



August 10, 2018

The Honorable Alex M. Azar, II
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

Kidney Care Partners (KCP) appreciates the opportunity to provide comments on the Proposed Rule entitled “End-Stage Renal Disease Prospective Payment System, 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 (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS” (Proposed Rule).¹

KCP is an alliance of members of the kidney care community that includes patient advocates, dialysis care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with both CKD and irreversible kidney failure, known as ESRD.²

In this letter, KCP focuses on the ESRD Quality Incentive Program (QIP) proposals; the ESRD PPS and recommendations on home dialysis and transplant are discussed in a separate letter. Specifically, in this letter KCP:

- Supports focusing the ESRD QIP on Meaningful Measures and Recommends Streamlining the ESRD QIP and Dialysis Facility Compare (DFC) to Reduce Administrative Burden and Improve Transparency for Patients, Caregivers, and Consumers.
- Reiterates our support for the effort to assess and account for Social Risk Factors in the ESRD QIP Program through adjusters and other mechanisms.
- Recommends that CMS revise the proposed regulatory text to align with the statute and current policies.
- Generally supports the Retirement Factors outlined in the Proposed Rule, but recommends refining them, as described below.
- Seeks clarification about the projected Increase in QIP Payment Penalties.

¹83 *Fed. Reg.* 34304 (July 19, 2018)

²A list of KCP members is provided in Appendix A.

- Recommends changes to the PYs 2021 and 2022 Measures Sets based on our previous comments, consistent with the recommendations to streamline the QIP and DFC, as well as recommendations related to the specifications.

KCP is deeply troubled by the proposed weighting of the QIP measures and has questions about the structural issues, which we will provide in a follow-on letter.

Finally, we appreciate the request for information and reiterate previous comments recommending that CMS use the conditions of participation/conditions for coverage or other tools to address the difficulties dialysis facilities experience when seeking information about patients when they are or have been hospitalized.

I. KCP supports focusing the ESRD QIP on Meaningful Measures and Recommends Streamlining the ESRD QIP and Dialysis Facility Compare (DFC) to Reduce Administrative Burden and Improve Transparency for Patients, Caregivers, and Consumer

KCP is pleased that CMS has launched the Meaningful Measures Initiative and its purpose of “reduc[ing] the regulatory burden on the healthcare industry, lower health care costs, and enhance[d] patient care.”³ We share the aim CMS has outlined for the Meaningful Measures Initiative and provide specific comments recommending “the highest priority areas for quality measurement and quality improvement in order to assess the core quality of care issues that are most vital to advancing”⁴ the kidney care community commitment and efforts to improve patient outcomes. In developing this list, we reviewed and considered the objectives CMS has set forth in the Proposed Rule:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program’s statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as electronic clinical quality measures);
- Significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

In developing our recommendations, KCP also applied these principles to the broader structure of the ESRD quality programs, particularly the relationship between the

³83 *Fed. Reg.* at 34334.

⁴*Id.*

ESRD QIP, which is mandated by statute, and the Dialysis Facility Compare (DFC) website that now includes star ratings. KCP, patient advocates, MedPAC, and others have repeatedly articulated concerns about the overlap and inconsistencies of these programs. The current structure has led to patients not trusting or using the information, increased burden on providers, and inconsistent requirements that can negatively impact patient care. Thus, we also provide our recommendations on Meaningful Measures in the context of restricting the ESRD QIP and DFC so that they fulfill the purposes the Congress and CMS had when establishing them.

Specifically, KCP recommends that CMS clarify that the ESRD QIP is a pay-for-performance (P4P)/value-based purchasing (VBP) program, which was the intent of the Congress when it established the program. CMS has also repeatedly clarified that DFC is meant to be a public reporting program. While both are quality accountability programs, the latter is best described as a quality assurance program. Yet despite these clear distinctions, the current relationship between the two programs is extremely confusing and unnecessary.

To address this problem and, most importantly, to empower patients and provide them with reliable tools they can use to make decisions about their health care, KCP recommends that CMS separate the programs clearly by using different measures in each program, using the star ratings based on the ESRD QIP penalty distribution, and improving the functionality of the DFC website.

The ESRD QIP would include a parsimonious set of measures consistent with the recommendations below. The public reporting certificates required by the statute should be returned to the previous format that includes meaningful information, not just the number that provides patients with no specific information on the measures. If CMS continues to promote star ratings, the stars should be incorporated into the ESRD QIP certificates and be set using the QIP penalty distribution. MedPAC also has supported eliminating the star ratings on DFC.⁵ All measures should be valid, reliable, feasible, and be NQF-endorsed.

The DFC would be a public reporting, quality assurance, program. This return to its purpose would in no way diminish the program, rather it would allow DFC to achieve its intended purpose. Public reporting is considered by NQF and others to be an

⁵MedPAC, Comment Letter to CMS on ESRD PPS CY 2017 (July 2016) (“In our August 15, 2014 comment letter to your predecessor, the Commission questioned why CMS believed it necessary to develop a second quality system for dialysis facilities. We also raised concerns that beneficiaries and their families might be confused if a facility’s star and QIP scores diverge, which could occur because the measurement systems use different methods and measures to calculate a facility’s performance score. The Commission believes the ESRD quality measurement process needs greater simplicity and clarity. Moving to one quality measurement system that is based on a reasonable number of outcomes-based performance measures would be easier to understand for beneficiaries and their families and would reduce administrative costs for providers and CMS.”)

accountability program, so measures publicly reported should not be viewed as “second class.” Measures that are important, but not in the QIP, should be included in DFC. To improve the patient experience, the DFC website should be improved in a way that allows patients and caregivers to understand the site and use it more often. Specifically, we recommend that CMS:

- Allow patients to compare facilities using multiple measures at the same time, consistent with the recommendations of the TEP, rather than the current approach of being able to compare facilities using only one measure. This capability is standard in many online tools.
- Establish a true mobile experience for patients that allows them to use their mobile devices to access the system.
- Engage with all in the kidney care community to encourage its use among stakeholders.

While the DFC would report on measures that are not in the QIP, it could list the QIP measures – using the same specifications, benchmarks, and results. As you know, KCP has been discussing with CMS staff that the specifications for the “same” measures, but different programs, do not align, leading we believe to anomalies in penalties and star ratings. Having specifications for the “same” measure that differ based on the program is confusing and unduly burdensome. This would allow patients and caregivers to compare all the measures in one easy place and eliminate the confusing inconsistencies among the programs. Because star ratings are more aligned with the Total Performance Score requirements of the QIP, they should be used for the QIP TPS, while the DFC should provide a more detailed and comprehensive assessment of facilities that can be accessed in a manner that allows users to tailor the results to their individual needs.

Once the purpose of the two programs is clearly delineated, the measures used in each program should be refined. First, all measures in the programs must be valid, reliable, and feasible and meet the scientific acceptability criterion for measure endorsement used by the NQF. While we understand that the statute allows CMS to add a measure to the QIP if there is no existing measure in a domain that has received NQF endorsement, if there is an NQF-endorsed measure it must be used.⁶ This authority does not allow CMS to adopt a measure that NQF has rejected even if there is no endorsed measure in the domain. The Congress provided flexibility to CMS to adopt measures when a gap existed,⁷ but it did not authorize the use of rejected measures or measures that do not meet the basic endorsement criteria. Reading the statute to allow such authority would be

⁶42 U.S.C. § 1395rr(h)(2)(B)(i).

⁷*Id.* at § 1395rr(h)(2)(B)(ii).

inconsistent with the provision that requires the use of NQF-endorsed measure when available and ignores a basic tenant of statutory interpretation.⁸

Based upon the measures currently included in the two programs and measures under current development, KCP recommends that CMS use the following measures for the ESRD QIP, with an important caveat. Specifically, if there is no measure that has been endorsed in the domain or the measure currently being used has been rejected by the NQF, CMS, working with KCP and the kidney care community, should prioritize addressing the problems with the existing measure and refine it or develop a new measure that would meet the NQF criteria and submit the measure to NQF for endorsement. Once endorsed, it would be added to the ESRD QIP or the DFC.

Even with this bifurcated approach, CMS should not simply create more and more measures. In brief, each program should contain a parsimonious set of measures about which performance among facilities can be distinguished, that measure facility action – not that of other providers – and that matter to patients.

A. QIP Measure Recommendations

Please note for a full discussion about recommendations regarding the specifications of these measures, please see Sections VI.A., VII.A., and Appendices B and C.

As CMS recognizes, too many measures in any P4P or VBP program can be unduly burdensome on providers and dilute the impact of important measures, no matter the weighting scheme, so that patients can no longer distinguish performance. As we have discussed, CMS should reduce the measures in the ESRD QIP so that when patients and caregivers see the TPS, they can easily understand how the measures are driving the overall performance of the facility. Reducing the measures to those that drive critical aspects of care for which there is a gap in performance will incentivize facilities to devote resources to the measures that matter the most in improving patient outcomes. Because the Congress established the ESRD QIP to create such incentives, it is important that the measures used in the program reflect that intent.

In making these recommendations, the KCP spent several months with a cross-sectional work group of our members. All voices of the community were represented – patients, facilities, physicians, nurses, technicians, manufacturers, and suppliers. This group carefully reviewed the reports from the various CMS quality and measure development technical expert panels (TEPs), comments from non-KCP members, recommendations from MedPAC, and the CMS Meaningful Measures Initiative, as well as

⁸See *American Nat'l Red Cross v. S.G.*, 112 S. Ct. 2465, 2472 (1992) (relying upon the statutory canon of construction that prohibits interpreting a provision in a way inconsistent with the policy of another provision of the same statute).

policies and measures used in other Medicare P4P/VBP programs. As a result of this work, KCP recommends that CMS use the following measures in the ESRD QIP.

- **Standardized hospitalization rate measure**
 - The current ratio measure should be abandoned. A true risk-standardized rate measure should be developed. CMS can start with the current numerator and denominator, and build a valid risk model from there. CMS should eliminate the manipulation of the current ratio, which merely applies a multiplication factor to convert the ratio into a rate.
 - CMS should target the measure to admissions that are within the control of dialysis facilities, focusing on “avoidable” hospitalizations—i.e., avoidable because the measure focuses on reasons for admissions that can be stopped with appropriate medical intervention by the facility. There is no reason to hold dialysis facilities responsible for hospitalizations out of their control, when other providers have more targeted measures. While an all-cause measure may make more sense in a hospital or broader health care setting that treats patients for multiple conditions, dialysis facilities provide a single service – dialysis treatments – and should be held accountable for what they can control. CMS has been testing a similar measure for skilled nursing facilities through its innovation center.⁹
 - Assessment of standardized ratio measures of hospitalization (as well as mortality and readmission) has demonstrated that such standardized measures are highly imprecise. For example, the standardized hospitalization ratio is estimated so imprecisely that nearly three quarters (74.7 percent) of facilities have confidence intervals that span from the top to the bottom quintiles of overall performance. Put simply, the imprecision makes it impossible to determine if an individual facility is among the best or the worst performing facilities. Such consideration would apply equally to standardized ‘rates’ (the currently reported metrics) which are derived as scaled up versions of their corresponding standardized ratio. A better approach would be to simply develop an actual risk-standardized rate rather than try to convert the existing ratio to a rate.
 - KCP continues to recommend development of true risk standardized rates (not the CMS “conversion factor” rates). As we have noted in the preceding bullet, the ratios are highly imprecise and make it impossible to distinguishing quality among facilities. Penalizing facilities based on scores that do not have meaningful differences, as we have just described, is inappropriate.

⁹See <https://innovation.cms.gov/initiatives/rahnfr-phase-two/>.

- **Standardized readmissions rate measure**
 - Like the hospitalization measure, the current readmissions ratio measure should be abandoned and a true risk-standardized rate should be developed, as noted above.
 - Again, as previously noted, CMS should target the measure to re-admissions that are within the control of dialysis facilities and focus the measure on “avoidable” readmissions—*i.e.*, avoidable because the measures focus on reasons for readmissions that can be stopped with appropriate medical intervention by the facility.
 - The concerns with the confidence interval noted above apply here as well.
- **Catheter > 90 Days Clinical Measure**
 - The current catheter > 90 days measure should be maintained as is, but the VAT topic would be eliminated.
 - Clinical consensus is that one of the most important factors in dialysis patient outcomes is the removal of a catheter after 90 days. While the placement of a fistula often is preferred, it is not the medically appropriate choice for all patients, including a fistula and/or graft measure only dilutes the impact of the removal of catheter measure in the TPS. Adopting it alone would appropriately emphasize the importance of removing catheters.
- **Bloodstream infection measures**
 - While KCP supports having a bloodstream infection measure, it needs to meet the scientifically acceptable measure development criteria.
 - The two current measures, NHSN Dialysis Event Reporting Measure and Infection Monitoring: National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Patients Clinical Measure, should be revised to include a single, valid and reliable BSI outcomes measure.
 - As discussed in greater detail in KCP’s 2016 and 2017 comment letters and articulated by several members of previous TEPs, the current outcome measure is not valid and has produced errant results. Retaining it provides patients and caregivers with inaccurate information that may lead to medical decisions that are contrary to their goals. The NHSN BSI Measure is inappropriate as a clinical measure because it is not valid, as shown by the measure developer, CDC’s et al. own research, and CMS’s own data. It is also unreliable for facilities with small census populations. CMS has stated that its review shows that as many as 60-80 percent of dialysis events may be

under-reported with the NHSN BSI measure. We have heard during TEP meetings that this amount now might be slightly lower, but even at half this value, it still remains unacceptably high. The high under-reporting rate associated with this measure demonstrates that the measure is simply not a valid measure. A lack of validity means that we cannot be certain that the measure results in scientifically acceptable findings. Making sure that measures are valid in the context of public reporting and value-based purchasing is essential to the success of these 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. In addition, if the measure is not producing valid findings, it does not help patients who are trying to use measures to make informed decisions about their care.

- The Dialysis Event Reporting Measure specifications now incorporate the reporting of several subjectively interpreted signs of infection (*e.g.*, swelling, redness). This expansion of the reporting protocol is highly subjective, burdensome, and does not contribute to the measure's underlying premise—to identify BSIs verified by positive blood cultures. These modifications will not serve the purpose of reducing BSI events.
- CMS should make the development of a valid and reliable measure that meets the NQF endorsement criteria a top priority for its work.
- **Patient Experience of Care: In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Clinical Measure**
 - This measure should be revised along the lines KCP has previously recommended and as outlined in Appendix B.
 - A home and pediatric CAHPS survey should be established as well.
 - With respect to changes in the ICH CAHPS specifications, KCP seeks clarification on the proposed elimination under Additional Information: "Missing data are not included in the calculations. Only data from a 'completed' survey are used in the calculations." If CMS means that the elimination of the completed survey requirement permits the use of data wherein only global ratings questions are answered or only all questions pertaining to a composite are answered, KCP opposes this change. KCP recognizes the potential to increase sample size in this manner, but KCP has on multiple occasions proposed administering the instrument by domains (Appendix B) in a manner that both reduces burden and maintains the scientific integrity of the testing. An approach that merely increases response rate by accepting answers from randomly incomplete surveys calls

into question validity and introduces cherry-picking of questions and domains. Again, KCP supports burden reduction and increased sample sizes, but not at the expense of scientific acceptability.

- **Anemia management measure**

- The current two measures in this domain Standardized Transfusion Ratio (STrR) Clinical Measure and Anemia Management Reporting Measure should be replaced with a Hgb < 10 g/dL measure. While it will be necessary to develop updated specifications, exclusions, and business rules, CMS has developed a similar measure several years ago that would be an appropriate starting point. We are aware such a measure was not endorsed by NQF, but believe NQF's updated evidence algorithm provides a path for its consideration anew.
- A lower hemoglobin measure is preferable as an outcome measure to a reporting measure. Most importantly, this measure is actionable by physicians and will have a direct and positive impact on an issue of critical importance to patients.
- It also is a better measure than the STrR because facilities and physicians have access to patient hemoglobin data in the facility, whereas they do not have access to STrR data. ; moreover, it is actionable by physicians and will have a direct a positive impact on an issue of critical importance to patients. Additionally, we have identified a significant validity issue with the STrR data since the ICD-9 to ICD-10 conversion. KCP has historically been concerned about under-counting and has documented that different coding practices for transfusions leads to under-reporting (Appendix C). Put simply the STrR's validity is in further question due to increased under-reporting by hospitals after the switch to ICD-10.
- Overall, we have found that for the STrR measure, 545 of 4,541 of hospitals (12.0 percent) had an estimated reduction in transfusion coding >80 percent after the ICD-10 conversion, and 979 of 4,541 hospitals (21.6 percent) had an estimated reduction in transfusion coding >50 percent. As the technical appendix documents, such reductions occur for both non-critical access and critical access hospitals and are geographically widespread.
- While there is currently a downward trend in transfusion utilization in the United States, it defies logic that such a significant proportion of hospitals would reduce their transfusions by 80 percent, or even 50 percent after the conversion to ICD-10. Rather, we believe the original concern regarding under-reporting has been exacerbated. **Because there is no requirement that the ICD-10 procedure or value codes be**

used for a facility to be paid, valid transfusion claims that include only revenue codes will be missed by the STrR. With the switch to ICD-10 codes, we hypothesize that even more hospitals are using only revenue codes, and no accompanying ICD-10 procedure or value codes, which are required for the STrR. Dialysis facility performance that may appear to have drastically improved on the STrR (fewer transfusions), may in fact solely be due to hospitals not including the ICD-10 codes specified by the measure. Conversely, facilities associated with hospitals that use ICD-10 and revenue codes appear to perform poorly.

- Further to this point, the largest hospital by volume with a >80 percent apparent reduction in transfusion was a facility in the Northeast. In the last year before ICD-10-PCS and the first year after ICD-10-PCS, a blood transfusion occurred during 10.0 percent and 0.1 percent of hospitalizations, respectively. A dialysis facility (or facilities) associated with this hospital will show a significant improvement in the StrR due to the ICD-10 implementation and change in the hospital's reporting practices.
 - In summary, the STrR's validity is in question as well due to the under-reporting by hospitals after the switch to ICD-10. A review of the claims suggests that a substantial percentage of hospitals simply stopped including ICD-10 procedure codes for blood transfusions during hospitalizations, making it now impossible to determine if a transfusion has occurred.
- **Serum Phosphorous**
 - KCP supports maintaining the serum phosphorous measure as part the QIP and eliminating the hypercalcemia measure (as described below). Physicians rely upon the serum phosphorous measure to make clinical decisions.
 - We understand that the Agency must comply with the Protecting Access to Medicare Act (PAMA). To this end, the serum phosphorous measure is a more appropriate measure to meet the statutory requirement than the hypercalcemia measure.
 - **Transplant measure**
 - KCP agrees that it is important to have a transplant measure in the ESRD QIP. However, the two current measures – Percentage of Prevalent Patients Waitlisted (PPPW) and Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis patients (SWR) – are not appropriate because NQF has recommended against endorsement. In addition, facilities do not have control over how the transplant waitlists work, as KCP has commented in the past, so the measures are not actionable.

