMS to ensure that data are available to dialysis facilities on a comprehensive and timely basis, so that

they can understand and replicate the QIP scoring process and thereby target their quality improvement efforts.

In summary, KCP supports CMS's objective to improve the SFA. We believe this objective can be best achieved by adopting an alternative SFA formula that is similar to CMS's proposal, but which uses the 90th percentile of performance instead of the national mean. We believe that our alternative SFA will better ensure CMS's goals of providing some positive adjustment for all small facilities that may need it, while simplifying the overall SFA process.

B. KCP Supports Reinstating Qualifying Patient Attestations for the ICH CAHPS Clinical Measure.

As we described in detail in *A Strategic Blueprint for Advancing Kidney Care Quality*, KCP supports measuring patient experience. Improving patient experience with care is one of the four goals we outlined in the Blueprint.[7] We believe that there are ways to improve the ICH CAHPS that would reduce the burden on patients completing the survey and resolve concerns about its implementation. We describe these issues in more detail in Section V.A.1. below.

We appreciate that CMS recognizes the continued need for patient-level exclusions. We also appreciate the data challenges CMS has described and support reinstating the attestation process for identifying these patient-level exclusions. Given that the same issue pertains to PY 2016, we recommend that CMS implement this change for that payment year, as well as PY 2017.

To ensure the smooth implementation of the attestation, we encourage CMS to provide a detailed list of the specific exclusions that are the subject of the attestation. In addition, we recommend that CMS exclude homeless individuals. The Agency for Healthcare Research and Quality (AHRQ) administrative specifications acknowledge that 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. Facilities should not be penalized for an incomplete survey given these substantial challenges. While we appreciate that the CMS guidance recognizes that homeless patients may be difficult to reach, we are concerned that this guidance continues to penalize facilities for incomplete surveys given these challenges. Thus, we recommend that, consistent with the AHRQ administrative specifications, individuals who are homeless be removed from the list of eligible patients.

[7] KCP, *A Strategic Blueprint for Advancing Kidney Care Quality*, 4 (2014).

IV. Payment Year 2018

A. KCP Appreciates Efforts To Clarify the Scoring of Facility Performance for the Pain Assessment and Follow-Up Reporting Measure, but the Proposed Modifications Need Further Explanation.

In the Proposed Rule, CMS indicates that "[b]eginning with the PY 2018 ESRD QIP, if a facility treats no eligible patients in one of the two six-month periods, then that facility's score will be based solely on the percentage of eligible patients treated in the other six-month period for whom the facility reports one of six conditions." Facilities provide the attestation once a year and it is not clear how the modification's reference to two six-month periods applies in this situation. It is important to provide clarity about this point. Given that the attestations are provided in the same manner for the Clinical Depression Screening and Follow-Up reporting measure, we recommend that the same modifications suggested for the Pain Assessment and Follow-Up reporting measure apply to that metric as well.

B. KCP Supports the Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures, as well as the Clarification of the Payment Reduction for PY 2018.

In general, KCP supports the continuation of the PY 2017 policy of setting the Performance Standards, Achievement Thresholds, and Benchmarks at the 50th, 15th and 90th percentile respectively in PY 2018. We also support the continuation of the PY 2017 policy for determining payment reductions, including the process for setting the minimum Total Performance Score (mTPS), which becomes the cut point at which facilities begin receiving payment penalties, and CMS's process for setting the level of reductions received by facilities. However, we urge CMS to carefully monitor the implementation and impact of the QIP scoring model on the standardized ratio measures. These measures are different than the other QIP clinical measures in terms of how they are calculated and the level of control dialysis facilities have on the results. The QIP scoring model was originally designed for "rates of compliance" measures, and KCP is concerned how these measure will influence the QIP results. CMS has itself recognized the inherent challenges associated with the construction of the standardized ratio measures and interpreting their results, previously reporting the results categorically (*i.e.*, "worse than expected," "as expected," "better than expected"). KCP will track the results of these measures in the QIP and may, in the future, suggest changes to the QIP based on the impact of the ratio measures."

C. KCP Recommends Modifications to the Process for the NSHN Bloodstream Infection Measure Validation Study.

As noted in our 2014 comment letter, KCP raised concerns about the data validation study proposed once again for PY 2018. The validation study appears to be an audit of dialysis facility data to confirm the accuracy of the data being reported. Because facilities that do not comply with the audit risk a two percent cut, 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.

KCP and its member organizations would like to work with CMS to address the validation of measures and the accuracy of data reporting in a different manner. If CMS is concerned about the accuracy of the data being reported, it should work with facilities in a manner that fosters accurate data submissions rather than adopt a penalty-based audit system. It does seems rather draconian to establish a penalty for not complying with this study that equals the highest tier of the payment penalty that a facility faces for not meeting the quality benchmarks under the entire QIP. Therefore, KCP encourages CMS to suspend this validation study and instead work directly with facilities that appear to have data submission problems so that they identify workable solutions and can be remedied.

V. Payment Year 2019

A. KCP Recommendations Regarding PY 2019 Proposed Measures

1. KCP Supports the Continued Inclusion of Current Measures for PY 2019, but Suggests Recommendations for Some that Should Be Implemented Prior to PY 2019.

KCP supports the proposal to continue many of the PY 2018 measures for PY 2019. We also provide recommendations about how to improve these 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;[8]

[8] *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.

2. KCP Continues to Support CMS's Current Approach to Dialysis Adequacy Performance Measures in the ESRD QIP—*i.e.*, the Use of Four Separate Measures for the Four Dialysis Subpopulations—and Opposes Use of the Proposed Pooled Dialysis Adequacy Measure; KCP also Recommends that CMS Adopt Modifications for the Upper Kt/V Threshold Recommended by the NQF Renal Standing Committee.

KCP supports the current individual adequacy measures and would support a well-constructed composite of such. KCP's examination of the proposed *Kt/V Dialysis Adequacy Measure* specifications as released in the Proposed Rule revealed that the measure is a *pooled* measure. Specifically, based on the QIP specifications in the Proposed Rule, CMS intends to pool all patients from the four dialysis populations (adult and pediatric peritoneal and hemodialysis) into a single denominator and calculate scores as would be done for a single measure, rather than calculating 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.

