KIDNEY CARE PARTNERS

August 11, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS–1674–P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program

Dear Administrator Verma:

Kidney Care Partners (KCP) appreciates the opportunity to provide comments on the "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program" (Proposed Rule). This letter addresses the proposals related to the ESRD Quality Incentive Program (QIP). We have provided our comments on the ESRD Prospective Payment System, payments for Acute Kidney Injury patients, and the Request for Information in separate letters.

In sum, KCP:

- Generally, supports the effort to assess and account for Social Risk Factors in the ESRD QIP Program through adjusters and other mechanisms.

- For PY 2019, recommends that CMS maintain the current Performance Score Certificate for those patients who want the detailed information, but use star ratings to allow patients who want a more simplified tool.

- For PY 2020:
  - Reiterates that CMS should not include AKI patients in the ESRD QIP and notes that the statute limits the QIP to ESRD patients.

  - Recommends that CMS adopt a minimum sample size of 26 patients and eliminate the small facility adjustment.

- Supports proposed modifications to the Extraordinary Circumstances Exception (ECE) policy.

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

- Recommends that CMS adopt criteria for assessing the weights of measures and apply them for PY 2020 (and PY 2021) to increase the weight of the catheter reduction measure in the Vascular Access Topic area.

- Is concerned with the significant increase in the proposed payment reductions for PY 2020 (and PY 2021) and seeks clarification.

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

- Continues to recommend changes to the PY 2020 measure set.

- For PY 2021:
  - Reiterates our concerns described in Section III.H. and urges CMS to adopt these recommendations before simply maintaining PY 2020 Measures for PY 2021.

  - Appreciates the clarifications to the STrR measure, but notes that these clarifications do not address the underlying concerns with the measure.

  - Recommends that CMS weight the catheter reduction measure greater than the fistula placement measure.

  - Supports the proposed performance period, but once again asks that CMS align the performance period for the NHSN Healthcare Personnel Influenza Vaccination Reporting Measure with clinical and federal guidelines.

  - Supports the proposed performance standards, achievement thresholds, and benchmarks for the PY 2021 ESRD QIP.

  - Supports the scoring the PY 2021 ESRD QIP.

- Recommends that CMS apply the recommended criteria in PY 2021 to increase the weight of the catheter reduction measure in the Vascular Access Topic area.

- Continues to recommend that CMS eliminate the small facility adjustment process and adopt a minimum sample size of 26 patients scoring measures.

- Is concerned about the substantial change in the number of payment reductions and seeks clarification.

I. KCP supports the effort to assess and account for Social Risk Factors in the ESRD QIP Program through adjusters and other mechanisms.

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.[1] 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

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.

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[1] *See generally,* Assistant Secretary for Planning and Evaluation (ASPE), "Report to the Congress: Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs" (Dec. 2016).

- 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 lead 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 wait-lists. 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 wait-list 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.[2] We also agree with the ASPE report's recommendation that innovative care models could help "achieve better outcomes for beneficiaries with social risk factors,"[3] 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

[2] *Id.* at 95.
[3] *Id.* at 16.

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."[4] 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.

II. PY 2019: KCP recommends that CMS maintain the current Performance Score Certificate (PSC) for those patients who want the detailed information, but use star ratings to allow patients who want a more simplified tool.

Since the inception of the ESRD QIP as a legislative provision, KCP has strongly supported including the public reporting component of the program. However, we are concerned with the proposed modifications and recommend against adopting them.

It is important that the information shared on the PSC is meaningful and clear. Beneficiaries need to understand the information being presented in order to make informed choices. In addition, facilities and providers should not be represented as providing or not providing quality of care in a particular year without the details as to how that conclusion was made being clear and understandable.

Additionally, over-simplifying the information presented assumes that patients do not need or cannot understand it; both views are inappropriate.

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[4] *Id.* at 220.

Eliminating all information except for the total performance score (TPS), facility identifying information, and the comparison to the national average would be counter to CMS's stated goal of benefiting facilities and enhancing the public's understanding of the TPS.