- Regarding the specifications for the SWR, we note that during the NQF Renal Standing Committee's consideration of the SWR in June 2018, the Committee discussed whether a patient with a previous transplant was excluded. CMS responded in the affirmative. Our impression is that this satisfied the NQF Committee. The specifications proposed for the QIP, however, eliminate this exclusion. We request justification for the modification of this exclusion.
- CMS should prioritize developing an appropriate transplant measure that is actionable by dialysis facilities. A measure that recognizes what is actionable by facilities would better support the Meaningful Measures Initiative priority area of increased focus on effective communication and coordination. The problem is not with facility assessment and evaluation, but with the criteria hospitals set for the waitlists. We recognize the need to avoid a "check-box measure," but believe that a transplant measure must be actionable.

B. DFC Measure Recommendations

Please note for a full discussion about recommendations regarding the specifications of these measures, please see Sections VI.A., VII.A., and Appendices B and C.

- **KCQA UFR Measure**
 - KCP continues to believe that fluid management is an important quality area, which is why it funded the KCQA to undertake such measure development. The KCP members identified addressing fluid management as the highest priority from KCP's *Strategic Blueprint for Kidney Care Quality*. We commend CMS for using KCQA's NQF-endorsed measure, *2701: Avoidance of Utilization of High Ultrafiltration Rate (≥ 13 ml/kg/hour)*. CMS should use the specifications for this measure that NQF-endorsed and not modify them.
 - KCP requests justification as to why the Additional Information item, "A facility is excluded from a reporting month if its certification date falls on or after the first day of the reporting month (the scenario can only occur once during January 2019-June 2019)" has been struck. We recognize the cases are likely rare, but when they do occur, those facilities should be excluded (and the dates altered to reflect future payment years).
 - This measure should be part of the DFC, but not the QIP.
- **KCQA Medication Reconciliation (MedRec) Measure**
 - KCP supports the KCQA MedRec, as evidenced by our prioritizing its development using community resources. However, as noted above, we believe the ESRD QIP should include a parsimonious set of measures that can

be relied upon over time to provide an overarching assessment of facility performance. More specific outcomes measures should reside in the DFC.

- With respect to the specifications, rather than strike the definitional elements of “medication reconciliation,” we recommend the specifications restore the endorsed verbiage as “Additional Information/Definition” to ensure standardized reconciliation. Additionally, page 148 of the Proposed Rule notes the measure is calculated using administrative claims; this should be deleted, as claims are not required for the measure. Finally, page 150 states that the measure “is endorsed by NQF as #2988.” Given the specification changes, it is more accurate to state “the specifications are based on NQF #2988.”
- **NHSN Healthcare Personnel Influenza Vaccination Reporting Measure**
 - KCP continues to believe that influenza vaccination of healthcare personnel is an important public health concept and has supported including NHSN Healthcare Personnel Influenza Vaccination as a reporting measure, but the performance period needs to be aligned with the CDC’s guidelines and the NQF’s standard specifications for influenza immunization measures. Specifically, both define the acceptable immunization period as “October 1 or whenever the vaccine became available.” Vaccine shipments typically begin in August, and the measure should be specified to allow for this fact. The measure also lacks the ability for facilities to batch submit. Thus, as currently specified the measure should be eliminated from the QIP under Factor 3 because it does not align with clinical practice.
 - Because this area is important, but not a critical driver of key patient outcomes, it is more appropriate that the measure be in DFC.
- **Kt/V Dialysis Adequacy Comprehensive Clinical Measure**
 - While dialysis adequacy is a core metric of facility performance, there is little gap in performance, so under Factor 1 it should not be included in the QIP. However, it remains an important measure to patients and should be included in DFC.
 - Unfortunately, the current pooled measure masks performance for home dialysis and pediatric patients. CMS indicated the purpose of creating the pooled measure was to address the problem that most facilities that care for pediatric patients do not meet the minimum sample size for their pediatric population. If the measure is eliminated from the QIP and included in DFC, the individual measures for adequacy should be what is reported and accessible to patients and caregivers. What is paramount is that patients

have access to information that is personally meaningful to them. Pooling the adequacy measure serves none of the patients.

- **Vascular Access Type (VAT) Measure Topic – Arteriovenous Fistula (AVF) Clinical Measure/Standardized Fistula Measure**
 - As noted already, reduction in catheters drives better patient outcomes more than the placement of a fistula, so under Factor 5, the VAT Topic and AVF measure should not be included in the QIP. However, understanding performance on this measure in a public way is important and it should be included in DFC.
 - We recommend that the specifications be edited to explicitly state that the patient must be on maintenance HD using an AVF “without a dialysis catheter present” to emphasize importance of removing long-term catheters. We also note that the denominator should use a “patient-months” construction (as do the numerator and measure description).
- **Clinical Depression Screening and Follow-Up Reporting Measure**
 - Clinical Depression Screening does not drive a core outcome for patients, but is important more generally to the population. Inclusion in the QIP dilutes the TPS and make it more difficult for the QIP to drive improvement. However, this measure should be used in the DFC and publicly available to patients and caregivers.
- **Standardized Mortality Rate measure**
 - Like the hospitalization measure, the current morality ratio measure should be modified to be a true risk-standardized rate, as noted above.
- **Patient Reported Outcome Measure**
 - KCP supports further development of a measure in this domain.

C. Measures That Should Not Be Used in QIP or DFC

Please note for a full discussion about recommendations regarding the specifications of these measures, please see Sections VI.A., VII.A., and Appendices B and C.

- **Pain Assessment and Follow-Up Reporting Measure**
 - KCP agrees with the CMS proposal to eliminate this measure from the ESRD QIP because “measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made.”¹⁰ If distinctions among facilities

¹⁰83 Fed. Reg. at 34338.

cannot be made by a measure, it is not appropriate or useful to patients to include the measure on DFC as well.

- **Hypercalcemia Clinical Measure**

- KCP has consistently raised concerns with the use of the hypercalcemia measure. 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. Thus, the hypercalcemia measure also should be eliminated under Factor 1.
- In previous rulemaking, the preamble indicated that despite these facts, CMS felt bound to maintain the measure because the statute requires including measures specific to oral-only drugs.¹¹ It has stated that hypercalcemia is the only measure of which we are aware that meets the statutory requirements in PAMA for an NQF-endorsed quality measure of conditions treated with oral-only medications. The measure focused on the administration of oral Sensipar® (cinacalcet), which with the development and launch of the IV Parsabiv® (etelcalcetide), is no longer an oral-only drug. Because there are no longer any oral-only calcimimetics, the hypercalcemia measure is no longer required by the statute and thus the rationale for maintaining this topped out measure is no longer relevant.

- **Emergency Department Utilization**

- This measure should not be included in either the QIP or DFC because it has failed to be endorsed by the NQF. The measure was rejected for low and/or insufficient validity and/or reliability by NQF Methods Panel. A measure that is not reliable or valid should not be used because its results cannot be trusted to be accurate. It would seem clearly to come within Factor 2 because “[p]erformance or improvement on a measure does not result in better or the intended patient outcomes,” since the measure is not accurately measuring performance. In addition, as noted above, the fact that NQF did not endorse the measure cannot be circumvented by referencing the authority the Congress provided is no measure has been endorsed by NQF in a particular domain.

D. Implementation

KCP appreciates that CMS has developed a process that provides proposals for future payment years well in advance of the actual performance period. However, we do

¹¹42 U.S.C. § 1395rr(h)(2)(e).

believe the changes outlined above and consistent with the Administration's Meaningful Measures Initiative should be implemented as quickly as possible and not resigned to PY 2021 or 2022.

II. KCP reiterates our support for the effort to assess and account for Social Risk Factors in the ESRD QIP Program through adjusters and other mechanisms.

As part of our comment letter last year, KCP provided detailed comments and recommendations in response to the request for comment on social risk factors from CMS. Given that the Proposed Rule seems to request the same information without making any specific recommendations, we reiterate our comments in this letter and strongly urge CMS to adopt them before another round of rulemaking occurs. These recommendations address the current QIP measures, but we recommend strongly that CMS reduce the measures consistent with the recommendations in Section I of this letter.

KCP appreciates the opportunity to provide comments and suggestions as to how CMS might incorporate social risk factors, commonly referred to as socio-demographic status (SDS) factors, in the ESRD QIP measures (and other quality programs). We agree that the Agency must strike the correct balance to ensure that it meets the goals of both assessing providers and suppliers in as fair a manner as possible, while also not masking potential disparities or dis-incentivizing the provision of care to more medically complex patients. To that end, KCP pledges its support for the effort to assess and account for SDS factors through adjusters or other mechanisms.

A. Recommendations Regarding Existing Measures

The measures used in the ESRD QIP should continue to be examined to determine if SDS adjustment is appropriate. We need to better understand for each measure whether differences in quality measure performance might underlie the observed relationships between social risk and performance. We also need to understand whether better adjustment for SDS factors might improve the ability to differentiate true differences in performance between facilities. As an initial recommendation, KCP believes that the following measures should be assessed for establishing SDS risk factor adjustments.

- Standardized Readmission Ratio (SRR)
- Standardized Transfusion Ratio (STrR)
- Standardized Mortality Ratio (SMR)
- Standardized Hospitalization Ratio (SHR)

While the SMR is already adjusted for race/ethnicity, the other standardized ratio measures are not. SDS factors should also be considered, even as CMS shifts these measures from ratios to rates. Whether the measure is expressed as a rate or ratio is

immaterial to evaluating the need for SDS factors. In other settings, there is a wide and increasingly deep evidence base that performance on these measures is driven in part by patient-level SDS factors. Similar trends appear to be occurring in the context of readmission measures in other health care settings as well. There is no reason to believe that the ESRD population is any different.

We believe CMS should examine whether insurance status at the time of dialysis initiation should be applied to the following measures:

- Vascular Access Type (VAT) Measure Topic – Arteriovenous Fistula (AVF) Clinical Measure
- Vascular Access Type (VAT) Measure Topic – Catheter > 90 Days Clinical Measure

Patients initiating dialysis without insurance likely have difficulties in securing appropriate pre-dialysis care by a nephrologist, including referral and placement of, and payment coverage for, permanent access. We recognize some allowance has been made (e.g., the catheter measure is three consecutive months) to assess this concern, but believe additional review of an insurance coverage risk variable is warranted given the time that often elapses for appointment availability, placement, and maturation of permanent access.

We do not believe SDS factors should be applied to the following measures:

- Kt/V Dialysis Adequacy Comprehensive Clinical Measure
- Hypercalcemia Clinical Measure
- Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) Measure (NQF #2988)

Based on the experience of KCP members, as well as other research, there is no evidence suggesting that performance on these measures is so influenced by SDS factors that they should be adjusted to ensure that the information they provide accurately reflects the true performance of each facility.

Similarly, while we remain deeply concerned about the validity of the National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Patients Clinical Measure, we also do not think that this measure should be adjusted for SDS factors.

Finally, we also do not believe that reporting measures need to be adjusted for SDS factors because the focus is on whether the facility has reported the necessary data and not patient outcomes. Thus, in the current set of ESRD QIP measures, we do not think the following measures should be adjusted for SDS factors.

- Mineral Metabolism Reporting Measure

- Anemia Management Reporting Measure
- Pain Assessment and Follow-Up Reporting Measure
- Clinical Depression Screening and Follow-Up Reporting Measure
- NHSN Healthcare Personnel Influenza Vaccination Reporting Measure
- NHSN Dialysis Event Reporting Measure

It is less clear as to whether SDS factors affect the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Clinical Measure scores. While this measure continues to be problematic because of the administration parameters that result in substantial patient fatigue in completing it, which has led to a declining response rate, it is simply not clear what impact SDS factors might have on the patients who responds to the survey. Therefore, we believe the Agency should review and make publicly available the data required to evaluate the impact of SDS factors.

Finally, as CMS considers adopting measures around transplantation, we urge the Agency to engage with KCP to evaluate the SDS factors that clearly impact transplant referrals and patient placement on organ waitlists. 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 additional/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 wait-listing. 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 SDS factors, any wait-listing measure risk model should adjust for them.

B. Suggested methods for accounting for SDS factors.

KCP appreciates that CMS seeks comments on the best method or methods for accounting for SDS factors in quality programs. We believe that it is appropriate to report measures – both at the facility and the public reporting level – stratified by SDS factors. We also reiterate our strong preference for adopting an SDS adjustment for those measures where it has been shown, or is clearly suspected based on research from other care settings, that SDS factors and not dialysis facility performance are driving differences in the outcomes being reported.

C. Suggested SDS factors to evaluate.

As we have noted, there are clearly some SDS factors that have been identified as driving outcomes in a manner that results in certain measures not reflecting the quality care being provided by providers or suppliers. For dialysis patients, we believe that the following SDS factors, at minimum, likely impact outcomes:

- Income, e.g., dual eligibility/low-income subsidy;
- Race and ethnicity;
- Insurance status at dialysis initiation; and
- Geographic area of residence.

We believe that each of these factors should be studied. While they are likely to overlap in some ways, they may not always do so. Additionally, we do not believe this is an exhaustive list and would like to work closely with CMS as it and the community review the current measures to determine if there might be other factors that might also drive outcomes regardless of the quality of care being provided.

In terms of collecting such data, we believe that it should be fairly straightforward for CMS to use its data to identify dual eligibility/low-income subsidy data, as well as geographic area of residence. We know from our experience with the ESRD Prospective Payment System (PPS) and the consideration of adopting a race/ethnicity payment adjuster that it can be difficult to collect such data. However, we believe that patient self-reporting is the most appropriate way to collect such data.

D. Operational Considerations

Adjusting measures for SDS factors is important, but CMS should also consider how it could provide “targeted technical assistance to facilities that disproportionately serve beneficiaries with social risk factors to improve quality and ensure they can successfully participate in the reporting required for the ESRD QIP,” as recommended by the ASPE report. We also agree with the ASPE report’s recommendation that innovative care models could help “achieve better outcomes for beneficiaries with social risk factors,” which is one of the reasons KCP has supported efforts to allow dialysis facilities and nephrologists to lead and participate in such programs. Even so, SDS factors will continue to influence performance scores for a significant portion, if not most, patients in the Medicare fee for service program. Thus, it is critically important that CMS provide sufficient funding to care for these patients through the Medicare ESRD PPS and not reduce these rates directly through reductions in the base rate or indirectly through the application of case-mix adjusters that result in dollars being removed from the rate.

Finally, we also agree with the ASPE report that suggests that HHS support “further research to examine the costs of caring for beneficiaries with social risk factors and to

determine whether current payments adequately account for these differences in care needs.” KCP has strongly supported legislation, most recently introduced in the U.S. House of Representatives, H.R. 2644 “The Chronic Kidney Disease Improvement in Research and Treatment Act of 2017” that includes provisions that seek to improve patients’ lives and quality of care through research and innovation, as well as better understanding how the progression of kidney disease and treatment of kidney failure in minority populations.

E. Conclusion

KCP is pleased that CMS plans to work with the kidney care community generally and urges CMS to work with KCP and the Kidney Care Quality Alliance more specifically, to evaluate and develop appropriate SDS factor stratifications and/or adjusters for measures. We strongly encourage CMS to review, respond to, and implement these recommendations as part of this year’s final rule.

III. KCP recommends that CMS revise the proposed regulatory text to align with the statute and current policies.

KCP appreciates that CMS is proposing to provide statutory text for the basic framework of the ESRD QIP. While we understand that these proposals are not meant to change current policy, we do have some suggestions that we recommend CMS adopt in the final rule.

A. The measure selection regulatory text should align with the statutory text.

With regard to the proposed language that would be codified at § 413.178(c), KCP is concerned that measure specification section has a direct parallel statutory text with which the regulatory text does not align. This deviation from the statute is surprising considering that CMS aligns the section on judicial review that would be codified at § 413.178(f) with its statutory counterpart.

The statute specifically discusses measure selection at 42 U.S.C. § 1395rr(h)(2).

(2) MEASURES.—

(A) IN GENERAL.— The measures specified under this paragraph with respect to the year involved shall

include—

(i) measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management and measures on dialysis adequacy;

(ii) to the extent feasible, such measure (or measures) of patient satisfaction as the Secretary shall specify;

(iii) for 2016 and subsequent years, measures described in subparagraph (E)(i); and

(iv) such other measures as the Secretary specifies, including, to the extent feasible, measures on —

- (I)** iron management;
- (II)** bone mineral metabolism; and
- (III)** vascular access, including for maximizing the placement of arterial venous fistula.

(B) USE OF ENDORSED MEASURES.—

(i) IN GENERAL.— Subject to clause (ii), any measure specified by the Secretary under subparagraph (A)(iv) must have been endorsed by the entity with a contract under section 1890(a).

(ii) EXCEPTION.— In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(C) UPDATING MEASURES.— The Secretary shall establish a process for updating the measures specified under subparagraph (A) in consultation with interested parties.

(D) CONSIDERATION.— In specifying measures under subparagraph (A), the Secretary shall consider the availability of measures that address the unique treatment needs of children and young adults with kidney failure.

(E) MEASURES SPECIFIC TO THE CONDITIONS TREATED WITH ORAL-ONLY DRUGS.—

(i) IN GENERAL.— The measures described in this subparagraph are measures specified by the Secretary that are specific to the conditions treated with oral-only drugs. To the extent feasible, such measures shall be outcomes-based measures.

(ii) CONSULTATION.— In specifying the measures under clause (i), the Secretary shall consult with interested stakeholders.

(iii) USE OF ENDORSED MEASURES

(I) IN GENERAL.— Subject to subclause (I), any measures specified under clause (i) must have been endorsed by the entity with a contract under section 1890(a).

(II) EXCEPTION.— If the entity with a contract under section 1890(a) has not endorsed a measure for a specified area or topic related to measures described in clause (i) that the Secretary determines appropriate, the Secretary may specify a measure that is endorsed or adopted by a consensus organization recognized by the Secretary that has expertise in clinical guidelines for kidney disease.