3. KCP Supports Inclusion of the Vascular Access Measures for PY 2019.

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 arteriovenous [AV] fistula, but in some instances, an AV graft when clinically appropriate) is arguably the most important factor in improving patient outcomes. As we have noted in the past, we are concerned that the lack of a graft measure or the current weighting for the catheter minimization measure disincentivizes the use of what is frequently the most clinically appropriate access, selected with and in the best interest of a patient. We, therefore, are pleased that CMS convened a Technical Expert Panel to review the approach to vascular access measurement, which appears to be in response to these concerns. Given that recognition, we also ask that CMS for PY 2016 through PY 2019 adjust the weight of the catheter measure as an interim mechanism to avoid potential harm to patients. Specifically, we suggest that CMS weight the catheter minimization measure two-thirds compared to one-third for the maximizing of AV fistulas.

4. KCP Supports the Inclusion of the NHSN Bloodstream Infection Measure as a Clinical Measure, as Long as CMS Does Not Use the ARM and Uses the Specifications as Previously Endorsed by the NQF.

In previous comment letters, KCP supported the inclusion of the NHSN Bloodstream Infection measure (NQF 1460) as a reporting measure. Our concerns about including it as a clinical measure related to the addition of the Adjusted Ranking Metric (ARM) and the lack of transparency, in the methodology and, in particular, the lack of validation, surrounding it. The NQF Renal Standing Committee initially recommended against endorsement of the modified NHSN Bloodstream Infection measure because of this lack of information and only recommended it without the ARM. We understand from discussions with CMS that the Agency does not plan to apply the ARM for PY 2019 (and we assume this decision should apply to prior years as well). To the extent CMS includes the previously endorsed NHSN Bloodstream Infection measure that does not include the ARM, the KCP supports its inclusion in the ESRD QIP.

5. KCP Recommends that CMS Work with the Kidney Care Community to Develop a More Appropriate Measure for the Bone Mineral Domain.

As noted in Section V.A.1., KCP remains concerned about the inclusion of the hypercalcemia measure in the ESRD QIP because of its limited clinical usefulness. Given that the

NQF Renal Standing Committee is recommending it for Reserve Status, we urge CMS to work closely with the kidney care community to develop a more meaningful and clinically appropriate measure to address our ongoing concerns with this measurement domain.

6. KCP Supports Efforts to Reduce Hospital Readmissions and Recommends Modifications to the Standardized Readmissions Ratio (SRR) Measure to Improve Its Actionability.

KCP recognizes the importance of measuring readmission rates in the context of assessing quality of care. We are pleased that, through the NQF process, CMS has agreed to exclude patients readmitted within the first one to three days following hospital discharge. As we have noted previously, hospitalization and readmissions data support this exclusion. 2011 Medicare claims data indicate that 17 percent of hospitalized ESRD patients had a readmission within three days following discharge, meaning the dialysis unit frequently did not have the opportunity to intervene and affect care prior to readmission. 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—again, 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 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. 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. Additionally, not all discharges are to home and a significant number of patients are readmitted before they receive care from a dialysis facility.

In addition, NQF set forth two additional endorsement stipulations that CMS has accepted. These are: (1) incorporating a number of clinical variables identified by the renal care community (such as sickle cell trait, angiodysplasia, myelodysplasia, diverticular bleeding, asthma) into the measure's risk model, and (2) making unadjusted readmissions data available to facilities in a more expeditious manner.

It appears that the measure specification modifications were not included in the specifications for the measure in the ESRD QIP. Therefore, we ask CMS to incorporate them for not only PY 2019, but also prior years in which the SRR measure is included.

In addition to these changes, which we applaud CMS for accepting, we also recommend that CMS make a few additional modifications to address concerns of the kidney care community. First, we appreciate the ongoing dialogue we have had with CMS about the importance of ensuring that the SRR focus on conditions that dialysis facilities have the ability to influence directly. We understand that we may not agree on all of these actions, but had understood the Agency to acknowledge that certain reasons for readmissions, such as automobile accidents, would be appropriate to remove from this measure. We recommend that the measure include admissions related to vascular access infections, fluid overload, and similar

conditions that reflect the care provided in dialysis facilities. In reviewing 2011 Medicare Claims, we identified that 27 percent of the admissions of dialysis patients are related to these types of conditions. There is clearly room for improvement based upon this analysis. Therefore, we encourage CMS to refine this measure to incentivize a focused reduction of hospital readmissions.

We also recommend that CMS align the SRR with the *Dialysis Facility Standardized Mortality Ratio (SMR)* and *Standardized Hospitalization Ratio* (*SHR)* measures. These measures include patients who have had ESRD for 90 days or more. We believe this criterion should also apply to the SRR and no reason has been identified to suggest that these measures should not be aligned on this point. Similarly, we would like to better understand whether the SRR should also be aligned with the *Hospital-Wide All-Cause Unplanned 30-Day Readmission Ratio* (NQF #1789). This measure excludes patients who have incomplete claims histories from the past year, but the proposed dialysis facility SRR does not. To assess the difference in these measures, it is necessary to have the 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. We ask that CMS provide this information so it is possible to determine whether there should be alignment across these measures.

We also seek clarification of the impact of the change of the specifications with regard to index hospitalizations. The SRR measure specifications submitted to NQF's 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." To better understand the impact of this change, especially on low volume facilities, we recommend that CMS 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.

In addition, we recommend that CMS revise the risk model to account for hospital-specific patterns and adjust for physician-level admitting patterns. As CMS has recognized in other settings, there is significant geographic variability in physician admission patterns. Adjusting for this situation as a random effects variable is not sufficient to account for these patterns. Similarly, the distance of a patient's home relative to the outpatient facility and to the hospital likely influences their care options and their utilization of care. The co-pay for transportation also may influence health utilization behavior. We suggest that CMS work with kidney care community to identify ways to appropriately adjust for these factors.

In sum, we look forward to working with CMS to address these concerns and improve the SRR for its use within the ESRD QIP.