If CMS believes it is important for patients to have access to the TPS in an easier to understand manner in addition to the other information currently provided on the PSC, we recommend that CMS eliminate the inconsistent ESRD Star Rating Program and instead use the ESRD QIP methodology to assign stars to the TPS. Based on the proposed TPS scoring methodology for PY 2019 for example, stars could be awarded as follows:

Total Performance Score	Reduction	Star
100-61	0%	☆☆☆☆☆
60-51	0.5%	☆☆☆☆
50-41	1.0%	☆☆☆
40-31	1.5%	☆☆
30-0	2.0%	☆

We understand that CMS has historically raised concerns that the ESRD QIP and the ESRD Star Rating programs are different and serve different purposes – the ESRD QIP incentivizing "good quality care" and the Star Rating program "to help consumers, their families, and caregivers compare" facilities. However, both programs seek to provide the public with information evaluating the quality of care provided. As described in detail in our comment letter on the Request for Information, there is no reason to have two programs with different measures and methodologies that are confusing patients. Eliminating the ESRD Star Rating program and applying stars to the PSC TPS tiers would achieve the Agency's goal of providing information in an easy to understand manner, while maintaining the specific information for each measure on the PCS allows patients, not the government, to view each measure individually and understand the overall performance of a facility. It also would empower patient decisionmaking by giving each patient the opportunity to review each QIP measure and make their own decisions about which measures are the most important to them.

In addition, concerns about the length of the PSC because of the number of measures being added suggests that there may simply be too many measures and KCP's recommendations regarding measures that matter should be adopted. We do not believe it is appropriate to reduce the information patients can access because there are too many measures included in the QIP.

We would welcome the opportunity how to engage in a meaningful way with CMS to best present information to patients to empower them to make health care decisions.

III. PY 2020

A. KCP reiterates that CMS should not include AKI patients in the ESRD QIP and notes that the statute limits the QIP to ESRD patients.

KCP is deeply concerned that CMS is considering adding acute kidney injury (AKI) patients to the ESRD QIP. First, the statute that established and governs the ESRD QIP is limited to "individuals who have been determined to have end stage renal disease as determined in section 226A."[5] Section 226A of the Social Security Act (SSA) states:

> Subject to subsection (c), entitlement of an individual to benefits under part A and eligibility to enroll under part B of title XVIII by reasons of this section on the basis of end stage renal disease—
>
> (1) shall begin with—
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> (A) the third month after the month in which a regular course of renal dialysis is initiated, or
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> (B) the month in which such individual receives a kidney transplant, or (if earlier) the first month in which such individual is admitted as an inpatient to an institution which is a hospital meeting the requirements of section 1861(e) (and such additional requirements as the Secretary may prescribe under section 1881(b) for such institutions) in preparation for or anticipation of kidney transplantation, but only if such transplantation occurs in that month or in either of the next two months, whichever first occurs (but no earlier than one year preceding the month of the filing of an application for benefits under this section); and
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> (2) shall end, in the case of an individual who receives a kidney transplant, with the thirty-sixth month after the month in which such individual receives such transplant or, in the case of an individual who has not received a kidney transplant and no longer requires a regular course of dialysis, with the twelfth month after the month in which such course of dialysis is terminated.[6]

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[5] 42 U.S.C. § 1395rr(a).

[6] *Id.* at § 426-1(b). The exceptions are limited to specific self-care training programs and transplant patients.

This limitation excludes AKI patients from the ESRD benefit and programs. CMS has recognized this distinction in its payment policy by defining AKI patients as "an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14) of the Act."[7] Thus, AKI patients are not ESRD beneficiaries and the Congress did not intend for such patients to be included in the "Quality Incentives in the End-Stage Renal Disease Program."[8] The QIP language further defines the quality incentive as avoiding a payment reduction to the rates paid under 42 U.S.C. § 1395rr(b)(14).[9] Facilities that provide services to AKI patients are paid under 42 U.S.C. § 1395m(r). Thus, while we agree that monitoring AKI patients is important and support the efforts of the Center for Medicare to do so, statutorily the ESRD QIP applies only to beneficiaries with ESRD and not AKI beneficiaries.

Last year, the Agency also assured the kidney care community that it recognized that AKI patients differ greatly from ESRD patients and, thus, should not be included in the QIP measurement. As the CMS payment team recognizes, AKI patients are different than ESRD patients because they have not completely and irrevocably lost their kidney function. Renal replacement therapy is a temporary treatment option rather than a requirement to remain alive. Thus, the same quality metrics that are used for the ESRD population are not appropriate to evaluate the quality of care provided to individuals with AKI who require dialysis.