It is not clear why CMS has not referenced the patient satisfaction provision. More concerning is that CMS has not codified the specific requirement that it use measures that are endorsed by the NQF unless the exception applies. As noted throughout this letter, KCP strongly supports this statutory requirement and urges CMS to include it as part of the codified regulatory text as well. The exception should also be referenced. Consistent with our comments in Section I, we also ask that the regulatory text explicitly state that if the contracting entity (NQF) has reviewed, but not endorsed a measure, then the exception does not apply.

In addition to the measure selection section, we are troubled by the codification of the recent changes to the performance score certification (PCS) (proposed § 413.178(e)(3)). Based on samples of the new PCS that have been circulating, KCP has serious concerns with the inclusion of only the TPS on these documents. The TPS alone does not provide useful information to consumers. While we understand that the detailed measure information is available at Dialysis Facility Compare (DFC), as noted in Section I, the website needs to be improved. Moreover, many patients may not have access to the internet and having only a single number on the PCS to describe facility performance falls woefully short of the intent of the Congress in mandating the PCS. Specifically, 42 U.S.C. § 1395rr(h)(6) indicates that the Secretary must make public “the performance score achieved by the provider or facility with respect to individual measures.” The historic inclusion of individual measure results on the PCS has created the expectation among patient that the PCS will provide them with more detailed information. While we appreciate CMS thought the PCS had become too difficult to read, the fault lies with the failure to adopt a parsimonious set of measures rather than with the concept of providing transparency behind the TPS. Therefore, we once again object to the modifications of the PCS and urge CMS not to codify these modifications in the regulatory text.

B. The performance scoring regulatory text needs to be modified to align with the current policies.

The proposed regulatory text for performance scoring that would be codified at § 413.178(d) does not reflect what KCP understands the current scoring policies to be. Therefore, we ask that CMS clarify this language before finalizing the text. Specifically:

- (d)(i) does not reference 0 as a scoring option. The FY 2019 Program Details indicate that a facility will receive an achievement score of 0 if its performance on that measure falls below the achievement threshold, 1 – 9 if its performance falls within this range, and 10 points if it is at or above the benchmark.
- (d)(ii) references 0 as a scoring option, but does not suggest it is provided if the performance falls below the facility’s comparison rate. KCP understands based on the FY 2019 Program Details that the improvement score of 0 if its performance falls below the facility’s comparison rate, 1-9 if its performance falls within the range, and 10 if the performance is at or above the benchmark.

In terms of (d)(iv), KCP is concerned that the references are very general and the Program Details recommend that detail about the reporting measure requirements are in the rule. If CMS intends to maintain this cross reference instead of including the specific reporting requirements, we recommend that the regulatory text include a reference to where the specific requirements can be located.

C. While the majority of the definitions are appropriate, a few need to be adjusted.

Finally, we have two recommendations in regard to the definitions. First, we ask that CMS revise its definitions of clinical and reporting measures that would be codified at § 413.178(a)(4) and (13), respectively. Within the measure development community, these are not terms that are widely used. It is more appropriate to classify measures as structural, process, outcomes, access, and efficiency. However, we do not expect CMS to change how it references measures in this rulemaking, although it may want to consider a different approach in the future. Even so, it is extremely confusing to define these terms in the context of how they are score for a payment year, rather than in terms of what they are. As currently defined, these terms seem open to manipulation. It may be more appropriate to indicate that CMS plans to define outcomes measures as “clinical” measures and structural measures as “reporting” measures. Then within the proposed scoring section § 413.178(d)(1) clarify that clauses (i)-(iii) apply to clinical measures and clause (iv) to reporting measures.

Second, the reference to the 50th percentile of national performance during the baseline period for the performance year (for clinical measures) appears to be missing

from the definition of “performance standards” at proposed § 413.178(a)(12). Given that the percentiles are included for the definitions of “attainment threshold” and “benchmark,” it would seem to be appropriate to include the percentile reference in the “performance year” definition as well.

IV. KCP generally supports the Retirement Factors outlined in the Proposed Rule, but recommends refining them.

As described in Section I of this letter, KCP agrees that it is important to have a parsimonious set of measures that are meaningful to patients, actionable by providers, and that meet well-established measure development criteria. Therefore, we appreciate that CMS has proposed changes to the criteria used for removing measures from the ESRD QIP, but as noted below we ask CMS to adopt the following refinements as part of the final rule.

KCP supports the following factors as set forth in the Proposed Rule:

- Factor 1. Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvement or performance can no longer be made (for example, the measure is topped-out).
- Factor 2. Performance or improvement on a measure does not result in better or the intended patient outcomes.
- Factor 3. A measure no longer aligns with current clinical guidelines or practice.
- Factor 6. Collection or public reporting of a measure leads to negative or unintended consequences.
- Factor 7. It is not feasible to implement the measure specifications.¹²
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the Program.¹³

We also support the list of costs outlined in the preamble¹⁴ that CMS would consider for purposes of Factor 8.

KCP suggests that Factors 4 and 5 should be modified to indicate that “become available” means that the replacement has been tested for patients with ESRD/at the dialysis facility level. Consistent with the statute, these measures should meet the scientifically acceptable measure development criteria set forth by the NQF, which includes being reliable, valid, and feasible among other things.

In addition, we are deeply troubled by the statements in the preamble that indicate that CMS reserves the right to retain a measure for other reasons. The entire purpose of

¹²83 *Fed. Reg.* at 34338.

¹³*Id.* at 34338-39.

¹⁴*Id.*

setting forth criteria is to provide predictability and consistency among programs. Maintaining the right to basically ignore the outcome of applying the criteria to specific measures undermines the entire process. Therefore, we ask CMS to affirmatively state it will honor the results of using the Retirement Factors when evaluating measures

Finally, we encourage CMS to adopt one additional factor. Measures that do not meet the scientifically accepted measure evaluation and testing criteria (represented by the NQF’s current criteria) should be removed from the program. While meeting these criteria should be a threshold issue given the mandate from the Congress, there unfortunately are several measures in the QIP that do not meet these criteria and that the NQF has in fact rejected. These measures should never have been added to the QIP, but now that they are there, CMS should recognize that their inclusion is inconsistent with the statutory authority and remove them.

With these refinements, we believe the Retirement Factors will be extremely helpful as the community reviews measures and considers them for inclusion in the QIP.

V. KCP seeks clarification about the projected Increase in QIP Payment Penalties.

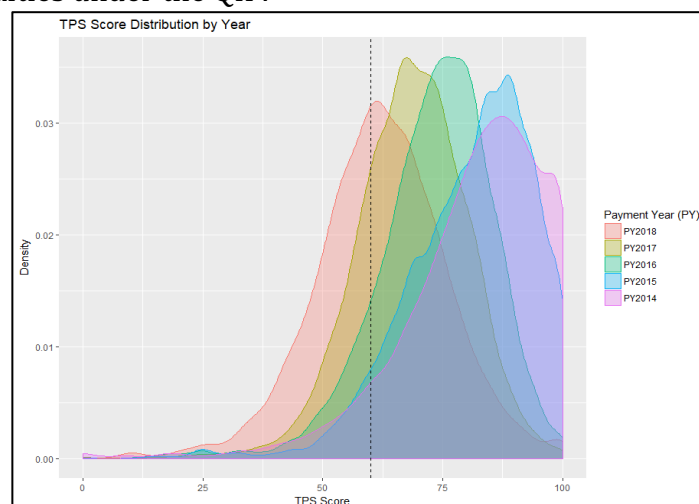
In the 2018 proposed rule, CMS is once again projecting an increase in the average payment penalty under the QIP (for PY 2022, see table below). The overall percentage of facilities receiving some payment penalty is doubling between 2017 and 2022, from about 20 percent to more than 44 percent, and the average payment penalty is tripling during the same period from 0.13 percent to 0.4 percent. Yet during the same period, mean performance for most QIP measures is stable or has improved.

Payment Reduction	PY 2017 Actual		PY 2020 Projected		PY 2021 Projected		PY 2022 Projected	
	Count	percent	Count	percent	Count	percent	Count	percent
0.0 percent	4,961	79.6 percent	3,174	52.8 percent	3,469	57.6 percent	3,639	55.7 percent
0.5 percent	970	15.6 percent	1,576	26.2 percent	1,507	25.0 percent	1,351	20.7 percent
1.0 percent	218	3.5 percent	903	15.0 percent	754	12.5 percent	923	14.1 percent
1.5 percent	50	0.8 percent	280	4.7 percent	228	3.8 percent	437	6.7 percent
2.0 percent	30	0.5 percent	81	1.4 percent	62	1.0 percent	185	2.8 percent
Weighted Average Payment Penalty	0.13 percent		0.38 percent		0.33 percent		0.40 percent	

We are concerned by the increasing projected payment penalties in the QIP, especially given that average performance on key QIP measures has been stable or increasing. KCP has raised this issue in the past, both in our comment letter on last year's proposed rule and in follow-up communications with CMS. To our knowledge CMS has provided no policy rationale for the projected increase in payment penalties, nor an analysis for why average penalties will increase even though performance is improving. Further, CMS has not shared details of the model it uses to predict future payment penalties.

From our perspective, the projected shifts in QIP penalties do not reflect underlying measure performance trends, but appear to be an anomaly of the QIP scoring model. KCP conducted an analysis of why payment penalties under the QIP are increasing. Our analysis, as detailed below, concludes that changes in the distribution of underlying measure performance may negatively impact QIP scores, even though average measure performance is stable or improving

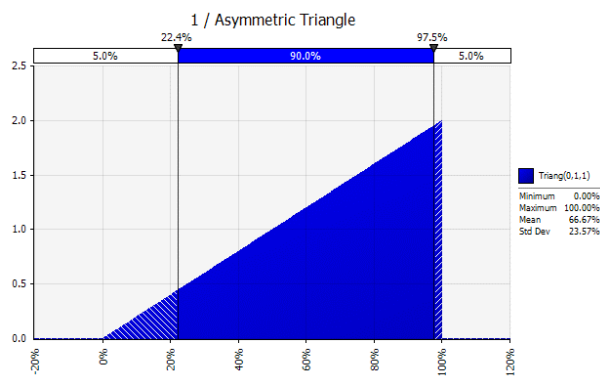
Over the past five years, the distribution of Total Performance Scores has become more normal and the median TPS has decreased, while measure benchmarks and achievement thresholds have remained somewhat constant. Changes in measure performance distribution and the QIP scoring model may explain why more facilities are receiving penalties than in the past. For this analysis, we confirmed that a change in the distribution in performance and subsequent measure scores may not be reflected in the mean, median, and other descriptive statistics. This was done both through an examination of the actual ESRD QIP measure-level data trends (see Appendices 1-9) and a Monte Carlo simulation of data. This analysis shows that medians may not be reliable descriptors of the trends in overall facility performance or lead to an accurate understanding of the underlying score distribution. Yet CMS uses medians when setting the measure scores that could result in penalties under the QIP.



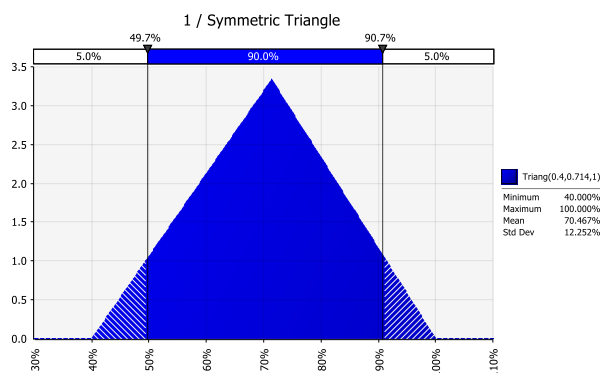
To explain the normalization of the TPS over time, we hypothesized that when raw scores are standardized to a 1-10 scale in the QIP, variation could increase, despite consistent overall performance. We analyzed the raw and standardized scores for several individual measure scores (see Appendices 1-5,7). While most available raw score distributions appeared to be similar between years, it seems that variation in the standardized score increased over time, with fewer facilities scoring 10 and a more homogenous distribution of scores. The increasing variation could be explained by changes in benchmarks. Applying a 1-10 standardization score could lead to a change in distribution based on the placement and range of the cutoffs. The standardization process could magnify subtle or slight changes in raw scores.

Raw scores were not available for other measures (see Appendices 6,8-9), but changes in the standardized scores are still apparent. The ICH CAHPS measure score (see Appendix 6) experienced a significant change between PY 2017 and PY 2018. It switched from a binary reporting score (0 or 10) to a standardized range of scores. This measure is heavily weighted and any increased variation in score would likely have a strong impact on TPS.

In addition to analyzing actual QIP measure data, KCP also created two simulated data sets of 5,000 observations to test the impact that the shape of a data distribution could have on QIP scores. The first data set followed an asymmetrical distribution, as below:

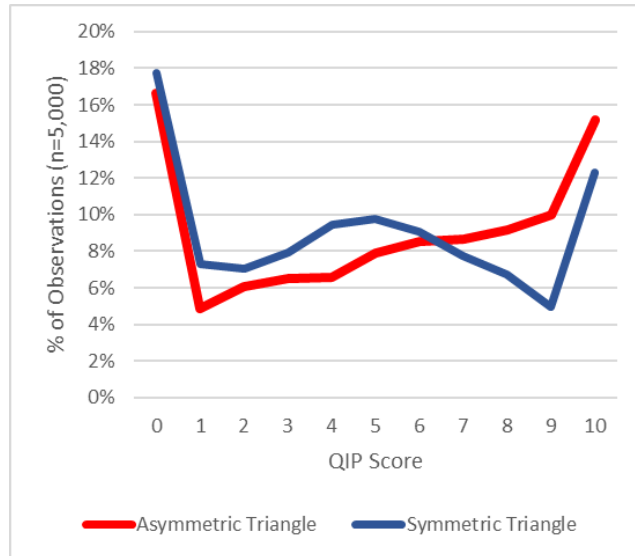


The second data set followed a symmetrical data distribution, as below:



Both distributions have a median value of 71 percent, and therefore would have the same threshold for QIP payment penalties. The symmetric data set has a higher mean value of 71 percent, compared to 68 percent for the asymmetric data set.

We scored each of the two data sets using the QIP methodology and compared the results. As illustrated in the graph at right, the symmetric data distribution resulted in more low QIP scores compared to the asymmetric distribution. The mean QIP score was also lower for the symmetric distribution (4.6) than for the asymmetric distribution (5.3). Therefore, any shift over time from asymmetric to symmetric distributions of measure scores – as we observe in the actual data – may result in lower QIP scores, even though median and mean performance stay the same or improve.



In summary, our analysis found that the basic statistics may not give a full picture of patterns in performance and score distribution (even though these statistics are used to set the scoring parameters). Second, the standardization process could increase variation in standardized scores even though the raw measure score may not vary significantly from year to year. This standardization process is (perhaps unintentionally) changes the distribution of QIP payment penalties and may not convey an accurate picture of quality.

We urge CMS to clarify its policy on the distribution of payment penalties and to implement program changes that ensure trends in payment penalties align with underlying facility performance, which is improving based on the measures in the program. We also request that CMS share details about how the methodology it uses to project payment adjustments under the QIP.

VI. PY 2021

KCP provides recommendations on the measures and data validation proposals in this letter and will provide additional measure comments and structural recommendations in a follow-up letter.

A. KCP recommends changes to the PY 2021 Measures Set based on our previous comments

The Appendix C sets forth the specific comments for each of these measures. In sum, KCP:

- Recommends replacing the **hypercalcemia measure** from the QIP using the **serum phosphorous measure**, as noted in Section I.
- Supports retiring the **anemia management reporting measure** and replacing the **STrR** measure with a hemoglobin less than 10 measure, as noted in Section I.
- Supports retiring the **Pain Assessment and Follow-Up** and the **National Healthcare Safety Network (NHSN) Healthcare Personnel Influenza Vaccination** measures.
- Asks that CMS eliminate the **pooled adequacy of dialysis measure** and replace it with the four individual dialysis quality measures to allow patients to see facility performance on home and pediatric dialysis, rather than have them rolled up in a single measure that disincentivizes the use of home dialysis. Addressing the problem of small numbers for pediatric facilities should not be resolved in a manner that disadvantages home dialysis.
- Requests that CMS move the **AV fistula measure/Standardized Fistula Rate** to DFC and remove it from the ESRD QIP; CMS should use the **long-term catheter measure** as a single measure in the ESRD QIP for vascular access, as noted in Section I.
- Recommends that CMS use a risk-standardized rate measures for the **standardized hospitalization and readmissions ratios**, as noted in Section I, and address the reliability concerns with the SHR.
- Recommends that CMS not use the **NHSN BSI measure** until it has addressed the validity issues, as noted in Section I, and does not support the use of the **NHSN Dialysis Event Reporting Measure** because it does not address the validity problem.
- Supports continued use of the **ICH CAHPS measures** as a reporting measure, as noted in Section I, but urges the modifications set forth in Appendices A and B.
- Support including an actionable transplant measure in the QIP, but cannot support the use of the **SWR** because the NQF has declined to endorse this measure, as noted in Section I.
- Recommends using the **KCQA Medication Reconciliation** measure in the DFC and not ESRD QIP, as noted in Section I, including the suggested changes outlined there.
- Requests that CMS move the **Depression Screening and Follow-Up Reporting Measure** to DFC and remove it from the ESRD QIP, as noted in Section I.
- Requests that CMS move the **Ultrafiltration Reporting Measure** to DFC and remove it from the ESRD QIP, as noted in Section I.

In addition to these recommendations, KCP continues to urge that CMS adopt a global set of exclusions that would consistently apply to all measures. The continuing inconsistency misaligns the measures across programs, creates confusion among patients, and imposes an unnecessary burden on providers. Please see Appendix C for the specific recommendations.

B. KCP reiterates our concerns with the data validation process and urges CMS to eliminate it entirely or at least modify it to establish due process rights

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. Despite years of requests, including a formal Freedom of Information Act (FOIA) request, CMS has not released the report summarizing the results of its attempt to validate these data collection tools. In terms of the NHSN Bloodstream Infection Clinical Measures, we have noted in previous letters that 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 has noted in previous rules, 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 TPS. As a threshold matter, CMS should address this problem before targeting facilities.

We also strongly oppose expanding the program. CMS has not released the data from its previous validation cycles, and an expansion of the program to even more facilities logically suggests that those cycles have yielded problematic, or at best inconclusive, results on the measure’s validity that call into question the measure’s continued use. CMS should be transparent and release the results of the previous cycles and permit researchers and the community the opportunity to examine them before continuing the program.