7. KCP has concerns about the specifications of the Standardized Transfusion Ratio (STrR) and recommends several improvements.

KCP agrees that proper anemia management is a critical component of high-quality dialysis care. While we continue to have concerns about the ability of facilities to act upon the

results of the Standardized Transfusion Ratio (STrR), as currently specified, we recommend specific modifications that would greatly improve the measure.

As you are aware, the NQF Renal Steering Committee has raised concerns about the measure reflecting the transfusion practices and behaviors at the hospital level and not for dialysis facilities. The Committee also raised concerns about the potential for coding inconsistencies threatening the validity of the measure. Because of these concerns, the Committee has recommended against endorsing the measure.

The Committee is correct that because transfusions do not occur in the dialysis facilities, it is difficult for facilities to influence whether or not a patient receives a transfusion, but more importantly, facilities often do not know if a patient has received a transfusion. Providing patient transfusion data would help facilities know when transfusions occur and give them the opportunity to try to determine the reason for the transfusions. CMS should provide transfusion data directly to facilities on a quarterly basis by using Dialysis Facility Report calculations and the six-month lagged data file.

Data confirm the relevance of the NQF Committee's concerns about inconsistency in coding. In 2011-2012, short-term, critical access, and long-term hospitals administered 98.5 percent of transfusions in the inpatient setting and 82.9 percent 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. To address this issue, CMS should conduct an audit of the transfusion data to determine the extent of the problem and adjust the measure accordingly to address any problems it discovers.

In addition, the measure could be improved by incorporating hospital- or physician-related factors into the risk model. Because physicians independently or following hospital protocols make decisions about whether or not to transfuse a specific patient, it is important to account for the variability these factors create.

We also urge CMS, as part of the ESRD Measures Manual, to provide the microspecifications for the measure along with detailed flowcharts or computer codes to allow the public to replicate the mathematics used. Ideally, this information would be provided through rulemaking prior to adopting any measure as well.

Finally, we ask that CMS provide a clear and consistent definition of when patients are no longer considered ESRD and, thus, are excluded from the measure calculations. For example, it is important to ensure that all facilities define returning renal function, selecting hospice care/withdrawal from dialysis, or other patient choices affecting ERSD status the same way.

8. KCP Supports the ICH CAHPS Measure as a Reporting Measure and Urges CMS to Modify the Measure before Shifting to a Clinical Measure.

As described in Section III.B., KCP agrees that it is critically important to evaluate patients' experiences when receiving dialysis, and commends CMS for reincorporating the Qualifying Patient Attestations for the ICH CAHPS measure. As we noted above, 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.

Before shifting the ICH CAHPS survey to a clinical measure, KCP recommends that CMS to 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.[9] 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 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.

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[9] *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. December 2006.

9. KCP Supports the Inclusion of the Anemia Management and Mineral Metabolism Reporting Measures in the QIP and the Important Modifications to the Specifications.

KCP supports CMS's proposal to maintain both the anemia management and mineral metabolism reporting measures QIP measures. We are pleased that CMS will revise the mineral metabolism measure to include plasma as an acceptable substrate for PY2018 and recommend that this modification also be applied for PY 2017. As far as we can determine, there is no barrier that would prohibit this modifications from being implemented a year earlier. We also agree that it is important to continue monitoring Medicare ESRD patient mineral metabolism and hemoglobin levels. Finally, we applaud CMS for standardizing the exclusions for both reporting measures.

10. KCP Could Support the Pain Assessment and Follow-Up If CMS Provides Additional Modifications.

KCP recognizes that pain assessment should be part of the evaluation of every patient. The measure as currently specified does not distinguish between chronic and immediate pain. 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 distinguish between types of pain. 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 recommends that CMS clarify that this metric seeks to measure the facility's assessment and follow-up of immediate pain that relates to the care being provided in the dialysis facility.

11. KCP Supports *Clinical Depression Screening and Follow-Up*, Based on NQF 0418, but Emphasizes the Importance of Continued Progress to Improve it Through a Standardized ESRD Tool.

KCP is acutely sensitive to the importance of clinical depression in ESRD patients,[10] and has supported this measure in the broader context of the Comprehensive ESRD Care Initiative. We previously have been concerned about deployment as a facility-level measure for the QIP, however, because of the lack of a standardized ESRD tool. We are pleased to report that the Chief Medical Officers of many of the dialysis facilities have been working to identify a standardized tool that can be used to meet these measure requirements. KCP supports the current approach to use *Clinical Depression Screening and Follow-up* as a reporting measure and looks forward to working with the Agency to improve it when the tool becomes available.

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[10] Weisbord, SD, Mor, MK, Sevick 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.

12. KCP Supports in Principle the NHSN Healthcare Personnel Influenza Vaccination Measure, Based on NQF #0431, as a Reporting Measure, but Recommends Modifications to the Specifications and 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, but recommends modifications to the specifications before final implementation.

First, we note that CMS proposes that the performance period for this measure be defined as October 1 through March 31. KCP objects to these parameters and instead encourages the Agency to 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.*"[11,12] Penalizing providers when practicing according to established clinical guidelines is insupportable and could in fact 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.[13] Vaccine shipments typically begin in August,[13] and we believe the measure should be specified to allow for this fact.

Second, 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.

13. KCP Supports the Inclusion of an Ultrafiltration Rate Measure in the QIP, but Opposes the Use of the Proposed Measure and Supports NQF 2701, *Avoidance of Utilization of High Ultrafiltration Rate*.

KCP believes fluid management is a critical area to address through performance measurement, but opposes use of the proposed ultrafiltration measure in the QIP and instead strongly supports and recommends NQF 2701, *Avoidance of Utilization of High Ultrafiltration Rate* (developed by the Kidney Care Quality Alliance [KCQA]).

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[11] NHSN. *Healthcare Personnel Safety Component Protocol.* Available at: http://www.cdc.gov/nhsn/acute-care-hospital/hcp-vaccination/. Accessed July 25, 2015.
[12] NQF. *National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations.* Washington, DC:NQF;2008.
[13] CDC. *Key Facts about Seasonal Flu Vaccine.* Available at: http://www.cdc.gov/flu/protect/keyfacts.htm. Accessed July 25, 2015.