There is strong consensus among medical experts that ESRD and AKI patients are different, have different treatment goals, and have different outcome goals. The Renal Physicians Association (RPA) notes in its consensus White Paper entitled, "Acute Kidney Injury Patients Requiring Outpatient Dialysis," "[t]here is also no evidence that existing ESRD clinical practice guidelines for anemia management, metabolic bone disease, vascular access management, dialysis adequacy, and nutrition are applicable to AKI-D patients."[10] Given that more work is needed to better understand the progression of AKI, it would not be appropriate to apply the ESRD measures to this group of patients.

The RPA also notes that individuals with AKI "are not in a steady state."[11] This means that, while the services provided to individuals with AKI may be the same, the frequency with which they are provided those services and the labor required to provide them differ from that required for individuals with ESRD. RPA's White Paper notes that:

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[7] 42 C.F.R. § 413.371.
[8] *See* 42 U.S.C. § 1395rr(h).
[9] *Id.* at § 1395rr(h)(1).
[10] Renal Physicians Association, "Acute Kidney Injury Patients Requiring Outpatient Dialysis" 7 (2016).
[11] *Id.* at 6.

> None of these care needs is beyond the capability of most dialysis facilities, but the cumulative degree of care and attention required for the [acute kidney injury requiring dialysis] AKI-D patient typically exceeds that for a patient with ESRD. Additional staff time per patient and specialized staff training may be needed to address the increased needs of these patients.
>
> AKI-D patients may require more frequent lab testing to review kidney function and assess drug levels, nutritional status, infection, and other organ function. They may require antibiotic administration and monitoring for infections unrelated to the dialysis procedure. Intercurrent illness, hospital-based treatments and debility may increase the frequency of missed treatments.[12]

Throughout the CY 2017 Proposed Rule, CMS recognized the real differences in these patient populations as well.[13]

There is much still to learn about the treatment of patients with AKI who require dialysis, including the utilization of renal dialysis services. Because the ESRD QIP measures are based on treatment protocols and scientific literature related to ESRD treatments, and not AKI treatments, it is simply inappropriate to incorporate these patients with the ESRD QIP. It is not clinically appropriate to try to "pool" these patients into existing ESRD patients by adding them into the numerator and denominator. Therefore, we ask that in the final rule CMS acknowledge this difference and clarify that individuals with AKI who receive dialysis will not be included in the quality programs within the Center for Medicare, as well as those under the jurisdiction of the Center for Clinical Standards and Quality, the Centers for Disease Control and Prevention, and other entities involved in collecting ESRD data for federal quality programs.

We agree that these patients should receive high quality care and to that end encourage the Center for Clinical Standards and Quality to work with the Center for Medicare as it monitors AKI patients through its formal monitoring program to learn more about the clinical needs of this unique patient population.

B. KCP recommends that CMS adopt a minimum sample size of 26 patients and eliminate the small facility adjustment.

We appreciate that CMS has recognized and sought to address its mistake in the proposed rule. However, as we have in that past, KCP recommends that CMS adopt a minimum sample size of 26 patients scoring measures and eliminate the

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[12] *Id.*

[13] "[W]e recognize that the utilization of items and services for beneficiaries with AKI receiving dialysis may differ from the utilization of these same services by ESRD beneficiaries." *Id.* at 81.

small facility adjustment process. Using sample sizes as small as 11 is inconsistent with measurement best practice and exposes the QIP results to random results that are not fully compensated by the small sample size adjustment. As KCP documents elsewhere in our comments on specific measures, there are ample technical ways in which small facilities can be included, yet random results avoided.

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

C. KCP supports proposed modifications to the Extraordinary Circumstances Exception (ECE) policy.

KCP continues to support the Agency's policy that recognizes the need for an exception from program reporting due to an extraordinary circumstance not within a facility's control. We agree that the following proposed modifications would assist facilities that find they cannot report because of an extraordinary circumstance:

- Allowing the facility to submit a form signed by the facility's CEO or designated personnel;

- Expanding the reasons for which an ECE can be requested to include an unresolved issue with a CMS data system which affected the ability of the facility to submit data (an unresolved data system issue would be one which did not allow the facility to submit data by the data submission deadline and which was unable to be resolved with a work-around); and

- Specifying that a facility does not need to be closed in order to request and receive consideration for an ECE, as long as the facility can demonstrate that its normal operations have been significantly affected by an extraordinary circumstance outside of its control.

We are also pleased that CMS proposes to clarify that it intends to provide a decision on an ECE request within 90 days of the date that it is received.