Once the data collection tools are validated, then we would support efforts to promote accuracy in data submission for the quality programs. However, any such effort should provide facilities with their due process rights under the U.S. Constitution. The current timeframes and penalties attached to the process do not provide due process to dialysis facilities required to participate in them. CMS has remained silent with regard to these serious problems and we strongly urge that they be addressed in the final rule. In making the changes below, CMS would still achieve its goals but it would also be abiding by the fundamental principle that individuals accused of wrong doing have the object to the

charge and the right to refute them. As we have noted before, CMS is auditing facilities, not validating them, and it should be transparent about what it is doing.

A true audit process should provide appropriate due process that includes the right to appeal adverse decisions. We remain concerned about the response period. The timeframe is inadequate and the penalty for failing to comply with it is disproportionately severe when compared to the problem being identified. Now that CMS plans to make the process permanent, it is more important than ever to provide due process rights before CMS assesses a penalty. We ask that CMS acknowledge the audit process and set forth specific appeal and due process rights in the final rule.

VII. PY 2022: KCP recommends changes to the PY 2022 Measures Set based on our previous comments

KCP reiterates the recommendations set forth in the Meaningful Measures section and our comments outlined above for PY 2022, including the recommended specification changes outlined in Appendices A and B, as well as the need for global exclusions. In addition, we provide the following recommendations on the proposal to add two new measures: Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure and the KCQA Medication Reconciliation for Patients Receiving Care at Dialysis Facilities reporting measure.¹⁵ KCP:

- Supports including an actionable transplant measure in the QIP, but cannot support the use of the **PPPW** because NQF has declined to endorse this measure, as noted in Section I.
- Recommends using the **KCQA Medication Reconciliation** measure in the DFC and not ESRD QIP, as noted in Section I, including the suggested changes outlined there.

KCP will provide comments on the structural issues and weighting proposals, as well as additional measure comments, in a separate letter.

VIII. Request for Information

- A. KCP reiterates previous comments recommending that CMS use the conditions of participation/conditions for coverage or other tools to address the difficulties dialysis facilities experience when seeking information about patients when they have been hospitalized.**

KCP appreciates the ongoing focus to promote the use of health information technology (HIT). As we have described in previous comment letters, we believe that HIT

¹⁵*Id.* at 142.

can improve the quality of care provided to patients by allowing for a seamless flow of information between providers. As Department of Health and Human Services (HHS) continues to promote interoperable HIT and standards, across the continuum of care, it is important that CMS update the requirements on health care providers to share information with other providers responsible for treating the patients.

Sharing hospital treatment and discharge information is particularly important to ensuring the continuity of care for dialysis patients. Dialysis patients who have multiple comorbidities, require a substantial number of medications and require dialysis treatments three to four times a week need their providers to coordinate care across the continuum of care. Dialysis facilities and nephrologists must calibrate their treatment protocols to ensure appropriate care. This includes appropriately removing volume to prevent either heart failure or hypotension; administering and dosing medications in such a way to ensure that important medications are not removed with dialysis; ensuring that medication dosing is correct for a person with no kidney function; knowing what medications need to be administered with dialysis; treating other complications and health issues (including blood pressure and nutrition); addressing important social issues that may have arisen during the hospitalization (including awareness of changes in advance directives); and managing bleeding and clotting issues that can occur with the provision of dialysis. All of these are critical to providing quality care for our patients.

Yet, for the vast majority of patients, their dialysis centers and nephrologists are never told of the care they are provided when hospitalized. This lack of sharing of information creates a black hole that places patients at higher risk of complications, unnecessary treatment, and future hospitalizations.

Despite efforts by KCP members, it has been extremely difficult to obtain discharge information from hospitals. We appreciate that there are many demands on hospital staff. Often, requests from dialysis facilities or nephrologists go unanswered. Thus, we ask that CMS require hospitals through their conditions of participation, especially those using certified health IT, to send to patient's other health care providers: (1) the discharge instructions and discharge summary within 48 hours; (2) pending test results within 72 hours of their availability; and (3) all other necessary information specified in the "transfer to another facility" requirements. While some patients may tell hospitals about their nephrologists and dialysis facilities, others may forget. Therefore, we encourage CMS to clarify that hospitals must also provide this information upon request by a dialysis facility, as well as when a request is made by a nephrologist. If the hospital knows the dialysis facility and/or nephrologist is treating the patient, the information should be automatically sent; if the hospital does not know, then the hospital should send it upon request. This requirement will promote efficiency and patient safety as patients transition from a hospital to a dialysis facility, as well as promote HHS' interoperability and information exchange goals.

The Honorable Alex Azar
The Honorable Seema Verma
August 10, 2018
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IX. Conclusion

KCP appreciates the opportunity to provide comments on the ESRD QIP. As noted, we will provide the remainder of our comments in a follow-on letter. We look forward to working with the Department and Agency on addressing the concerns in this letter. We would welcome the opportunity to meet to discuss some of how we can help the Administration achieve the critically important goals outlined in the ESRD QIP. Please do not hesitate to contact Kathy Lester at (202) 534-1773 or klester@lesterhealthlaw.com if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Allen Nissenson".

Allen Nissenson
Chairman
Kidney Care Partners

cc: Reena Duseja, M.D., Director, Division of Quality Measurement
Jesse L. Roach, M.D., ESRD Measures Development Lead, Division of Quality Measurement
Debra Dean-Whittaker, Ph.D., Division of Consumer Assessment & Plan Performance

Appendix A: List of KCP Members

Akebia Therapeutics, Inc.
American Kidney Fund, Inc.
American Nephrology Nurses Association
American Renal Associates
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen, Inc.
AstraZeneca
Atlantic Dialysis Management Services, LLC
Baxter International, Inc.
Board of Nephrology Examiners Nursing Technology
Cara Therapeutics, Inc.
Centers for Dialysis Care
Corvidia Therapeutics, Inc.
DaVita, Inc.
Dialysis Clinic, Inc.
Dialysis Patient Citizens, Inc.
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Keryx Biopharmaceuticals, Inc.
Kidney Care Council
Medtronic
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical, Inc.
Otsuka America Pharmaceutical, Inc.
Renal Physicians Association
Renal Support Network
Rogosin Institute
Satellite Healthcare, Inc.
U.S. Renal Care, Inc.

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Appendix B: KCP Letter to CMS on ICH CAHPS

July 2, 2018

Kate Goodrich, M.D.
Director and CMS Chief Medical Officer
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems Survey and Experience of Care (ICH CAHPS)

Dear Dr. Goodrich:

On behalf of Kidney Care Partners (KCP), I am writing to expand upon recommendations the coalition has offered in previous communications with CMS regarding the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems Survey and Experience of Care (ICH CAHPS). Our goal in providing more background on these recommendations is to ensure that the original purposes of the ICH CAHPS tool and the measures that rely upon it are met.

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).

As noted in previous letters, KCP believes that it is critically important to evaluate patients' experiences when receiving dialysis and continues to support the ICH CAHPS measure conceptually. However, as noted in previous KCP letters and conversations, the ICH CAHPS measure response rate is extremely low. These concerns are not isolated to KCP and our more than 30 member organizations; they have been echoed by members of the CMS Patient-Report Outcomes Technical Expert Panel (TEP) as well.

This low response rate leads to a small sample size, which results in random outcomes and does not provide useful information to patients, caregivers, or the community seeking to use ICH CAHPS to improve the patient experience. A recent report

sent to the National Quality Forum (NQF) stated that a target minimum of 200 completed surveys for each facility over each 12-month period would be needed to establish statistical precision. Thus, according to this CMS document, if fewer than 200 surveys are completed, the results will not be statistically appropriate to use. Yet, CMS currently requires only 30 completed surveys during the eligibility period as the minimum required.

Put simply, while the current 62-item ICH-CAHPS survey was created to allow:

- Consumers and patients to make comparisons among dialysis facilities;
- Dialysis facilities to benchmark their performance;
- CMS to monitor facility performance; and
- Facilities to gather information for internal quality improvement purposes,¹⁶

it cannot achieve any of these goals because it lacks sufficient statistical power to provide accurate information to most facilities.

There is consensus within the vast majority of the kidney care community that the low response rate is likely due in large part to patient survey fatigue. A recent editorial in *The American Journal of Kidney Disease (AJKD)*, highlighted the severity of this problem:

[I]n its current form, the ICH-CAHPS survey is long and its administration imposes a substantial respondent burden. Patients are the only data source and it is vital to minimize their burden. In addition, mailing cost limits the number of pages over which the survey can be spread; this leads to a small font size that makes the survey inaccessible to patients whose comorbid conditions and/or age reduce their vision. CMS allows for telephone interviews in this circumstance; however, in our experience, hemodialysis patient telephone interviews are fraught with problems. CMS requires that the interview occur while the patient is outside the facility, but acceptable call hours are limited and many don't answer unless they recognize the number on caller ID. Furthermore, even well-conducted telephone interviews frustrate patients: the necessary scripting is stilted, response choices can be confusing, questions are perceived as repetitive, and calls are lengthy, on average 30 minutes.¹⁷

If CMS remains serious about understanding patient experience and having facilities work to improve it, then ICH CAHPS needs to be adjusted immediately to reduce the current questions related its validity that result from the low response rates currently being seen during implementation and that were not seen not during testing.

¹⁶Crawley B. CAHPS In-Center Hemodialysis (ICH) Survey Overview. (cited in Michelle M. Richardson, PharmD, Megan E. Grobert, BA Am J Kidney Dis. 2014;64(5):670-672).

¹⁷ Michelle M. Richardson, PharmD, Megan E. Grobert, BA Am J Kidney Dis. 2014;64(5):670-672

While a severe problem, the low response rate is not insurmountable. KCP has proposed four specific ways to address the patient fatigue problem, two of which could be implemented immediately in the upcoming rulemaking cycle. The third and fourth do not require rulemaking, but are rather technical issues that CMS could address, assuming it has sufficient funds and expertise.

First, CMS should address the fatigue problem by administering one of the three independently validated sections to individual patients during the survey period; not all patients need receive the same section, but a single patient would receive only one. In previous letters, KCP has 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. These three sections yield three multi-scales or composite measures: (1) nephrologists' communication and caring (NCC); (2) quality of dialysis center care and operations (QoC); and (3) providing information to patients (PI). Three of 62 items are single-item global ratings of kidney doctor, dialysis center staff, and dialysis center.

As you are aware, when it developed ICH CAHPS, the Agency for Healthcare Research and Quality (AHRQ) validated the instrument in three sections. The first peer-reviewed analysis of ICH CAHPS appeared in 2014 testing ICH CAHPS's internal validity using the three sections.¹⁸ CMS already reports these measures as composites on Dialysis Facility Compare, so appears to recognize the independent validation of these sections as well.

Using the three independently validated sections would allow CMS to establish three separate instruments with fewer questions in each of the three areas and include the three single-item global rates as well. The Appendix includes how these three individual instruments would be set. The total number of questions in each instrument would be respectively 27, 41, and 33. Each grouping is significantly less than the 62 questions patients are being asked to complete today.

The vendor would then distribute these individual instruments to patients to complete. The font could be larger and patients would be able to complete to survey more quickly.

This recommendation is consistent with comments made by the recent dialysis CAHPS TEP. When asked the optimal number of questions for individual CAHPS surveys for home and pediatric patients, some participants suggested no more than 10, while

¹⁸Wood R, Paoli CJ, Hays RD, Taylor-Stokes G, Piercy J, Gitlin M: Evaluation of the Consumer Assessment of Healthcare Providers and Systems In-Center Hemodialysis Survey (CAHPS-ICH). Clin J Am Soc Nephrol 9: 1099-1108, 2014

others indicated there should be no more than 30.¹⁹ The hospital CAHPS survey has only 32 questions, nearly half as many questions as the ICH CAHPS, despite the fact that hospitals are treating a variety of patient conditions and ESRD facilities only kidney failure.

Second, CMS should administer the survey only once a year. While we are pleased that CMS is not administering the survey monthly, as some staff had suggested was optimal, twice a year remains incredibly burdensome for a patient population that has multiple caregivers and is likely being asked to provide survey data for hospitals and other providers in addition to the ICH CAHPS. In addition, the ESRD Networks also are asking dialysis patients to complete the ICH CAHPS as part of their own work, which means some patients are asked to complete the ICH CAHPS survey three or more times a year.

We acknowledge that CMS has consistently rejected KCP's recommendations to administer the survey only once a year, but the Agency has provided no information or rationale explaining why reducing the administration is inadequate or fails to provide CMS with the information it seeks to obtain from it. 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.²⁰ Again, if the purpose is to improve the patient experience and allow patients to meaningfully compare facilities, administering the survey more than once a year has been shown to be not only unnecessary, but harmful in achieving these goals. Given that there is no evidence countering the RAND work, we ask that CMS reduce the burden on patients by administering ICH CAHPS annually.

Third, CMS should address delivery problems and modernize the delivery options. 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 consequence to validity that results from 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.

¹⁹RTI International, In-Center Hemodialysis CAHPS: Examining the Feasibility of Administering a CAHPS Survey of Home, Peritoneal, and Pediatric Dialysis Patients: Summary of Discussions During the Technical Expert Panel Telephone Conference 13 (2018).

²⁰ 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).

We appreciate that CMS is considering ways to shorten the entire questionnaire and recommend in particular that CMS closely review the need for the questions that CMS had already excluded from the composite measures it developed. These are questions: 18, 20, 23, 37, 41, 42, 43 and 44. We also believe that questions 45-62 could arguably be truncated since they provide patient demographic data that are not being used for stratifying the data or establishing appropriate risk adjusters. However, CMS should not wait to complete the review of the questions and testing a new instrument before trying to reduce the burden on patients. The division of questions outlined in the Appendix is one way for CMS to accomplish this goal while it seeks to further refine the questions.

Moreover, as the ICH CAHPS TEP participants emphasized allowing patients to respond to ICH CAHPS on mobile devices is critically important. Sixty percent of ESRD patients are under the age of 65.²¹ This means that, contrary to some assumptions, they are not too old to understand electronic devices. In fact, CMS seems to have recognized that even those 65 years and older are electronically savvy by creating online tools, such as the Medicare consumer guides, blogs from the Administrator, and even email tips for seniors. According to the Pew Research Center, 85 percent of Americans 65 years and older own a cellphone and 60 percent of those cellphones are smart phones. Even Americans struggling with poverty are likely to own a smart phone as well; Pew found that nearly 100 percent American making \$49,999 or less a year own a cell phone and of that 60 percent are smartphones.²² If CMS makes it easier for patients to respond to ICH CAHPS through a modern survey delivery mode, the likelihood of an improved response rate may increase substantially.

Finally, in addition to improving the response rate, we ask that CMS expedite the process for establishing a home dialysis CAHPS, as well as a pediatric CAHPS. We appreciate that CMS has established a process for developing these instruments. We understand that the current survey was established for in-center patients, but according to the recent ICH CAHPS TEP, the vast majority of the ICH CAHPS questions are applicable to these populations, especially home dialysis patients.²³ Given that approximately 11 percent of dialysis patients have selected home dialysis,²⁴ a significant group of patients have been excluded. We urge AHRQ and CMS to act quickly by continuing to work with the community, in particular the University Washington, to ensure home and pediatric surveys are available sooner, rather than later.

In conclusion, KCP urges CMS to adopt these recommendations to make the ICH CAHPS measure more effective and meaningful. As always, we would welcome the chance to partner with CMS to provide assistance in addressing these recommendations as quickly

²¹USRDS, 2017 Annual Data Report, Reference Tables B.1.

²²Pew Research Center, "Mobile Fact Sheet" available at <http://www.pewinternet.org/fact-sheet/mobile/> last accessed (June 29, 2018).

²³*Supra* note 4.

²⁴MedPAC, *Report to the Congress* 158 (2017).

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as possible. Please do not hesitate to contact Kathy Lester, our counsel in DC, at (202) 534-1773 or klester@lesterhealthlaw.com if you have questions or would like to talk about these recommendations in more detail.

Sincerely,

A handwritten signature in black ink, appearing to read "Allen Nissenson".

Allen Nissenson
Chairman
Kidney Care Partners

cc: Reena Duseja, M.D., Director, Division of Quality Measurement
Jesse L. Roach, M.D., ESRD Measures Development Lead, Division of Quality Measurement
Debra Dean-Whittaker, Ph.D., Division of Consumer Assessment & Plan Performance

Example: Independently Validated ICH CAHPS Instrument Question

Please note that the question numbers correspond to the current ICH CAHPS survey's numbering system.

Nephrologists' Communication and Caring (27 questions)

Q1. Where do you get your dialysis treatments? At home (if At home, Go to Question 45); At the dialysis center; I do not currently receive dialysis (If I do not currently receive dialysis, Go to Question 45)

Q2. How long have you been getting dialysis at [SAMPLE FACILITY NAME]? Less than 3 months (If Less than 3 months, Go to Question 45); At least 3 months but less than 1 year; At least 1 year but less than 5 years; 5 years or more; I do not currently receive dialysis at this dialysis center (If I do not currently receive dialysis at this dialysis center, Go to Question 45)

Q3. For the questions that follow, your kidney doctors means the doctor or doctors most involved in your dialysis care now. This could include kidney doctors that you see inside and outside the center. In the last 3 months, how often did your kidney doctors listen carefully to you? Never, Sometimes, Usually, Always

Q4. In the last 3 months, how often did your kidney doctors explain things in a way that was easy for you to understand? Never, Sometimes, Usually, Always

Q5. In the last 3 months, how often did your kidney doctors show respect for what you had to say? Never, Sometimes, Usually, Always

Q6. In the last 3 months, how often did your kidney doctors spend enough time with you? Never, Sometimes, Usually, Always

Q7. In the last 3 months, how often did you feel your kidney doctors really cared about you as a person? Never, Sometimes, Usually, Always

Q8. Using any number from 0 to 10, where 0 is the worst kidney doctors possible and 10 is the best kidney doctors possible, what number would you use to rate the kidney doctors you have now? (0 Worst kidney doctors possible to 10 Best kidney doctors possible)

Q9. Do your kidney doctors seem informed and up-to-date about the health care you receive from other doctors?