We note that the proposed CMS measure relies on a single data point per month, whereas NQF 2701 relies on an average across all treatments provided over the course of a week (*i.e.*, the week the Kt/V is performed). Relying on a single data point will disadvantage those facilities on a Monday/Tuesday draw, since patients typically have greater fluid at the first treatment of the week. KCQA documented in its submission to NQF that such facilities were indeed disadvantaged merely because of the timing of the sampling, thus raising questions about the CMS measure specifications' validity. A single data point also is easier to game.

The CMS measure also lacks a time component, which in contrast is specified in NQF 2701. This measure includes patients in the numerator only if they have an average dialysis time of <240 minutes for the calculation period. The inclusion of the time component is critical to avoid an unintended adverse consequence that could result from the cascading effect of extending an individual's treatment time, given the upper rate of fluid removal is limited by the measure. Specifically, if an individual goes beyond his/her stated treatment time such that the following patient must start later, the second patient is likely to expect and want treatment to end at the "usual" time and, thus, be under-treated. Including the time component is important to mitigate a very real potential for unintended harm to this "third-party" individual due to measurement-related actions for other patients.

The NQF Renal Standing Committee, in its recent review of both ultrafiltration measures, also supported NQF 2701 and did not support the CMS measure. While the NQF Committee acknowledged that high ultrafiltration rates and short dialysis session times are independently associated with increased morbidity and mortality, it noted that the time component strengthens the KCQA measure because it acts as a "safety valve" to the ultrafiltration component. The NQF Committee noted that the KCQA measure allows a second path to meet the dialysis goal and is, because of this, at the same time more patient-centric. In contrast, the CMS measure can address intradialytic weight gain only in terms of the ultrafiltration rate—*i.e.*, if a patient is unwilling or unable to extend the time of his/her session, there is no alternative way to meet dialysis goals for that patient for that session.

14. Influenza Immunization Is a Critically Important Component of Clinical Care in the ESRD Population; KCP Recommends that CMS adopt the NQF-endorsed NQF 0226, *Influenza Immunization in the ESRD Population,* Rather than the Proposed Full-Season Influenza Vaccination of ESRD Patients in the QIP.

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. However, we oppose use of the proposed *Full-Season Influenza Vaccination of ESRD Patients* measure because it is not NQF-endorsed, not harmonized with the standardized specifications from NQF's 2008 immunization report and has not been tested. We strongly recommend instead adoption 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.

With respect specifically to the specifications for the proposed CMS measure, we note the measure 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.

CMS notes in the Proposed Rule that it has determined that NQF 0226 is not appropriate to use as the basis for a reporting measure because it excludes patients for whom data during the flu season are incomplete—potentially excluding patients who died from influenza, but might not have died had they been vaccinated. KCP notes, however, that NQF 0226 has no exclusions per se. In an April 2013 response to a question on implementation from a CMS contractor, KCQA, the measure developer noted that the measure excludes *un*vaccinated patients who die prior to March 31; patients who die prior to March 31 who ***were*** vaccinated are included. KCP believes that this operationalization construct is both appropriate and important, so as to not unfairly penalize facilities for unvaccinated patients for whom time remained to meet the measure specifications.

To assess the validity of CMS's concern regarding patients who died from influenza, KCP reviewed influenza-related mortality rates and have determined that a maximum of 0.167 percent of dialysis patients might not be captured by NQF 0226 because of the exclusion of unvaccinated patients who die prior to March 31. In reality, this number is likely to be significantly smaller, given we erred towards the maximum rate and the likelihood that a proportion of patients suffering a flu-related death will have received the vaccine prior to death, and would thus be captured in the NQF 0226 numerator.[14,15,16,17,18] We posit that the CMS rationale for not using the NQF-endorsed 0226 is unfounded. We strongly recommend, therefore, that CMS adopt the fully tested and NQF-endorsed measure, 0226.

We recognize that measurement specifications, like evidence, evolve. However, we believe CMS and the kidney care community are best and most efficiently served if CMS

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[14] Establishing flu-related mortality rates is difficult for a number of reasons—e.g., states aren't required to report adult flu cases or deaths to the Centers for Disease Control and Prevention (CDC), secondary complications (e.g., bacterial pneumonia) are frequently listed as the cause of death. Risk-specific flu-related mortality rates are even more difficult to establish and are not published as such. KCP extrapolated from the CDC's general population data to estimate flu-related deaths in the ESRD population: During 1976-2007, CDC estimates an overall average of 23,607 influenza-associated deaths in the U.S. per year (range: 3,349 in 1986-87 to 48,614 in 2003-04). The average annual rate of influenza-associated death was 9.0 deaths per 100,000 population (range: 1.4-16.7).[16] Pulmonary infectious mortality is estimated to be ten-fold higher in the ESRD than in the general population.[17,18,19] Using these data, the average influenza-related annual mortality rate can be estimated as 90 deaths per 100,000, or 0.09% of dialysis patients. Alternatively, using the *highest* mortality rate seen in the general population between 1976 and 2007 (16.7 deaths per 100,000), the flu-related mortality rate in the dialysis population would be 167 deaths per 100,000, or 0.167%.

[15] CDC. Estimates of Deaths Associated with Seasonal Influenza—United States, 1976-2007. *MMWR.* 2010;59(33):1057-1062.

[16] Gilbertson D, Unruh M, McBean A, Kausz A, Snyder J, Collins A. Influenza vaccine delivery and effectiveness in end-stage renal disease. *Kidney Int.* 2003;63(2):738-743.

[17] Gilbertson D, Guo H, Arneson T, and Collins A. The association of pneumococcal vaccination with hospitalization and mortality in dialysis patients. *Nephrol Dial Transplant.* 2011;0:1-5.

[18] Sarnak M and Jaber B. Pulmonary infectious mortality among patients with end-stage renal disease. *Chest.* 2001;120:1883–1887.

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.