Q45. In general, how would you rate your overall health? Excellent; Very good; Good; Fair; Poor

Q46. In general, how would you rate your overall mental or emotional health? Excellent, Very good, Good, Fair, Poor

Q47. Are you being treated for high blood pressure? Yes, No

Q48. Are you being treated for diabetes or high blood sugar? Yes, No

Q49. Are you being treated for heart disease or heart problems? Yes, No

Q50. Are you deaf or do you have serious difficulty hearing? Yes, No

Q51. Are you blind or do you have serious difficulty seeing, even when wearing glasses? Yes, No

Q52. Because of a physical, mental, or emotional condition, do you have serious difficulty concentrating, remembering, or making decisions? Yes, No

Q53. Do you have serious difficulty walking or climbing stairs? Yes, No

Q54. Do you have difficulty dressing or bathing? Yes, No

Q55. Because of a physical, mental, or emotional condition, do you have difficulty doing errands alone, such as visiting a doctor's office or shopping? Yes, No

Q56. What is the highest grade or level of school that you have completed? No formal education; 5th grade or less; 6th, 7th, or 8th grade; Some high school, but did not graduate; High school graduate or GED; Some college or 2-year degree; 4-year college graduate; More than 4-year college degree

Q57. What language do you mainly speak at home? English, Spanish, Chinese, Samoan, Russian, Vietnamese, Portuguese, Some other language (please identify)

Q58. Are you of Spanish, Hispanic, or Latino origin or descent? No, not Spanish/Hispanic/Latino; Yes, Puerto Rican; Yes, Mexican, Mexican American, Chicano; Yes, Cuban; Yes, other Spanish/Hispanic/ Latino

Q59. What is your race? (One or more categories may be selected.) White, Black or African American, American Indian or Alaska Native, Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, Other Asian, Native Hawaiian, Guamanian or Chamorro, Samoan, Other Pacific Islander

Q60. Did someone help you complete this survey? Yes No

Q61. Who helped you complete this survey? A family member, A friend, A staff member at the dialysis center, Someone else (please print)

Q62. How did that person help you? Check all that apply. Read the questions to me, Wrote down the answers I gave, Answered the questions for me, Translated the questions into my language, Helped in some other way (please print)

Quality of Dialysis Center Care and Operations (41 questions)

Q1. Where do you get your dialysis treatments? At home (if At home, Go to Question 45); At the dialysis center; I do not currently receive dialysis (If I do not currently receive dialysis, Go to Question 45)

Q2. How long have you been getting dialysis at [SAMPLE FACILITY NAME]? Less than 3 months (If Less than 3 months, Go to Question 45); At least 3 months but less than 1 year; At least 1 year but less than 5 years; 5 years or more; I do not currently receive dialysis at this dialysis center (If I do not currently receive dialysis at this dialysis center, Go to Question 45)

Q10. For the next questions, dialysis center staff does not include doctors. Dialysis center staff means nurses, technicians, dietitians and social workers at this dialysis center. In the last 3 months, how often did the dialysis center staff listen carefully to you? Never, Sometimes, Usually, Always

Q11. In the last 3 months, how often did the dialysis center staff explain things in a way that was easy for you to understand? Never, Sometimes, Usually, Always

Q12. In the last 3 months, how often did the dialysis center staff show respect for what you had to say? Never, Sometimes, Usually, Always

Q13. In the last 3 months, how often did the dialysis center staff spend enough time with you? Never, Sometimes, Usually, Always

Q14. In the last 3 months, how often did you feel the dialysis center staff really cared about you as a person? Never, Sometimes, Usually, Always

Q15. In the last 3 months, how often did dialysis center staff make you as comfortable as possible during dialysis? Never, Sometimes, Usually, Always

Q16. In the last 3 months, did dialysis center staff keep information about you and your health as private as possible from other patients? Yes, No

Q17. In the last 3 months, did you feel comfortable asking the dialysis center staff everything you wanted about dialysis care? Yes, No

Q18. In the last 3 months, has anyone on the dialysis center staff asked you about how your kidney disease affects other parts of your life? Yes, No

Q20. In the last 3 months, which one did they use most often to connect you to the dialysis machine? Graft, Fistula, Catheter (If Catheter, Go to Question 22), I don't know (If Don't Know, Go to Question 22)

Q21. In the last 3 months, how often did dialysis center staff insert your needles with as little pain as possible? Never, Sometimes, Usually, Always, I insert my own needles

Q22. In the last 3 months, how often did dialysis center staff check you as closely as you wanted while you were on the dialysis machine? Never, Sometimes, Usually, Always

Q23. In the last 3 months, did any problems occur during your dialysis? Yes, No (If No, Go to Question 25)

Q24. In the last 3 months, how often was the dialysis center staff able to manage problems during your dialysis? Never, Sometimes, Usually, Always

Q25. In the last 3 months, how often did dialysis center staff behave in a professional manner? Never, Sometimes, Usually, Always

Q26. Please remember that for these questions, dialysis center staff does not include doctors. Dialysis center staff means nurses, technicians, dietitians and social workers at this dialysis center. In the last 3 months, did dialysis center staff talk to you about what you should eat and drink? Yes, No

Q27. In the last 3 months, how often did dialysis center staff explain blood test results in a way that was easy to understand? Never, Sometimes, Usually, Always

Q32. Using any number from 0 to 10, where 0 is the worst dialysis center staff possible and 10 is the best dialysis center staff possible, what number would you use to rate your dialysis center staff? (0 Worst dialysis center staff possible to 10 Best dialysis center staff possible)

Q33. In the last 3 months, when you arrived on time, how often did you get put on the dialysis machine within 15 minutes of your appointment or shift time? Never, Sometimes, Usually, Always

Q34. In the last 3 months, how often was the dialysis center as clean as it could be? Never, Sometimes, Usually, Always

Q43. In the last 12 months, how often were you satisfied with the way they handled these problems? Never, Sometimes, Usually, Always

Q45. In general, how would you rate your overall health? Excellent; Very good; Good; Fair; Poor

Q46. In general, how would you rate your overall mental or emotional health? Excellent, Very good, Good, Fair, Poor

Q47. Are you being treated for high blood pressure? Yes, No

Q48. Are you being treated for diabetes or high blood sugar? Yes, No

Q49. Are you being treated for heart disease or heart problems? Yes, No

Q50. Are you deaf or do you have serious difficulty hearing? Yes, No

Q51. Are you blind or do you have serious difficulty seeing, even when wearing glasses? Yes, No

Q52. Because of a physical, mental, or emotional condition, do you have serious difficulty concentrating, remembering, or making decisions? Yes, No

Q53. Do you have serious difficulty walking or climbing stairs? Yes, No

Q54. Do you have difficulty dressing or bathing? Yes, No

Q55. Because of a physical, mental, or emotional condition, do you have difficulty doing errands alone, such as visiting a doctor's office or shopping? Yes, No

Q56. What is the highest grade or level of school that you have completed? No formal education; 5th grade or less; 6th, 7th, or 8th grade; Some high school, but did not graduate; High school graduate or GED; Some college or 2-year degree; 4-year college graduate; More than 4-year college degree

Q57. What language do you mainly speak at home? English, Spanish, Chinese, Samoan, Russian, Vietnamese, Portuguese, Some other language (please identify)

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Q58. Are you of Spanish, Hispanic, or Latino origin or descent? No, not Spanish/Hispanic/Latino; Yes, Puerto Rican; Yes, Mexican, Mexican American, Chicano; Yes, Cuban; Yes, other Spanish/Hispanic/ Latino

Q59. What is your race? (One or more categories may be selected.) White, Black or African American, American Indian or Alaska Native, Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, Other Asian, Native Hawaiian, Guamanian or Chamorro, Samoan, Other Pacific Islander

Q60. Did someone help you complete this survey? Yes No

Q61. Who helped you complete this survey? A family member, A friend, A staff member at the dialysis center, Someone else (please print)

Q62. How did that person help you? Check all that apply. Read the questions to me, Wrote down the answers I gave, Answered the questions for me, Translated the questions into my language, Helped in some other way (please print)

Providing Information to Patients (33 questions)

Q1. Where do you get your dialysis treatments? At home (if At home, Go to Question 45); At the dialysis center; I do not currently receive dialysis (If I do not currently receive dialysis, Go to Question 45)

Q2. How long have you been getting dialysis at [SAMPLE FACILITY NAME]? Less than 3 months (If Less than 3 months, Go to Question 45); At least 3 months but less than 1 year; At least 1 year but less than 5 years; 5 years or more; I do not currently receive dialysis at this dialysis center (If I do not currently receive dialysis at this dialysis center, Go to Question 45)

Q19. The dialysis center staff can connect you to the dialysis machine through a graft, fistula, or catheter. Do you know how to take care of your graft, fistula or catheter? Yes, No

Q28. As a patient you have certain rights. For example, you have the right to be treated with respect and the right to privacy. Did this dialysis center ever give you any written information about your rights as a patient? Yes, No

Q29. Did dialysis center staff at this center ever review your rights as a patient with you? Yes, No

Q30. Has dialysis center staff ever told you what to do if you experience a health problem at home? Yes, No

Q31. Has any dialysis center staff ever told you how to get off the machine if there is an emergency at the center? Yes, No

Q36. You can treat kidney disease with dialysis, kidney transplant or with dialysis at home. In the last 12 months, did your kidney doctors or dialysis center staff talk to you as much as you wanted about which treatment is right for you? Yes, No

Q38. In the last 12 months, has a doctor or dialysis center staff explained to you why you are not eligible for a kidney transplant? Yes, No

Q39. Peritoneal dialysis is dialysis given through the belly and is usually done at home. In the last 12 months, did either your kidney doctors or dialysis center staff talk to you about peritoneal dialysis? Yes, No

Q40. In the last 12 months, were you as involved as much as you wanted in choosing the treatment that is right for you? Yes, No

Q41. In the last 12 months, were you ever unhappy with the care you received at the dialysis center or from your kidney doctors? Yes, No (If No, Go to Question 45)

Q42. In the last 12 months, did you ever talk to someone on the dialysis center staff about this? Yes, No (If No, Go to Question 45)

Q43. In the last 12 months, how often were you satisfied with the way they handled these problems? Never, Sometimes, Usually, Always

Q44. Medicare and your State have special agencies that check the quality of care at this dialysis center. In the last 12 months, did you make a complaint to any of these agencies? Yes, No

Q45. In general, how would you rate your overall health? Excellent; Very good; Good; Fair; Poor

Q46. In general, how would you rate your overall mental or emotional health? Excellent, Very good, Good, Fair, Poor

Q47. Are you being treated for high blood pressure? Yes, No

Q48. Are you being treated for diabetes or high blood sugar? Yes, No

Q49. Are you being treated for heart disease or heart problems? Yes, No

Q50. Are you deaf or do you have serious difficulty hearing? Yes, No

Q51. Are you blind or do you have serious difficulty seeing, even when wearing glasses?
Yes, No

Q52. Because of a physical, mental, or emotional condition, do you have serious difficulty concentrating, remembering, or making decisions? Yes, No

Q53. Do you have serious difficulty walking or climbing stairs? Yes, No

Q54. Do you have difficulty dressing or bathing? Yes, No

Q55. Because of a physical, mental, or emotional condition, do you have difficulty doing errands alone, such as visiting a doctor's office or shopping? Yes, No

Q56. What is the highest grade or level of school that you have completed? No formal education; 5th grade or less; 6th, 7th, or 8th grade; Some high school, but did not graduate; High school graduate or GED; Some college or 2-year degree; 4-year college graduate; More than 4-year college degree

Q57. What language do you mainly speak at home? English, Spanish, Chinese, Samoan, Russian, Vietnamese, Portuguese, Some other language (please identify)

Q58. Are you of Spanish, Hispanic, or Latino origin or descent? No, not Spanish/Hispanic/Latino; Yes, Puerto Rican; Yes, Mexican, Mexican American, Chicano; Yes, Cuban; Yes, other Spanish/Hispanic/ Latino

Q59. What is your race? (One or more categories may be selected.) White, Black or African American, American Indian or Alaska Native, Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, Other Asian, Native Hawaiian, Guamanian or Chamorro, Samoan, Other Pacific Islander

Q60. Did someone help you complete this survey? Yes No

Q61. Who helped you complete this survey? A family member, A friend, A staff member at the dialysis center, Someone else (please print)

Q62. How did that person help you? Check all that apply. Read the questions to me, Wrote down the answers I gave, Answered the questions for me, Translated the questions into my language, Helped in some other way (please print)

Appendix C: Technical Measure Appendix

1. Global Exclusions

As a threshold matter, KCP reiterates our recommendation for CMS to adopt a set of global exclusions that would consistently apply to all measures. 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; and²⁵
- Pediatric patients (unless the measure is specific to pediatric patients).

2. Dialysis Adequacy: KCP remains concerned about the use of the pooled ["comprehensive"] adequacy of dialysis measure and the unintended negative consequences for home dialysis; we recommend 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 previous comments, 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 roll up to a single score, as is done for true composite measures.

We understand CMS's goal is the inclusion of a measure of pediatric dialysis

²⁵ 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).

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 recommended *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.

KCP also notes that the pooled measure may lead to unintended consequences of the greater likelihood of a QIP penalty for facilities that provide primarily home dialysis. Analyses from at least one KCP member appear to indicate that home facilities will have lower adequacy scores under the pooled measure, which will make them more likely to be penalized. Moreover, because these facilities are likely to be small, they also rely on fewer measures for their TPS, so the pooled measure exacerbates the situation. When the Agency seeks to promote home dialysis, it should not use measures that penalize facilities providing the treatment option.

In addition, there appear to be two errors in the specifications. First, the notation under "Additional Information" that facilities must have at least 11 patients should instead be explicitly identified as a "Facility-Level Exclusion" of those with less than 11 patients. This change would harmonize the specifications with CMS's presentation of this information for other measures. Second, the denominator should use the construction "patient-months" instead of "patients" to align with the construction in the description and the numerator.

3. Bone Mineral Measures (Hypercalcemia and Serum Phosphorous): KCP recommends replacing the topped-out hypercalcemia measure with the serum phosphorous measure.

While we appreciate that the Agency must comply with the statutory requirement to include a mineral metabolism measure, KCP remains concerned about the use of the hypercalcemia measure because nephrologists agree that this metric is not the best measure in the bone mineral metabolism domain to impact patient outcomes. In addition,

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. Thus, rather than continue to engage TEPs in the development of new measures for the ESRD QIP, 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 that CMS maintains this measure for PY 2021 and PY 2022, we ask that CMS modify the exclusion so that the measure does not penalize a facility for patients who switch from in-center dialysis to home dialysis. Specifically, we recommend that the exclusion state: "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.

4. Vascular Access Measures: KCP that CMS eliminate the AV fistula measure in the ESRD QIP and use the catheter measure as a single measure instead.

Catheter measure (NQF #2978). KCP also supports inclusion of NQF-endorsed catheter measure (#2978) in the ESRD QIP. However, we ask that CMS provide some additional clarifications. First, we ask that CMS clarify how data with missing access type will be handled. Second, we believe the denominator also mistakenly uses the construction "patients," when it should use the term "patient-months" to be consistent with the numerator and the description.

AV Fistula Measure (NQF #2977). While AV fistula is important, KCP believes it is more appropriate to prioritize the catheter removal measure, which has a greater impact on patient outcomes, in the ESRD QIP and use the AV fistula measure on DFC. We also recommend that CMS address ongoing concerns with the specifications.

We also recommend that the specifications address how a patient with a co-existing AV graft should be handled. As we have noted previously, given that removal of an AV graft is complex and not without risk of complications, the presence of a graft is acceptable even when using a fistula. As this is not the case when a catheter is present, we agree with CMS that the continued presence of a catheter when a fistula is being used should not constitute success on the measure.

Finally, we believe the denominator mistakenly uses the construction "patients," when it should use the term "patient-months" to be consistent with the numerator.

5. Hospitalization and Readmission: KCP recommends that CMS use a risk-standardized rate measure for all of the standardized ratio measures, including the Standardized Hospitalization Ratio (SHR) and Standardization Readmissions Ratio (SRR) measures.

KCP recommends that CMS use a risk-standardized rate measure for all of the standardized ratio measures, including the SHR and SRR. A ratio that is then multiplied by a national median is not a true risk-standardized rate. CMS has acknowledged in previous rulemaking that rate measures are more transparent and easier for patients and caregivers to understand, yet it has not shifted away from the ratio measures. CMS's approach to calculate a rate is not a true risk-standardized rate.

KCP also remains concerned about the lack of consistency in minimum data requirements and lack of a clear, transparent, and empirical rationale for the Small Facility Adjuster (SFA). We again recommended that CMS implement the measure and/or adjustment to yield a reliable result (reliability statistic of 0.70 or greater), which is consistent with how NQF bases its evaluation of measures and is more generous than the literature.²⁶ This step is necessary to prevent small facilities from having scores that are highly subject to random variability and/or to update the SFA ranges.

We appreciate that CMS has recognized the overlap with the SRR and the standardized hospitalization ratio measure (SHR), which results in a facility being twice penalized for a readmission occurring within 30 days of the index discharge. As described below, we recommend changes to the SHR to avoid this "double penalty."

We ask that CMS provide additional information as to why it removed amputation status and added functional disability to the list of past-year comorbidity adjustments in the risk model. We also request clarification on how "functional disability" is defined and how this variable is categorized for the purposes of risk adjustment.

KCP would like to support the Standardized Hospitalization Ratio in the ESRD QIP, but cannot until its reliability has been demonstrated for all facilities. As we have noted in previous letters, KCP agrees that hospitalization is an important quality domain; however, the SHR measure should not be included in the ESRD QIP until its reliability at the proposed facility size is demonstrated. Although the overall reliability statistic for 2013 (and previous years) is 0.7, the minimally accepted threshold 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 with less than or equally to 50 patients, more than half a facility's score (54 percent) is due to random noise and is not a signal of quality. Even for

²⁶ Kline, P. (2000). *The handbook of psychological testing* (2nd ed.). London: Routledge, p. 13; DeVellis, RF. (2012). *Scale development: Theory and applications*. Los Angeles: Sage. pp. 109-110; Adams, JL. (2009). The reliability of provider profiling. RAND Health.

medium facilities, the IUR is significantly below the 0.7 threshold, with 43 percent of a facility's score attributable to random noise and not signal. Penalizing facilities for performance due to random chance is not appropriate.

As noted in the discussion of the STrR measure, the Discern analysis indicates that a 4-year look-back period would address this problem, achieving reliability statistics of 0.90 and 0.74 for medium and small facilities, respectively. A 3-year look back results in statistics of 0.83 for medium and 0.68 for small facilities. CMS should deploy a measure that provides reliable results.

Additionally, we ask that CMS include an exclusion in the SHR for hospitalizations that occur within 29 days of the index discharge. Incorporating this exclusion will avoid readmissions being captured as a hospitalization by the SHR, but it will be captured as a readmission by the SRR. This change prevents a facility from being penalized twice for each such readmission.

Finally, we reiterate our request that that CMS develop a risk-standardized rate measure, which would more transparent and useable by all stakeholders.