Finally, we note that the proposed measure has not been established as a valid and reliable indicator of quality. The proposed influenza measure was submitted to NQF's MAP for consideration for use in Federal Programs during its 2013-14 cycle. At that time, KCP noted that this was one of seven measures being proposed for use in the ESRD QIP that could not be adequately evaluated because of a lack of reliability and validity testing information. CMS has posited to MAP that reliability and/or validity testing is not applicable or necessary because the measures are "reporting measures." As we have noted elsewhere to CMS[19], KCP is particularly troubled by this assertion. NQF requires testing data before it will consider measures for endorsement because it considers the criterion "Scientific Acceptability"—*i.e.*, validity and reliability—to be an essential component of a measure's properties. NQF describes reliability and validity testing at either the data element level or the level of the computed measure score, as follows:

> Reliability of data elements refers to repeatability and reproducibility of the data elements for the same population in the same time period. Validity of data elements refers to the correctness of the data elements as compared to an authoritative source. Reliability of the measure score refers to the proportion of variation in the performance scores due to systematic differences across the measured entities (or signal) in relation to random error (or noise). Validity of the measure score refers to the correctness of conclusions about the quality of measured entities that can be made based on the measure scores (i.e., a higher score on a quality measure reflects higher quality).

KCP upholds that the mere fact that data elements must be reported does not mean they can be reliably reported; it is incumbent upon measure developers to demonstrate this. As important, 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. The proposed measure fails to address either of these criteria because it has not been tested.

B. KCP Supports the Proposed Performance Period; the Proposed Performance Standards, Achievement Thresholds, and Benchmarks; Proposed Scoring Methodology; and Proposed Payment Reduction Methodology for the PY 2019 ESRD QIP.

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 PY 2017 and PY 2018 policy of setting the

[19] 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.

Performance Standard, Achievement Threshold, and Benchmark at the 50th, 15th and 90th percentile respectively in PY 2019. We also support the continuation of the PY 2017 and PY 2018 policy for determining payment reductions, including the process for setting the minimum Total Performance Score (mTPS).

In addition, we support using CY 2017 as the Performance Period for PY 2019. However, we recommend that CMS modify the Performance Period for the Full-Season Influenza Measure, consistent with our comments above. Specifically, if the vaccine is available before October 1, 2016, then the Performance Period should begin when the vaccine is available.

C. KCP Recommends that CMS Refine the Criteria for Establishing the Weights for the QIP Measures.

KCP supports the Agency's effort to establish criteria for determining the weights of the QIP measures. We continue to support the criteria CMS has set forth, but recommend that CMS include three additional criteria.

- **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 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, especially in terms of 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.

D. KCP Continues To Recommend that CMS Increase the Minimum Number of Cases to 26 and Supports the Proposed Performance Period Exclusions for the Ultrafiltration and Full-Season Influenza Measures.

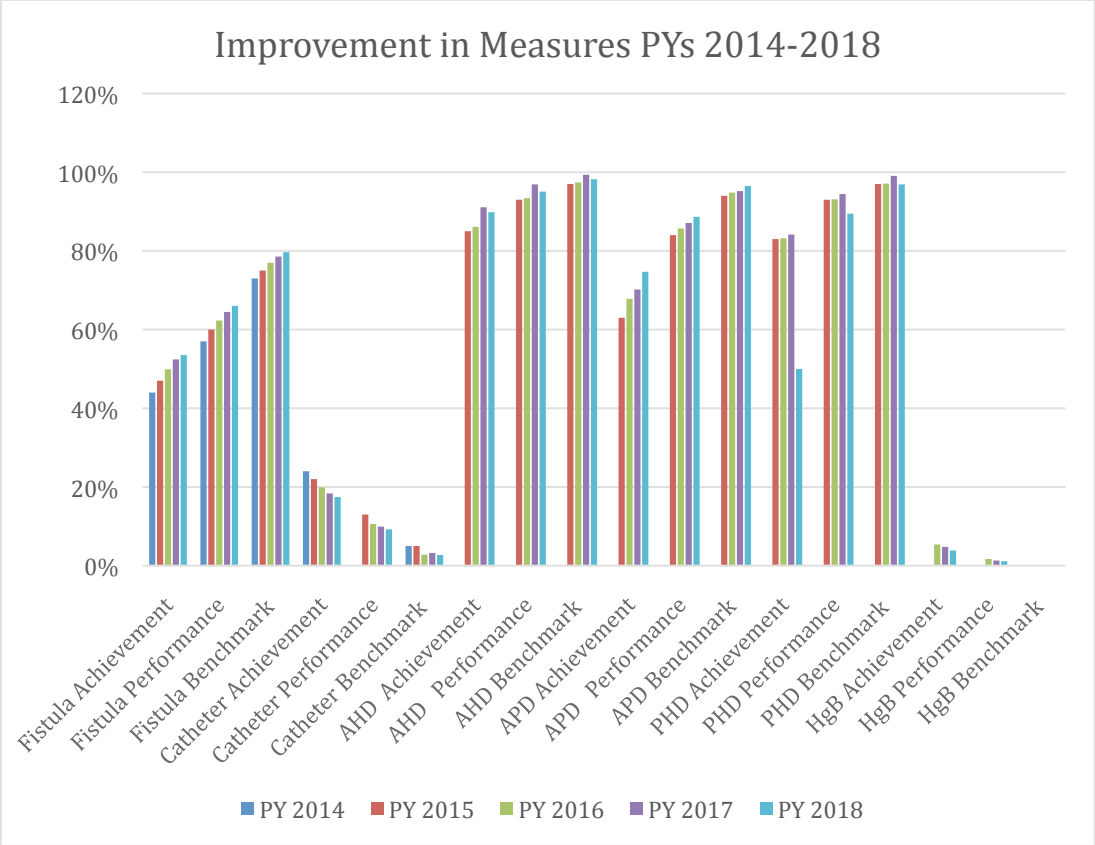
KCP continues to recommend that setting the minimum number of cases at 11 is too low to avoid anomalous results. We suggest that CMS align the minimum number of cases for the QIP with the policies used by commercial and managed care value-based purchasing programs. These plans rely upon a minimum of 26 cases.