6. Anemia Management (STrR): KCP recommends that CMS replace the STrR measure with a hemoglobin less than 10 g/dL measure because of the low reliability of the STrR measure problems with the measure's reliability.

KCP remains concerned with the use of the STrR and recommends that CMS replace it with a lower hemoglobin measure (less than 10 g/dL) that is actionable by facilities and has a clear impact on patient outcomes, including the risk of transfusions. Despite recommendations from KCP as to how the measure could be modified to address underlying concerns, CMS has made clarifications but not any material changes to address these concerns. Given that facilities cannot access information about patient transfusions and that CMS has declined to share such data with facilities, the measure is not actionable; that it is a ratio renders it even more difficult to parse how performance could be improved.

We also remain concerned that the STrR measure has inappropriately low reliability. This is not a relative concept, but rather one on which there is clear consensus among measure development experts. When the STrR measure was considered for NQF endorsement, it was found to have very low reliability, especially for small facilities. The inter-unit reliability²⁷ (IUR) for facilities with sample sizes below 46 patients was about 0.4,

²⁷ 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.

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 submitted by CMS, 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. While the small facility adjustment would raise scores for small facilities, it would not adequately offset the substantial effect of random variation for small sample sizes. 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.²⁸ 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.

An analysis by Discern Health suggests that longer look-back periods would result in a significant increase in reliability for the SHR and STrR measures. For small facilities in particular, the IURs for the 1-year measures are low. For small facilities in the STrR measure, the 1-year IUR for of 0.36 means that nearly two-thirds of the variance in the measure is due to random noise rather than real differences between facilities.

With a 4-year look-back period, the IURs for small facilities are similar to the IURs for large facilities in the 1-year look back period. These results suggest that with a 4-year look-back period, a minimum of two-thirds of the variance in both measures in all three groups would be due to actual differences between facilities. Moreover, if CMS continued to use the STrR despite the KCP consensus recommendations, using a 4-year look-back period would align these measures with the Standardized Mortality Ratio (SMR) measure, creating consistency across the measures and the DFC program.

In addition, KCP has serious concerns that the ICD-10 conversion has exacerbated the validity issues. NQF 2979 was endorsed on December 9, 2016. As part of the NQF submission process, CMS provided testing data from the period January 1, 2011 through December 31, 2014. CMS also provided a code table of the ICD-9 to ICD-10 crosswalk.

The ICD-9 to ICD-10 transition occurred on October 1, 2015. Accordingly, the testing and data provided for the measure were performed using ICD-9 data, but there is a new data source, i.e., ICD-10 data.

Even with ICD-9 codes, KCP has historically expressed concern to NQF and CMS about under-reporting of transfusions based on NQF 2979. KCP has maintained this posed a serious validity issue. Because there is no requirement that ICD codes be used by hospitals when billing for transfusions, many only use revenue codes. NQF 2979, however,

²⁸ J.L. Adams, "The reliability of provider profiling: A tutorial." *RAND Health* (2009).

requires ICD-9/ICD-10 codes to measure performance. Specifically, we noted:

“All inpatient transfusion events must now include an appropriate ICD-9 Procedure Code or Value Code to be captured in the measure; inpatient transfusion events for claims that include only transfusion revenue codes without an accompanying procedure or value code are not included in the numerator.

There is no existing coding requirement that procedure or value codes be used; valid transfusion claims that include only revenue codes will be missed, creating a significant threat to measure validity.

Current transfusion coding practices vary by hospital,²⁹ and hospital coding practices are beyond dialysis facilities’ sphere of control. For example, hospitals that exclusively use revenue codes for transfusions will appear to have no events assigned to a dialysis facility, while hospitals that do use procedure and/or value codes will have recorded events. Facilities within given catchment areas will thus be differentially affected by hospital coding variations, which will clearly impact STrR scoring.

²⁹ Weinhandl ED, Gilbertson DT, Collins AJ. *Dialysis facility-level transfusion rates can be unreliable due to variability in hospital-level billing patterns for blood*. Chronic Disease Research Group poster, ASN. 2014.”

As we describe in the following section, KCP’s analysis demonstrates that implementation of NQF 2979, now with ICD-10 codes, results in even more significant under-reporting can adversely impact facilities when used by CMS.

Analysis of STrR Transfusion Capture and ICD-9/ICD-10 Conversion

Using the 2014-2016 Medicare Limited Data Sets (100% sample) for Medicare fee-for-service beneficiaries, we analyzed inpatient facility claims to identify transfusions during admissions to short-term and critical access hospitals.²⁹ Specifically, we identify hospitals with large changes in transfusion coding after implementation of ICD-10. The analysis separates non-critical access hospitals and critical access hospitals, since the latter generally have smaller admission volumes, which influence the statistical model’s detection of a change. We also provide maps that illustrate that the changes are widespread and not geographically driven.

²⁹ The results provided are for all beneficiaries, not specific to dialysis patients; there is no reason to suggest a hospital’s coding practices differ between its general population and dialysis patients. An analysis limited to dialysis patients (which we can provide) leads to qualitatively similar conclusions, but there is more noise because there are fewer admissions to analyze.

- For non-critical access hospitals:
 - 473 of 3,259 hospitals (14.5%) had an estimated reduction in transfusion coding of >80% after the ICD-10 conversion was effected.
 - 733 of 3,259 hospitals (22.5%) had an estimated reduction in transfusion coding of >50% after the ICD-10 conversion was effected.
- For critical access hospitals:
 - 72 of 1,282 hospitals (5.6%) had an estimated reduction in transfusion coding of 80% after the ICD-10 conversion was effected.
 - 246 of 1,282 hospitals (19.2%) had an estimated reduction in transfusion coding of >50% after the ICD-10 conversion was effected.

Overall, 545 of 4,541 of hospitals (12.0%) had an estimated reduction in transfusion coding >80% after the ICD-10 conversion (Figure 1), and 979 of 4,541 hospitals (21.6%) had an estimated reduction in transfusion coding >50% (Figure 2).

Figure 1. Overall Distribution With Estimated Reduction in Transfusion Coding >80% after ICD-10 Conversion

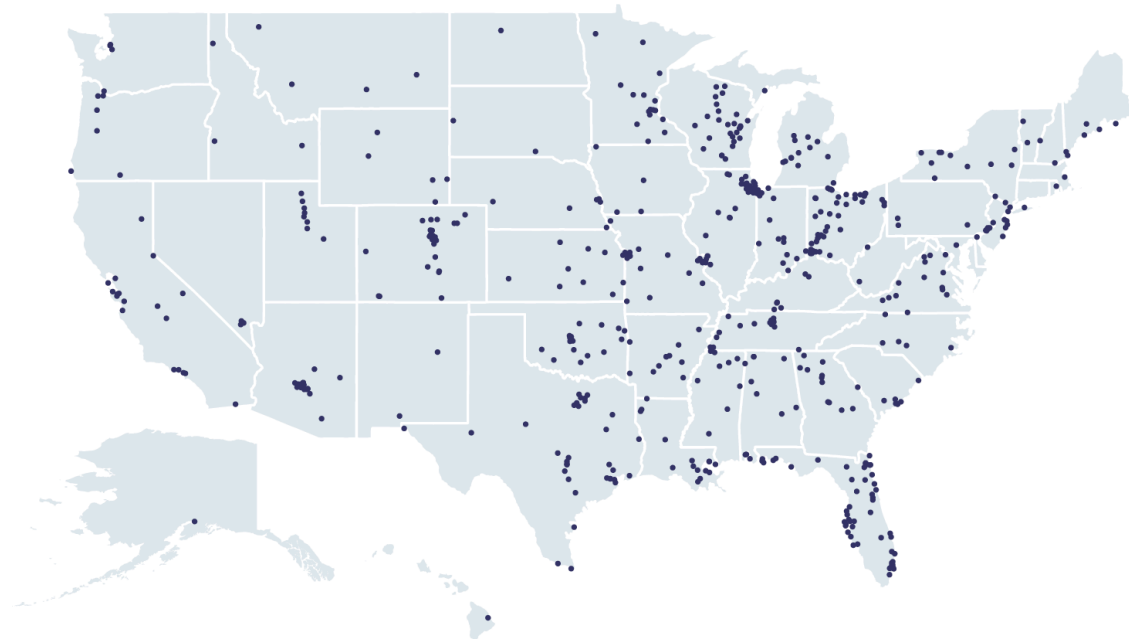
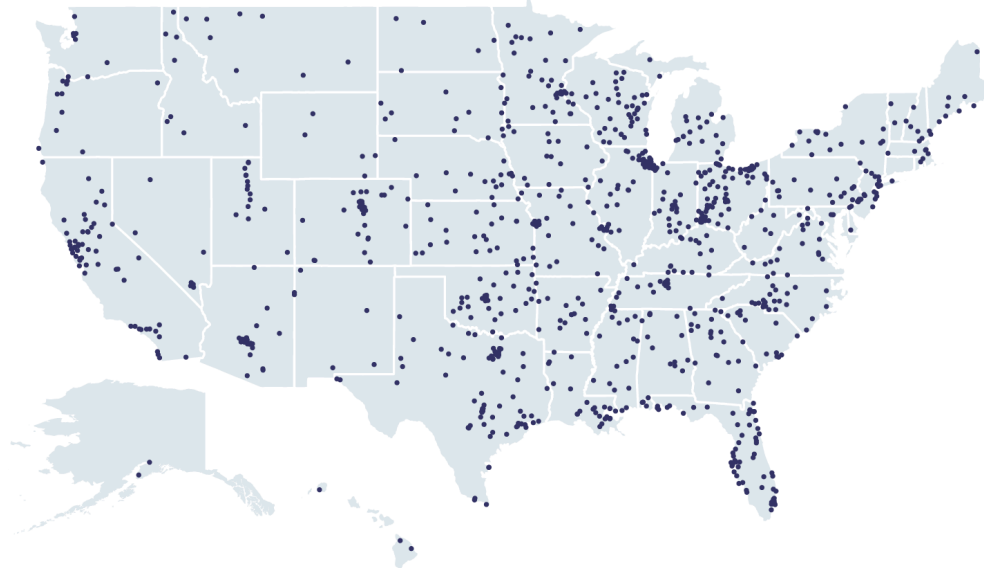


Figure 2. Overall Distribution With Estimated Reduction in Transfusion Coding >50% after ICD-10 Conversion



While it is hoped that fewer transfusions are being performed, it defies logic that such a significant proportion of hospitals would reduce their transfusions by 80%, or even 50% after the conversion to ICD-10. Rather, KCP submits that our original concern regarding under-reporting has been exacerbated. With the switch to ICD-10 codes, we hypothesize that even more hospitals are using only revenue codes, and no accompanying ICD-10 procedure or value codes, which are required for NQF 2979. Facility performance that may appear to have drastically improved on the STrR (fewer transfusions), may in fact solely be due to hospitals not including the ICD-10 codes specified by the measure.

Again, because there is no requirement that the ICD-10 procedure or value codes be used for a facility to be paid, valid transfusion claims that include only revenue codes will be missed by the measure. Facilities associated with hospitals that use the codes will appear to have more transfusions and hence perform more poorly on the STrR and be inappropriately penalized financially under CMS' Quality Improvement Program (QIP) or be inappropriately scored under CMS' Five Star Program because their score on the STrR relative to a significant number of other facilities is likely an artifact of coding practices by hospitals associated with the seemingly "good" facilities.

KCP posits these findings call into question the scientific acceptability (Validity criterion) of the STrR with the change to ICD-10 coding.

If CMS plans to maintain the STrR in the short-term, we ask that consistent with the statutory mandate to use NQF-endorsed measures when available, it use the actual NQF-endorsed measure.

In addition, if CMS continues to use the STrR in the short term, we also reiterate the recommendation that CMS adopt true risk-standardized rate measure, which would be more transparent and useable by all stakeholders. We have consistently supported using risk standardized rates instead of ratios not only because they are easier to understand, as CMS has also previously acknowledged, 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. Rather than continue to use a confusing set of measures, CMS in the short-term should 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 true 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. KCP posits that this conversion approach does not constitute a true risk-standardized rate measure. Under the conversion approach, 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 are both valid and have intrinsic meaning (rather than the abstract meaning expressed by ratios).

7. Bloodstream Infection Measures: 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 previous comment letters, KCP recognizes the vital importance of reducing infections and strongly supports efforts to do so. However, we remained troubled by the use of the NHSN BSI Measure as a clinical measure because it is not valid, as shown by the measure developer, CDC's *et al.* own research, and CMS's own data. Members of recent TEPs have reiterated this concern and urged 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 importance of monitoring bloodstream infections.

CMS has stated that its review shows that as many as 60-80 percent of dialysis events may be under-reported with the NHSN BSI measure.³⁰ We have heard during recent

³⁰81 Fed. Reg. 77834, 77879.

TEPs that this amount might be slightly lower, but still remains unacceptably high. This high under-reporting rate demonstrates that the measure is simply not a valid measure. A lack of validity means that we cannot be certain that the measure results in scientifically acceptable findings. Making sure that measures are valid in the context of public reporting and value-based purchasing is essential to the success of these 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 valid findings, it does not help patients who are trying to use measures to make informed decisions about their care.

Two recent studies found that the problem is 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.³¹

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.³²

³¹Duc 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).

³²Nicola D. Thompson, Matthew Wise, "Evaluation of Manual and Automated Bloodstream Infection Surveillance in Outpatient Dialysis Centers," *37 Infect. Control Hosp. Epidemiol.* 1-3 (2016).

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. Because it is not valid, it does not meet the basic NQF endorsement criterion that measures must be demonstrably valid and reliable.³³ The findings about the missing data were not available to NQF at the time of the last review of the NHSN BSI measure.

Therefore, we ask that CMS include the NHSN BSI measure as a reporting measure rather than a clinical one. As a result, CMS should not use the NHSN Dialysis Event Reporting Measure nor the Safety Measure Domain, because 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.

We continue to reiterate our commitment to working 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 NQF endorsement should not be included in the QIP as clinical measures.

In addition to the long-standing validity problem, CMS has revised the NHSN BSI clinical measure from the NQF-endorsed construction (number of positive blood cultures/number of patients) to an observed over expected construction. The revised construction is not transparent as to how expected rates are calculated; we ask that CMS return to the original NQF-endorsed methodology, which is more transparent, meaningful, and useable to all stakeholders.

Finally, the Dialysis Event Reporting Measure specifications now incorporate the reporting of several subjectively interpreted signs of infection (*e.g.*, swelling, redness). This expansion of the reporting protocol is highly subjective, burdensome, and does not contribute to the measure's underlying premise—to identify BSIs verified by positive blood cultures. These modifications will not serve the purpose of reducing BSI events and we ask that CMS not finalize this proposal.

8. ICH CAHPS: 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, as noted by several members of the recently convened Patient-Report

³³NQF, "Review and Update of Guidance for Evaluating Evidence and Measure Testing" (Oct. 2013).

Outcomes TEP, the ICH CAHPS measure response rate is extremely low, likely due in large part to patient survey fatigue. If CMS remains serious about understanding patient experience and having facilities work to improve it, then the ICH CAHPS measure needs to be adjusted immediately to address the following issues and should not be used as a clinical measure until that time.

First, CMS should address the fatigue problem by modifying the measure to address concerns about the burden on patients. CMS should also align the specifications with those that AHRQ relied on when it tested the measure 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.³⁴ We also recommend that CMS coordinate with the Networks to reduce duplication in the administration of the survey.

Second, we recommend that CMS ensure the accuracy of the administration of the survey. 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.

Third, it is important for CMS to clarify to whom the survey should apply. ICH CAHPS should include a specific list of the exclusions, which among other things should exclude homeless patients who cannot be reliably contacted under the current administration model. We appreciate CMS' willingness to consider expanding the ICH

³⁴ 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).

CAHPS survey to include peritoneal dialysis and home hemodialysis patients in future rulemaking.

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

9. Transplant Measures: KCP supports including an actionable transplant measure in the QIP, but cannot support the use of the NQF 3403: Percentage of Patients Waitlisted (PPPW) and NQF 3402: Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) because the NQF has declined to endorse them.

KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution to dialysis facilities of successful/unsuccessful waitlisting. KCP believes that while a referral to a transplant center, initiation of the waitlist evaluation process, or completion of the waitlist evaluation process may be appropriate facility-level measures that could be used in ESRD quality programs, the Percentage of Prevalent Patients Waitlisted (PPPW) and Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) are not. Waitlisting per se is a decision made by the transplant center and is beyond a dialysis facility's locus of control. However, the fact that NQF has concluded that neither of these measures meet the scientific measure development criteria, we cannot support including them in the ESRD QIP.

To assist CMS in addressing the problems with these measures, we have included our comments about each measure that we have previously shared. However, as noted in Section I of the comment letter, KCP encourages CMS to prioritize developing an appropriate transplant referral measure. A measure that recognizes what is actionable by facilities would better support the Meaningful Measures Initiative priority area of increased focus on effective communication and coordination. The problem is not with facility assessment and evaluation, but with the criteria hospitals set for the waitlists. We recognize the need to avoid a "check-box measure," but believe that a transplant measure could include both a referral and assisting the patient in getting to their first appointment. This type of measure would still encourage rapid evaluation of patients, but hold facilities accountable for what they can actual do and better incentivize the desired performance.

In reviewing these measures, we offer the following comments:³⁵

³⁵ Note: While information on the PPPW and SWR risk models were not released with the MUC list, we note that the measures' specifications are identical to those recently released by CMS for public review for use in Dialysis Facility Compare (DFC) Five Star Rating Program. We thus make the presumption that the technical details of the associated risk models also are unchanged.

Comments Relevant to both the PPPW and SWR Measures

Several of KCP's concerns apply to both the PPPW and SWR measures:

- **Facility attribution.** KCP appreciated the Measure Applications Partnership (MAP) Hospital Workgroup's recommendation that the Waitlist measures also be reviewed by NQF's Attribution Expert Panel to assess KCP's and other stakeholders' concerns about the measures' attribution models. However, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to dialysis facilities and believe this is a fatal structural flaw. 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 PPPW and SWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle", which states that measures' attribution models should fairly and accurately assign accountability.³⁶ KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued.
- **Age as the only sociodemographic risk variable.** KCP appreciated the MAP Workgroup's recommendation that the Waitlist measures also be reviewed by NQF's Disparities Standing Committee to assess KCP's and other stakeholders' concerns about the measures' risk of potentiating existing health inequities. KCP strongly believes age as the only sociodemographic 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. 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, like the Access to Kidney Transplantation TEP, KCP does not support adjustment for waitlisting based on economic factors or by race or ethnicity.