KCP appreciates that CMS recognizes the difficulties that facilities with certain CCN dates may have in meeting the requirements of the Full-Season Influenza Vaccination and Ultrafiltration Rate reporting measures. We agree that it is appropriate to exclude facilities with a CCN Open Date after January 1, 2017, from receiving a score on the Full-Season Influenza Vaccination reporting measure. We also support not scoring facilities with a CCN Open Date after July 1, 2017, for the Ultrafiltration Rate reporting measure.

VI. KCP Questions the Need to Move the Achievement Threshold from the 15th to the 25th Percentile of National Performance.

KCP does not believe that it is necessary to move the Achievement Threshold from the 15th to the 25th Percentile. The current policy of setting Achievement, Performance and Benchmarks at 15th, 50th and 90th percentile respectively is driving improvement among dialysis partners across all measures, which is the goal of the QIP. The chart below illustrates that under current policy there has been improvement in all measures from PY 2014 through 2018.[20] In particular, there has been consistent improvement in the Achievement Threshold, suggesting that lower performers have ample motivation to improve their scores. Given the evidence that the current benchmarks are working well, we would urge CMS to maintain consistency in the QIP program design and maintain the Achievement Threshold at the 15th percentile.

[20] For most of the measures, this means increasing scores. For the two measures where lower scores are better (Hypercalcemia and Vascular Access by Catheter), the trend over time is towards lower numbers, which indicates improvement.



Furthermore, we are concerned about changing the Achievement Threshold at this time because the inclusion of the new standardized ratio measures in the QIP may create unexpected effects in the QIP scoring. For measures such as the Standardized Transfusion Ratio and the Standardized Readmission Ratio, decisions to readmit patients and transfuse them are generally not made by the dialysis facility. Consequently, facilities have limited ability to drive improvement, or to control how their own quality efforts affect the patient outcomes in the standardized ratio measures. Many facilities may initially find themselves toward the lower end of the performance spectrum and need the opportunity to identify and implement effective quality strategies. Therefore, KCP believes that CMS should wait to see how the current QIP scoring affects facilities, and how facilities respond, before adding new uncertainty by moving the Threshold up to the 25th percentile.

VII. KCP Agrees that It Is Important To Include ESRD in Efforts to Establish Interoperability Standards.

KCP supports efforts to eliminate barriers to interoperability among all health care providers. It is important to include ESRD elements in these efforts. KCP members continue to work to develop health information exchanges and to add ESRD elements to the C-CDA standard for Meaningful Use Electronic Health Record certification. We look forward to continuing to with the Department of Health and Human Services, as well as CMS, to ensure that the ESRD program is included in health information exchange initiatives.

VIII. Conclusion

KCP appreciates the opportunity to provide comments on the ERSD 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 if you have any questions.

Sincerely,

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

Appendix A: KCP Members

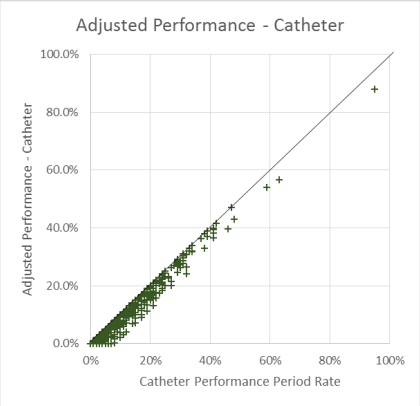
AbbVie
Akebia Therapeutics, Inc.
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
AstraZeneca
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners, Inc.
Dialysis Patient Citizens
Dialysis Clinic, Inc.
Fresenius Medical Care North America
Fresenius RTG
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
Renal Physicians Association
Renal Ventures Management, LLC
Rogosin Institute
Sanofi
Satellite Healthcare
U.S. Renal Care

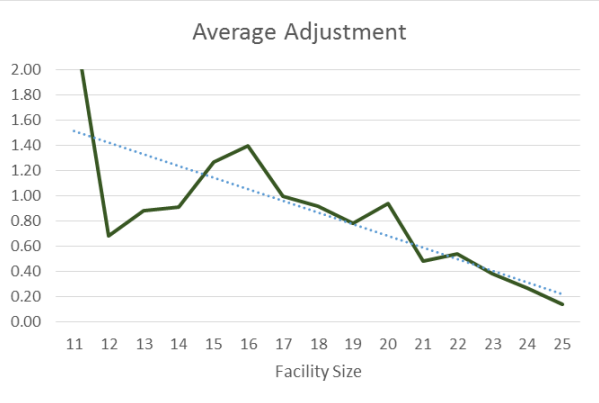
Appendix B:
Analysis of Different Methods of Small Facility Adjustment for QIP Measures

Catheter Measure

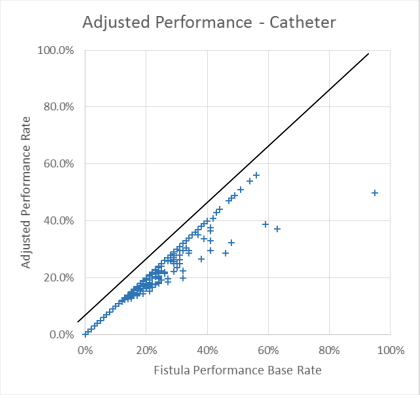
Note: Lower performance is better for this measure. Therefore, the SFA would adjust performance down, not up. The QIP measure score would still be adjusted up.

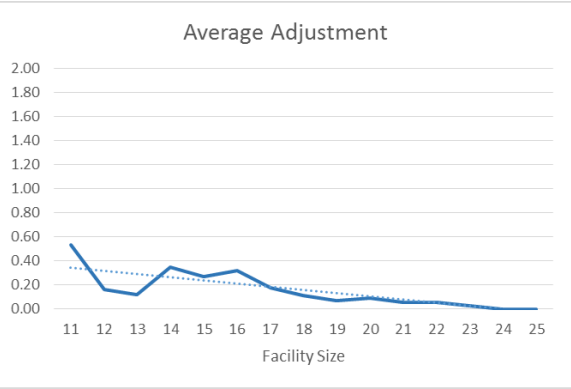
Current SFA



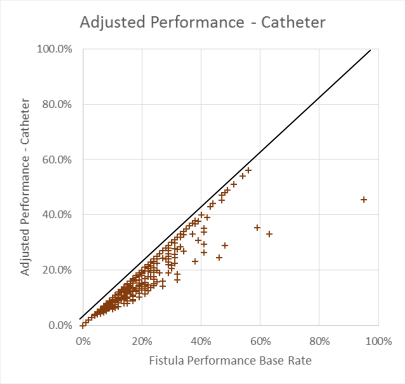


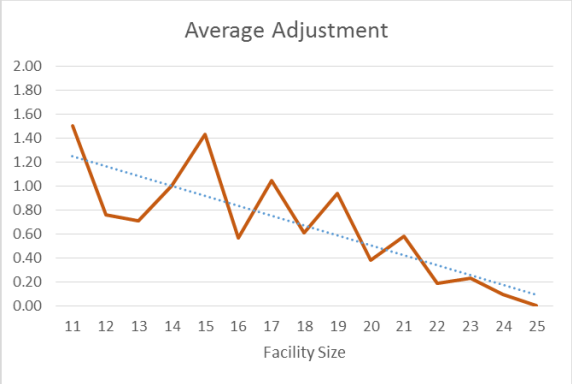
Proposed SFA





KCP Alternate SFA

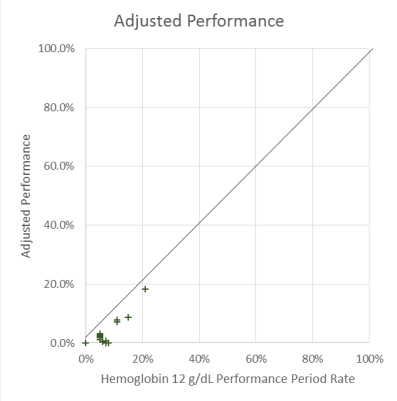


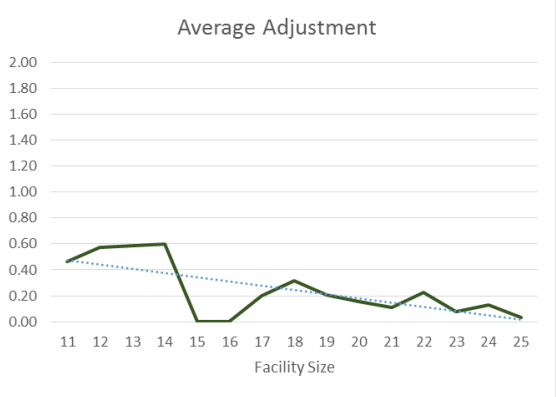


Hypercalcemia Measure

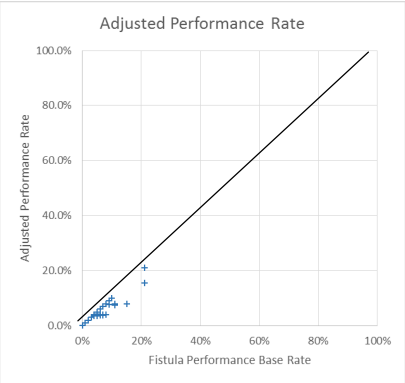
Note: Lower performance is better for this measure. Therefore, the SFA would adjust performance down, not up. The QIP measure score would still be adjusted up.
Note: The topped-out performance distribution for this measure creates anomalous results under most scoring models.