Geography, for instance, should be examined, since regional variation in transplantation access is significant. Waitlist times differ regionally, which will ultimately change the percentage of patients on the waitlist and impact performance measure scores. That is, facilities in a region with long wait times will "look" better

³⁶ NQF. *Attribution: Principles and Approaches. Final Report.* December 2016.

<http://www.qualityforum.org/ProjectDescription.aspx?projectID=80808>. Accessed December 21, 2017.

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 additional/ 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.

- Hospice exclusion. We note that an exclusion for patients admitted to hospice during the month of evaluation has been incorporated into both measures. KCP agrees that the transplantation access measures should not apply to persons with a limited life expectancy and so is pleased to see this revision.
- Risk model fit. KCP appreciates the MAP Hospital Workgroup’s recommendation that the Waitlist measures also be reviewed by NQF’s Scientific Methods Panel to assess KCP’s and other stakeholders’ concerns about the measures’ risk models. We note that risk model testing yielded an overall C-statistic of 0.72 for the PPPW and 0.67 for the SWR, raising concerns that the models will not adequately discriminate performance. Smaller units, in particular, might look worse than their actual performance. We reiterate our long-held position that a minimum C-statistic of 0.8 is a more appropriate indicator of a model’s goodness of fit, predictive ability, and validity to represent meaningful differences among facilities.
- Stratification of reliability results by facility size. CMS has provided no stratification of reliability scores by facility size for either measure; we are thus unable to discern how widely reliability varies across the spectrum of facility sizes. We are concerned that the reliability for small facilities might be substantially lower than the overall IURs, as has been the case, for instance, with other CMS standardized ratio measures. This is of particular concern with the SWR, for which empiric testing has yielded an overall IUR of only 0.6—interpreted as “moderate” reliability by statistical convention.³⁷ To illustrate our concern, the Standardized Transfusion Ratio for Dialysis Facilities (STrR) measure (NQF 2979) also was found to have an overall IUR of 0.60; however, the IUR was only 0.3 (“poor” reliability) for small facilities (defined by CMS as ≤ 46 patients for the STrR). Without evidence to the contrary, KCP is thus concerned that SWR reliability is similarly lower for small facilities, effectively rendering the metric meaningless for use in performance measurement in this group of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all facilities by providing data by facility size.
- Meaningful differences in performance. We note that with large sample sizes, as here, even statistically significant differences in performance may not be clinically

³⁷ Landis J, Koch G. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33:159-174.

meaningful. A detailed description of measure scores, such as distribution by quartile, mean, median, standard deviation, outliers, should be provided to allow stakeholders to assess the measure and allow for a thorough review of the measures' performance.

- Additional language related to exclusions. We note that since KCP reviewed these measures and provided comment to CMS in 2016, one PPPW exclusion has been altered with the following boldface text: *Patients admitted to a skilled nursing facility or hospice during the month of evaluation are excluded from that month; **patients admitted to a skilled nursing facility at incidence or previously according to Form CMS 2728 are also excluded.*** Similarly, one SWR exclusion has been altered with the following boldface/strikeout text: ***Preemptive patients: Patients at the facility who had the first transplantation prior to the start of ESRD treatment or** ~~Patients at the facility who were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis.~~*

KCP supports these changes, but notes that the testing forms submitted by the developer do not provide information on the impact of these exclusions on performance, as required by NQF. We recommend the appropriate, required testing be reported.

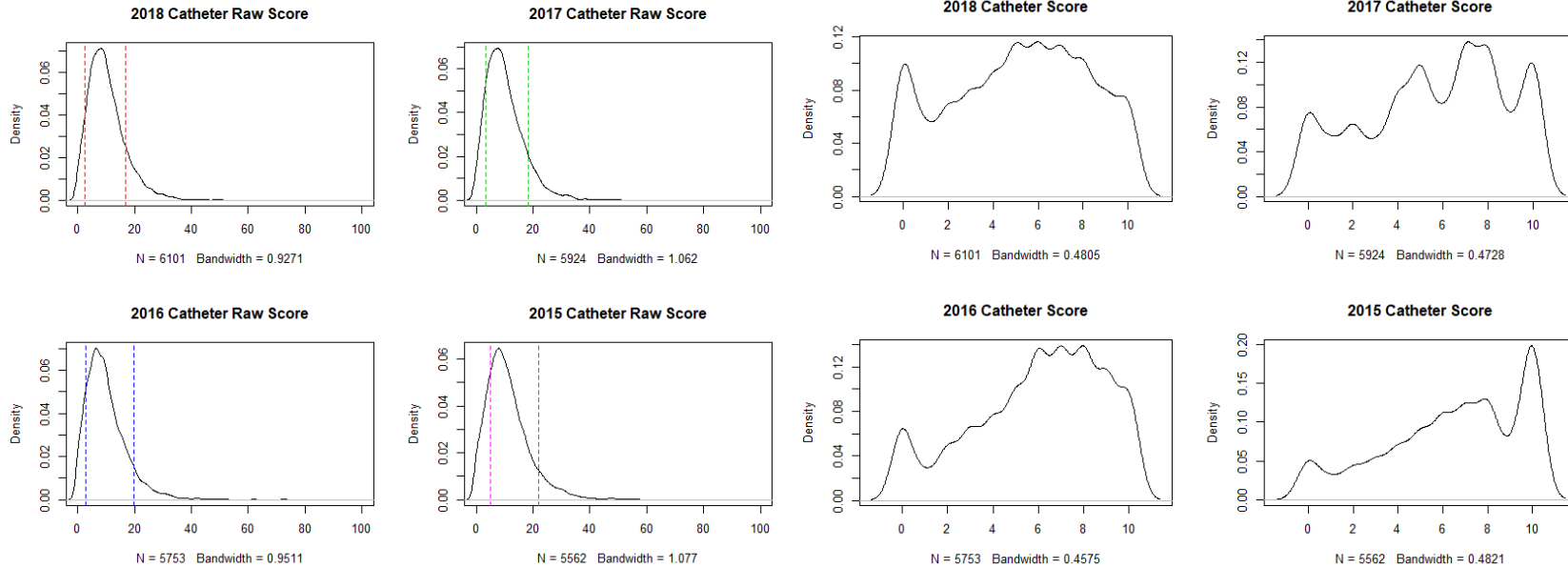
Comment Relevant to PPPW Only

- Process vs. intermediate outcome measure. The Measure Submission Form identified the PPPW as a process measure. KCP believes the PPPW is an intermediate outcome measure and recommends it be indicated as such.

Comments Relevant to SWR Only

- Incident comorbidities incorporated into risk model. We note that eleven incident comorbidities—heart disease, inability to ambulate, inability to transfer, COPD, malignant neoplasm/cancer, PVD, CVD, alcohol dependence, drug dependence, amputation, and needs assistance with daily activities—have been incorporated into the SWR risk model. All are collected through the CMS Form 2728. As we have noted before, we continue to be concerned about the validity of the 2728 as a data source and urge CMS to work with the community to assess this matter.
- Rate vs. ratio. 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.

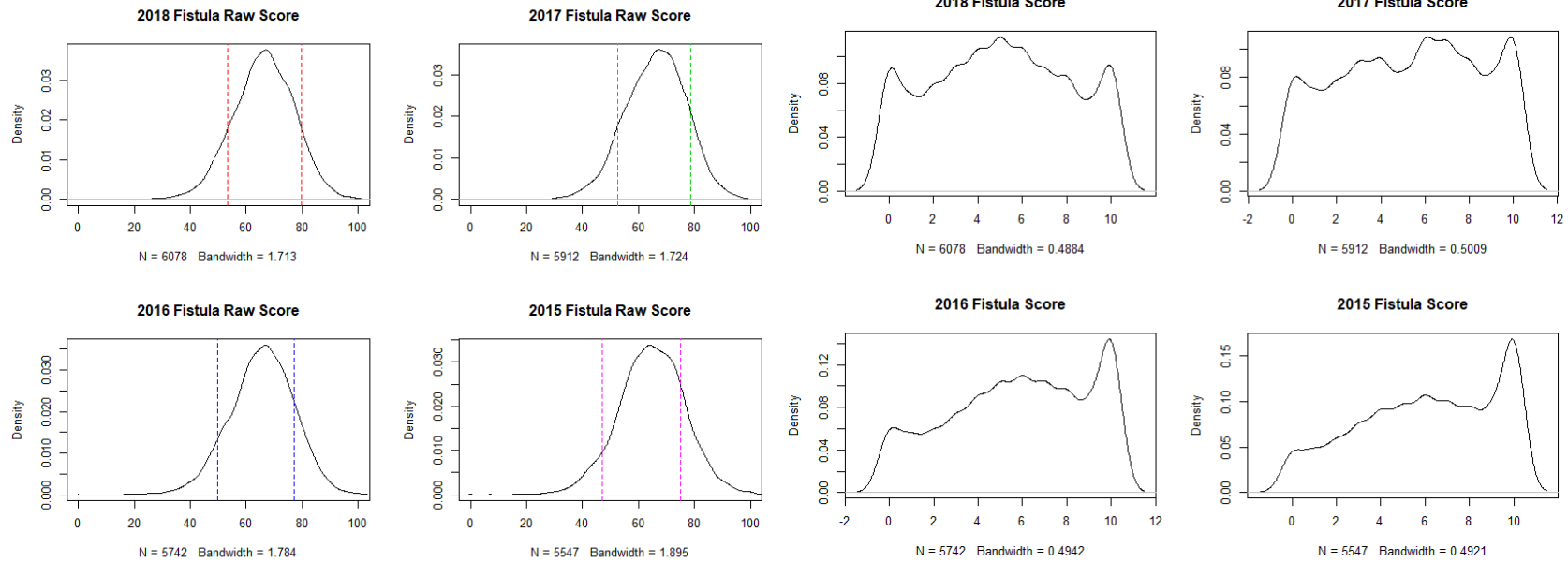
Appendix D1. VAT Measures: Catheter



Catheter Descriptive Statistics

	Raw Mean	Score Mean	Raw Median	Score Median	Raw Range	Raw Percentiles (15 th , 90 th)	Set Benchmark, Achievement Threshold	Raw Kurtosis	Score Kurtosis	percent No Score
2015	11.13	6.44	10	7	0.00-67.38	4.08, 18.74	5, 22	5.72	-0.65	9.38 percent
2016	10.07	5.97	9	6	0.00-65.00	4, 19	2.8, 29.9	5.78	-0.61	9.44 percent
2017	10.13	5.68	9	6	0.00-73.00	3, 19	3.23, 18.36	3.57	-0.95	9.53 percent
2018	10.30	5.12	9.17	5	0.00-95.00	4, 21	2.59, 16.79	3.72	-1.03	10.61 percent

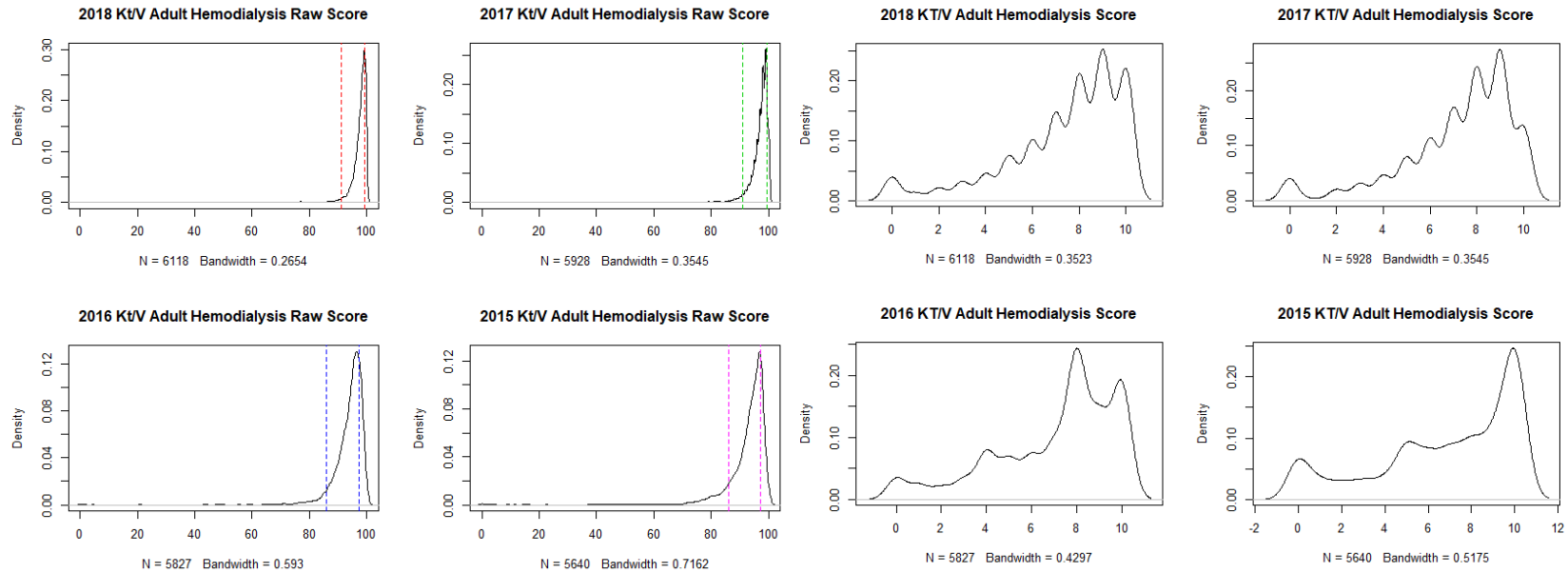
Appendix D2. VAT Measures: Fistula



Fistula Descriptive Statistics

	Raw Mean	Score Mean	Raw Median	Score Median	Raw Range	Raw Percentiles (15 th , 90 th)	Set Achievement Threshold, Benchmark	Raw Kurtosis	Score Kurtosis	percent No Score
2015	64.69	6.07	65	6	0.00-100.00	53, 79	47, 75	0.45	-1.00	9.63 percent
2016	65.57	5.80	66	6	0.00-100.00	54, 80	49.9, 77.0	0.48	-1.01	9.61 percent
2017	66.13	5.29	67	6	8.00-100.00	55, 80	52.42, 78.56	0.21	-1.15	9.71 percent
2018	66.25	5.02	66.53	5	0.00-100.00	54.88, 79.90	53.51, 79.60	0.32	-1.07	10.94 percent

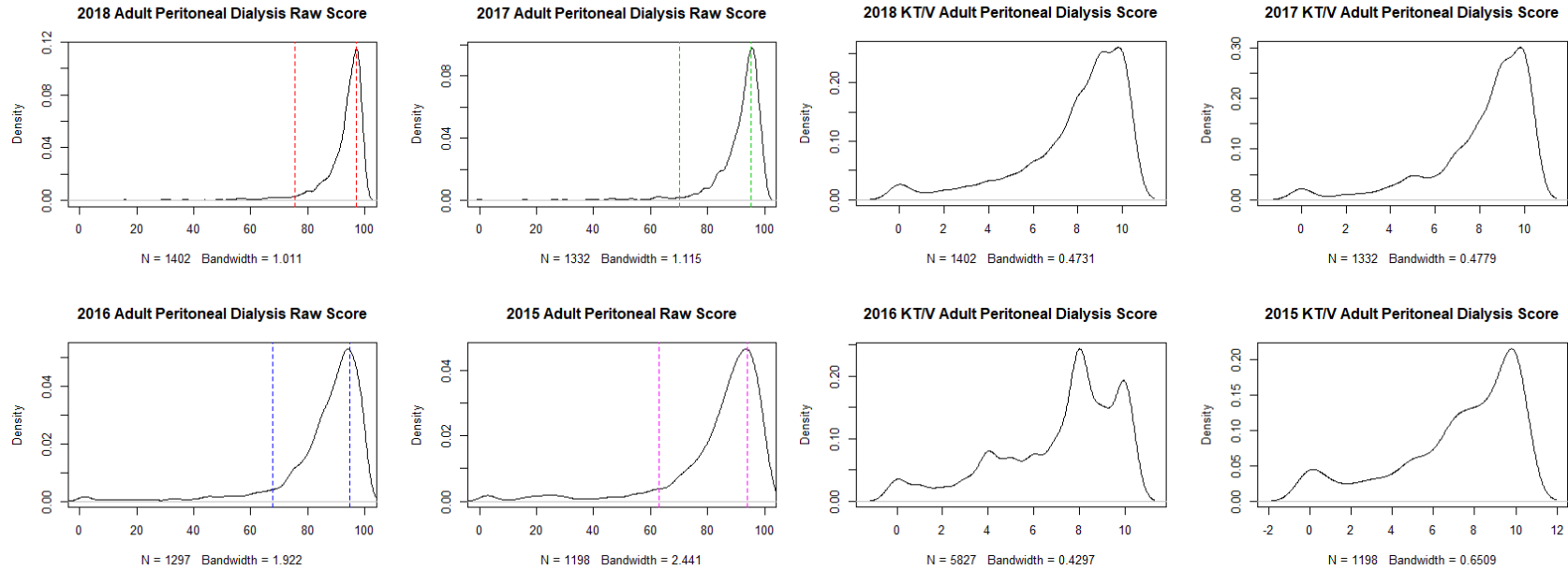
Appendix D3. Kt/V Measures: Adult Hemodialysis



Adult Hemodialysis Descriptive Statistics

	Raw Mean	Score Mean	Raw Median	Score Median	Raw Range	Raw Percentiles (15 th , 90 th)	Set Achievement Threshold, Benchmark	Raw Kurtosis	Score Kurtosis	percent No Score
2015	92.16	6.78	95	8	0-100	88.00, 98.00	86.00, 97.00	40.06	0.99	8.11 percent
2016	93.70	7.03	95	8	0-100	90.00, 98.00	86.00, 97.40	75.94	1.34	8.28 percent
2017	96.92	7.21	98	8	1-100	95.00, 100.00	81.08, 99.35	151.92	0.15	9.47 percent
2018	97.49	7.34	98.345	8	0-100	95.89, 99.74	91.08, 99.35	208.62	-0.55	10.36 percent