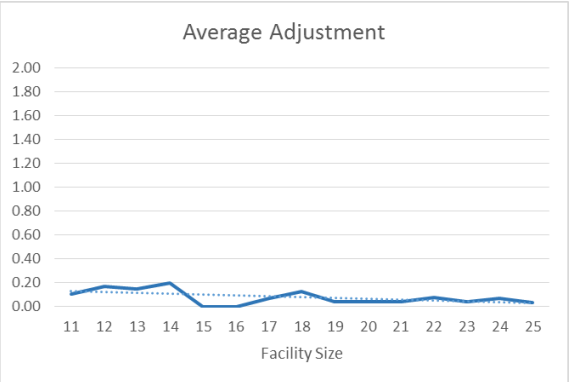
Current SFA



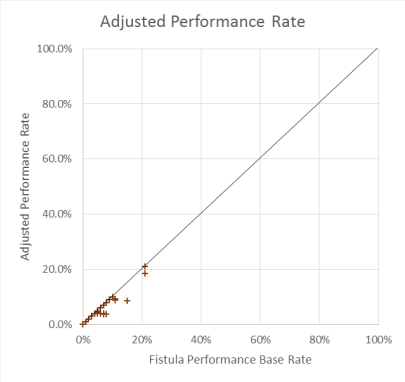


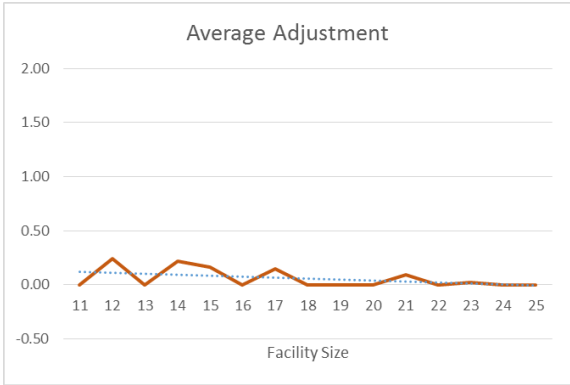
Proposed SFA





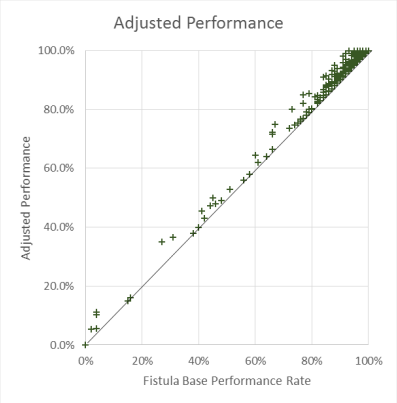
KCP Alternate SFA

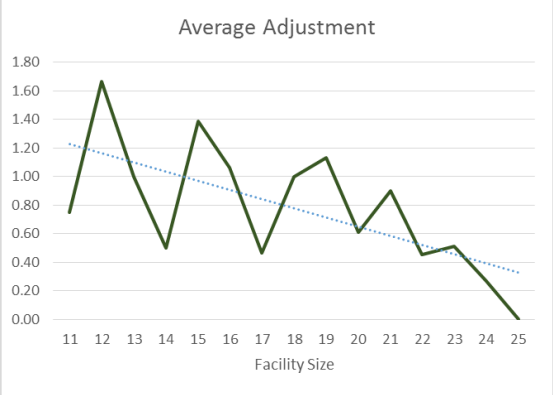




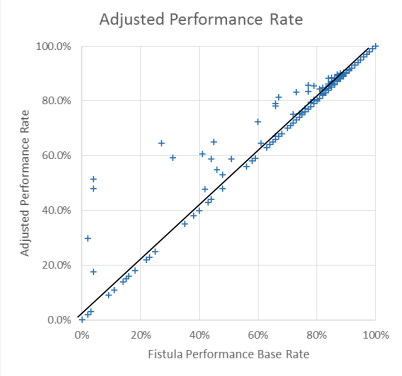
Adult Kt/V Hemodialysis Adequacy Measure

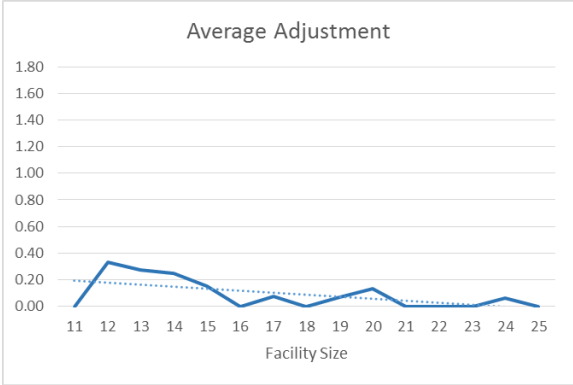
Current SFA



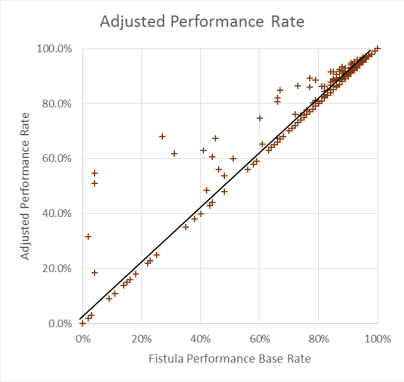


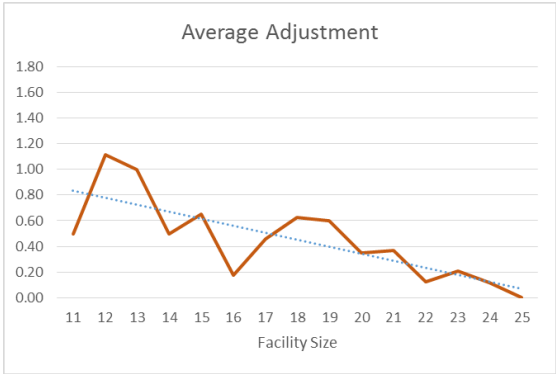
Proposed SFA





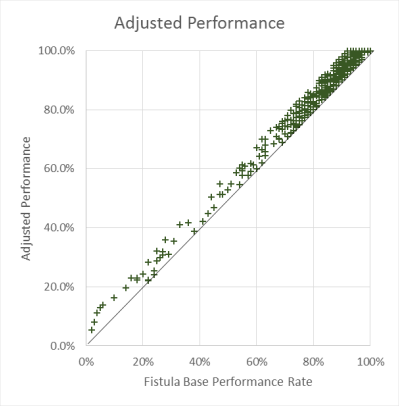
KCP Alternate SFA

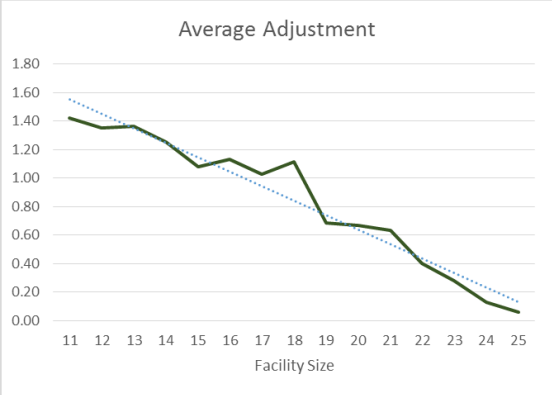




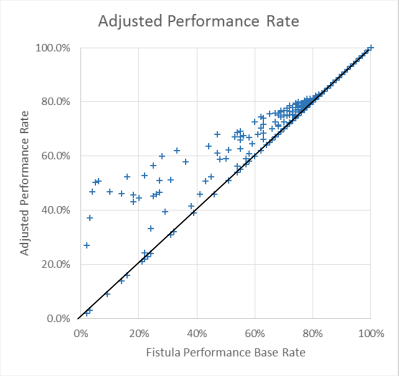
Adult Kt/V Peritoneal Dialysis Adequacy Measure

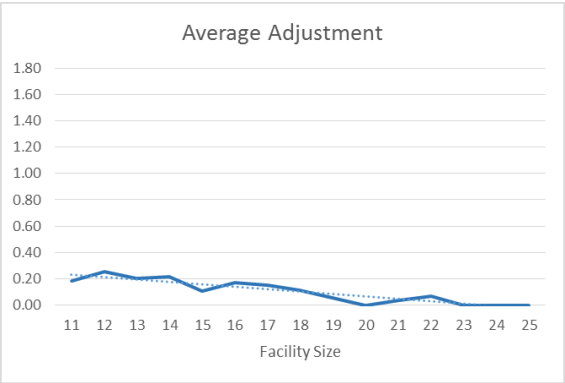
Current SFA





Proposed SFA





KCP Alternate SFA