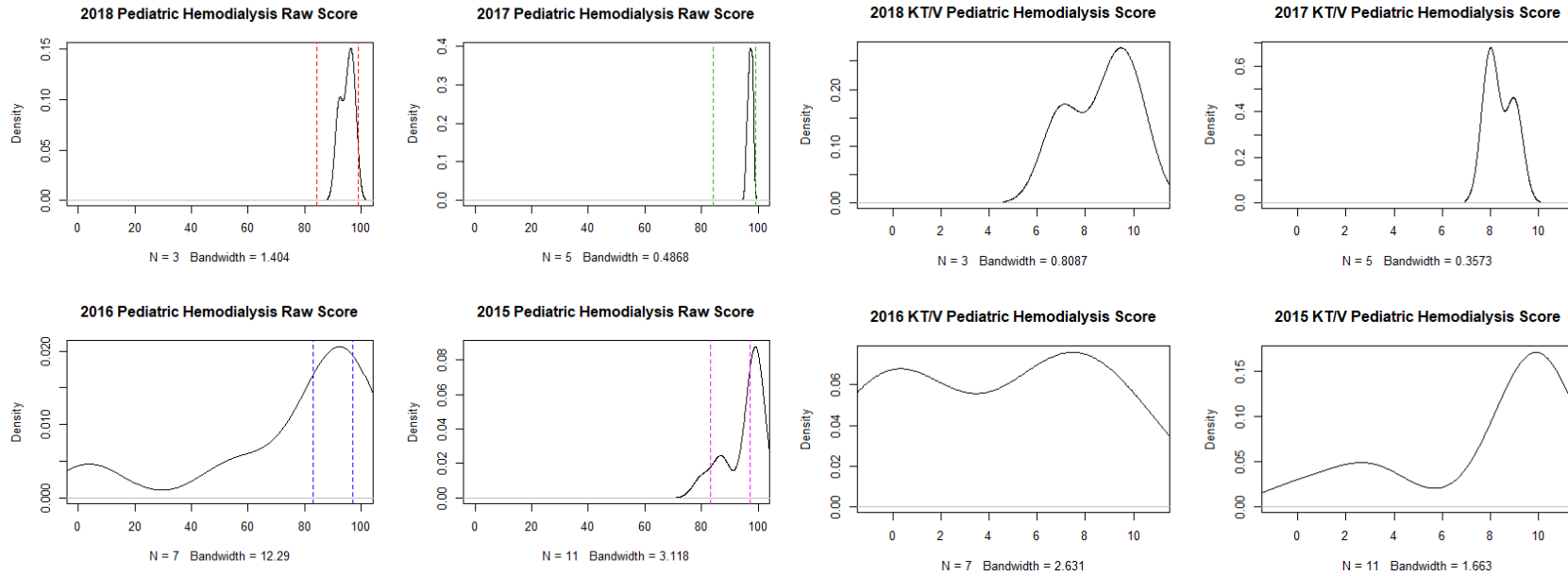
Appendix D4. Kt/V Measures: Adult Peritoneal Dialysis



Adult Peritoneal Dialysis Descriptive Statistics

	Raw Mean	Score Mean	Raw Median	Score Median	Raw Range	Raw Percentiles (15 th , 90 th)	Set Achievement Threshold, Benchmark	Raw Kurtosis	Score Kurtosis	percent No Score
2015	83.47	7.16	89	8	1-100	73-98	63.00, 94.00	6.47	0.10	80.48 percent
2016	85.55	7.16	90	8	0-100	76-98	67.80, 94.80	9.66	0.20	79.56 percent
2017	90.49	8.11	94	9	0-100	85-98	70.19, 95.20	20.34	2.98	79.63 percent
2018	91.87	7.81	94.87	9	1.8-100	86.73-98.38	75.42, 97.06	20.55	1.88	79.46 percent

Appendix D5. Kt/V Measures: Pediatric Hemodialysis

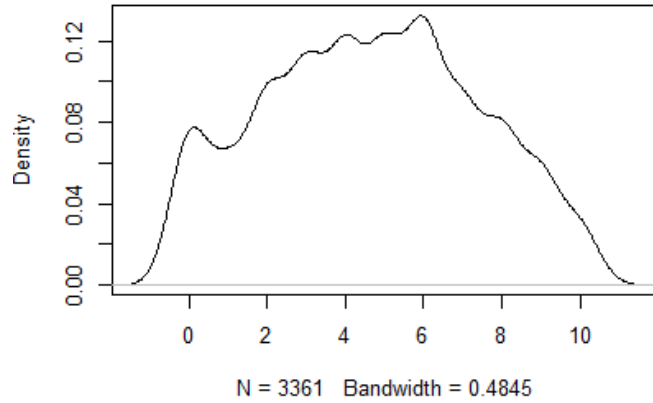


Pediatric Hemodialysis Descriptive Statistics

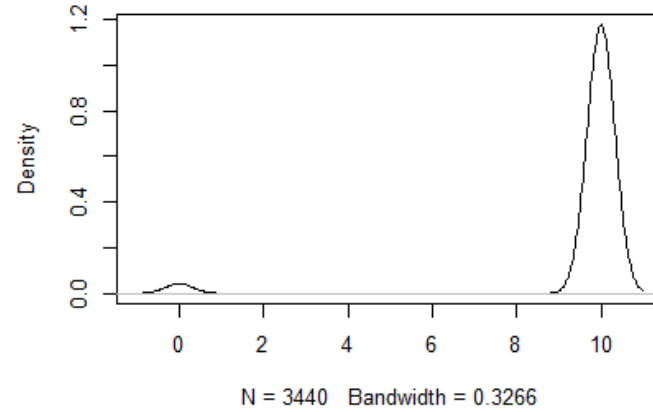
	Raw Mean	Score Mean	Raw Median	Score Median	Raw Range	Raw Percentiles (15 th , 90 th)	Set Achievement Threshold, Benchmark	Raw Kurtosis	Score Kurtosis	percent No Score
2015	95	7.73	99	10	80-100	93.09, 96.93	83.00, 97.00	-0.86	-0.62	99.82 percent
2016	73.71	4.43	92	6	4-98	49.9, 96.2	83.00, 97.10	-2.04	-0.41	99.89 percent
2017	97.2	8.4	97	8	96-98	96.6, 98.0	84.15, 99.06	-2.25	-1.82	99.89 percent
2018	94.94	8.67	95.39	9	92.11-97.32	93.09, 96.93	84.16, 99.06	-2.33	-2.33	99.96 percent

Appendix 6. ICH CAHPS

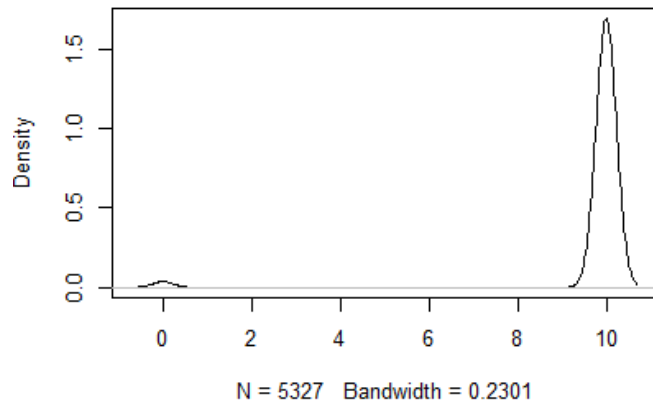
2018 ICH CAHPS Score



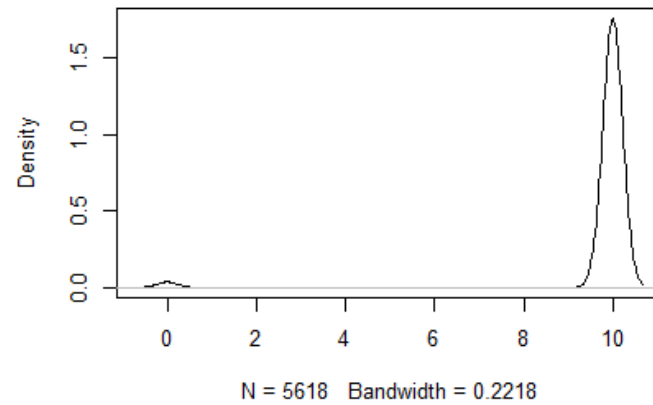
2017 ICH CAHPS Score



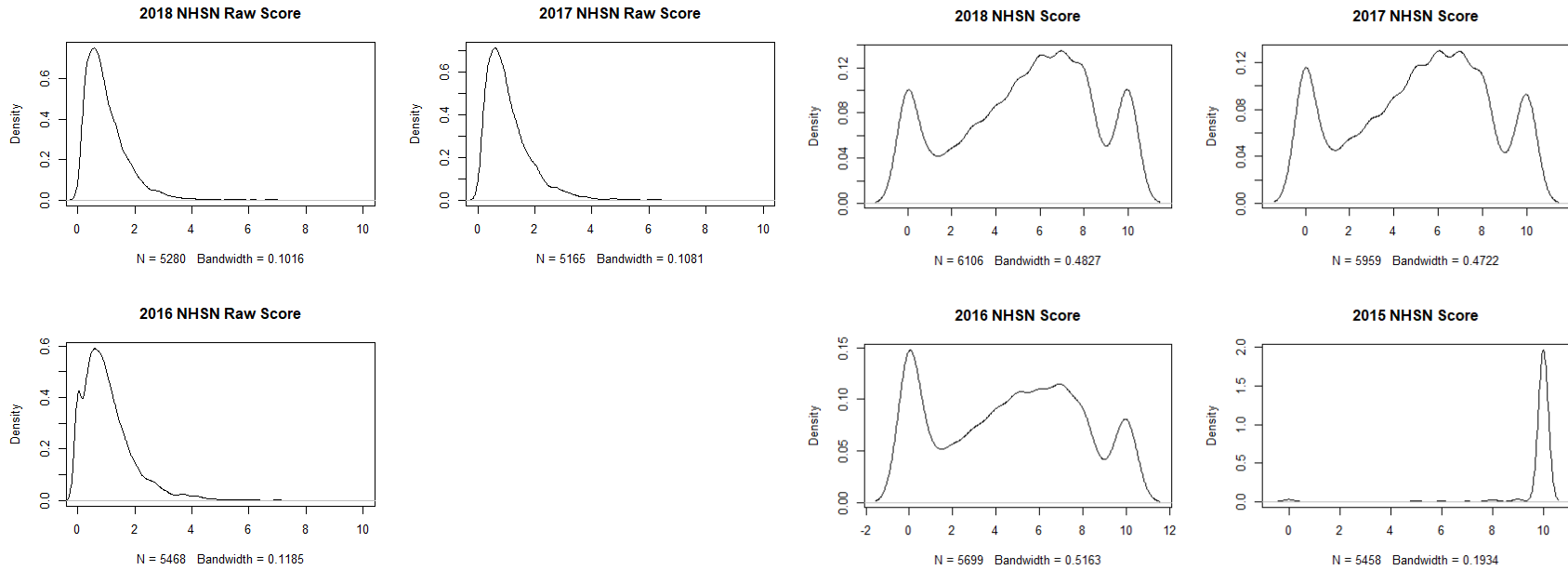
2016 ICH CAHPS Score



2015 ICH CAHPS Score



Appendix D7. NHSN Score

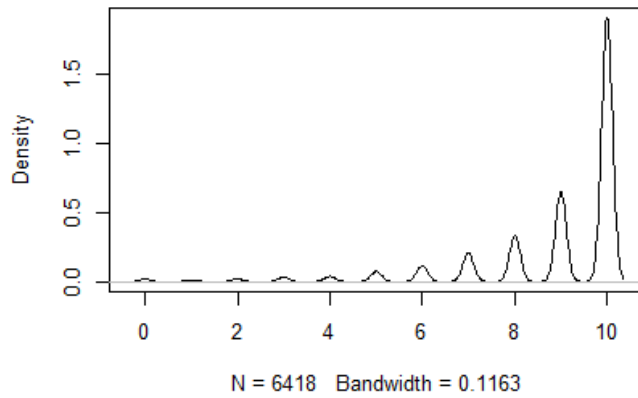


NHSN Descriptive Statistics

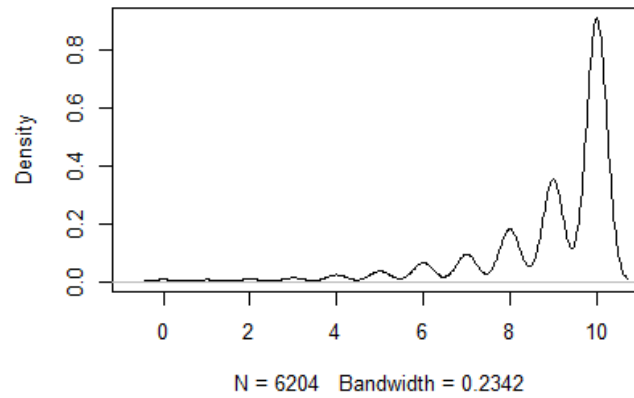
	Raw Mean	Score Mean	Raw Median	Score Median	Raw Range	Raw Percentiles (15 th , 90 th)	Set Achievement Threshold, Benchmark	Raw Kurtosis	Score Kurtosis	percent No Score
2015	--	9.81	--	10	--	--	Not listed	--	56.57	11.08 percent
2016	1.05	4.73	0.86	5	0.00-8.37	0.25, 2.15	Not listed	4.84	-1.13	10.29 percent
2017	1.08	5.16	0.89	6	0.00-9.8	0.38, 2.08	Not listed	9.68	-0.95	10.29 percent
2018	1.01	5.40	0.82	6	0.00-8.5	0.35, 1.93	1.812, 0	9.40	-0.88	10.51 percent

Appendix D8. Mineral Metabolism

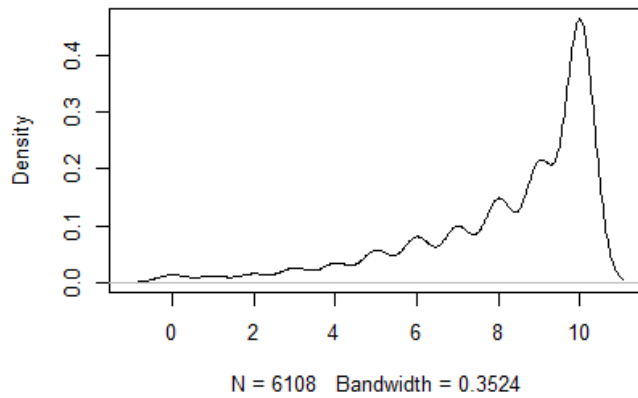
2018 Mineral Metabolism Score



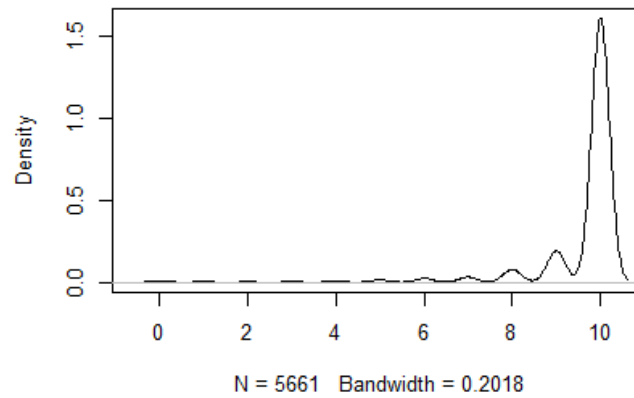
2017 Mineral Metabolism Score



2016 Mineral Metabolism Score

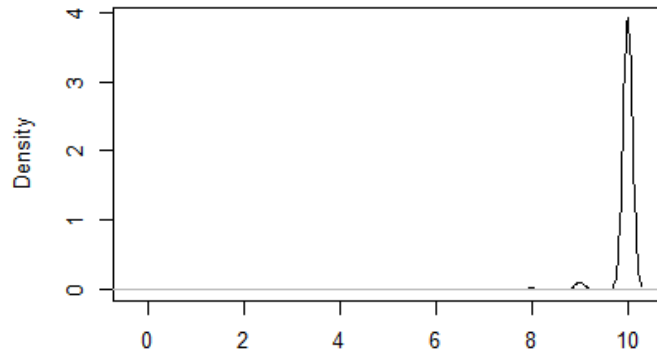


2015 Mineral Metabolism Score



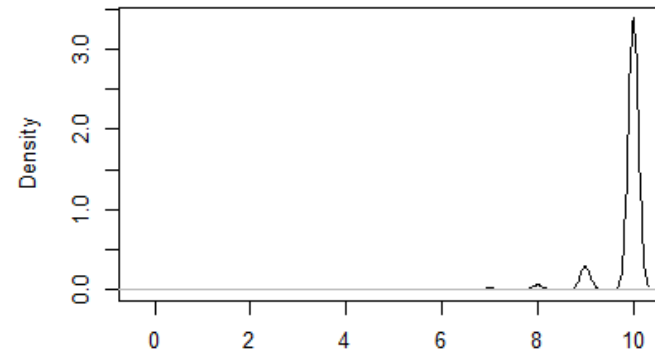
Appendix D9. Anemia Management

2018 Anemia Management Score



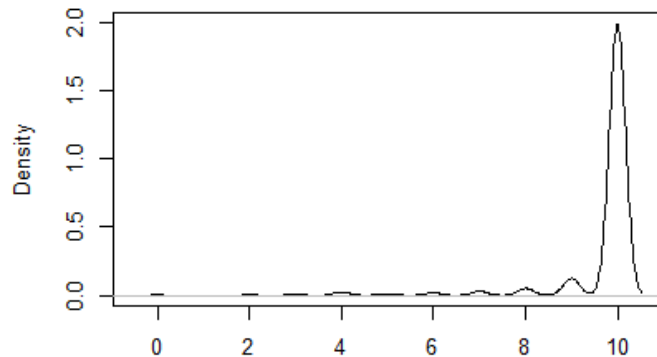
N = 6427 Bandwidth = 0.09661

2017 Anemia Management Score



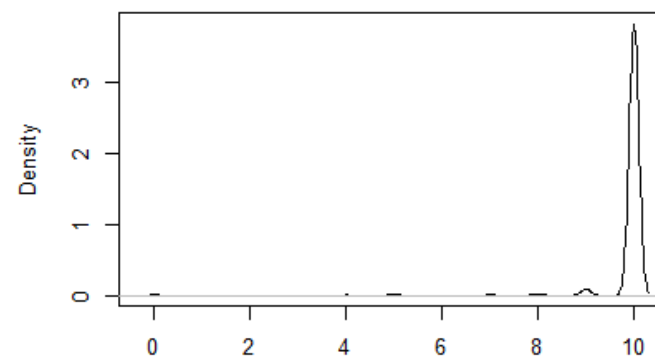
N = 6218 Bandwidth = 0.1047

2016 Anemia Management Score



N = 6116 Bandwidth = 0.1758

2015 Anemia Management Score



N = 5691 Bandwidth = 0.09982