It is important to try to align policies, such as the ECE policy, among Medicare providers when it is appropriate. However, we emphasize that there are circumstances that may be unique among provider groups that should be addressed as well. One such circumstance for dialysis patients is the establishment of short-term dialysis units. These "camps" often occur for short, well-defined periods

during the year and provide patients, especially pediatric patients, with the opportunity to experience a traditional camp similar to those enjoyed by individuals who are not living with kidney failure. As CMS expands the reasons for which an ECE can be requested, we suggest that the Agency allow facilities hosting such camps to apply for and receive an exception for reporting quality information from the camp. Under the current schema, these important programs are included in the QIP and their sponsoring programs are routinely penalized for providing this transient experience.

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

KCP continues to support relying upon the same basic methodology year-over-year for the ESRD QIP. Thus, we support the continuation of the previous policy of setting the Performance Standard, Achievement Threshold, and Benchmark at the 50th, 15th and 90th percentile respectively in PY 2020. We also support the continuation of the current policy for determining payment reductions, including the process for setting the minimum TPS.

E. KCP recommends that CMS adopt criteria for assessing the weights of measures and apply them for PY 2020 (and PY 2021) to increase the weight of the catheter reduction measure in the Vascular Access Topic area.

As in previous years, KCP urges CMS to consider additional criteria to adjust weights for the various QIP measures to emphasize the measures that have the greatest benefit to patient care. In particular, for the current rule-making cycle, we suggest that CMS weight the Catheter VAT measure more than the Fistula VAT measure, which will emphasize the clinical benefits of eliminating catheters.

KCP suggests that CMS include three additional criteria for determining weighting.

- **Strength of Evidence.** This criterion goes beyond the current CMS criteria by taking into account the extent to which a measure is supported by either suggestive clinical or epidemiological studies or theoretical rationale. Endorsement by the NQF could factor into this criterion. We believe that measures with stronger evidence should be weighted more than those with less.

- **Opportunity for Improvement.** The actual variation between excellent and poor performers on a measure matters. The coefficient of variation (Standard Deviation÷Mean) is one method to measure variation. Using such a weighting criterion would have

the advantage of reducing weight gradually as measures become more topped-out, making the decision to retire such measures less disruptive to overall scores.

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

Applying these criteria to the VAT measures, we believe it would be appropriate to give more weight to the Catheter VAT measure. In previous letters, we have highlighted the fact that the equal weighting and lack of a graft measure has lead to patients having to endure attempts to place AV fistulas when clinically inappropriate. We appreciate that the recent technical expert panel modified the specifications for these measures, but once again urge CMS to weight the reduction in catheters more than the placement of AV fistulas. The evidence is overwhelming that AV fistulas and AV grafts are preferable for improved outcomes. Weighting the catheter more heavily supports a "catheters last" approach to improve quality in this critical area.

Discern Health created a model to compare the scoring differences that could result if CMS changed the two VAT measure weights from equal to two-thirds for the Catheter measure and one-third for the AVF measure. Results are summarized in Table 2, which illustrates how scores would change for facilities that perform especially well or poorly on the two measures. With a differential weighting of the two measures, a facility that scores especially well on the catheter measure (*i.e.*, low numbers of catheters) compared to the AVF measure could achieve an increase of about 2 points in their TPS. Conversely, a facility that scores especially well on the AVF measure but still has high numbers of catheters could decrease about 2 points in their TPS. While these differences are not large, they could be meaningful for facilities that are near the TPS cut points for payment reduction levels. Facilities that score about the same on the two VAT measures would not see any notable change in their TPS.

Table 2. Change in TPS from Weighting the Catheter Measure 2/3 and the Fistula Measure 1/3

		Fistula VAT Score										
		0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Catheter VAT Score	**0**	0.0	-0.2	-0.5	-0.7	-0.9	-1.1	-1.4	-1.6	-1.8	-2.1	-2.3
	1	0.2	0.0	-0.2	-0.5	-0.7	-0.9	-1.1	-1.4	-1.6	-1.8	-2.1
	2	0.5	0.2	0.0	-0.2	-0.5	-0.7	-0.9	-1.1	-1.4	-1.6	-1.8
	3	0.7	0.5	0.2	0.0	-0.2	-0.5	-0.7	-0.9	-1.1	-1.4	-1.6
	4	0.9	0.7	0.5	0.2	0.0	-0.2	-0.5	-0.7	-0.9	-1.1	-1.4
	5	1.1	0.9	0.7	0.5	0.2	0.0	-0.2	-0.5	-0.7	-0.9	-1.1
	6	1.4	1.1	0.9	0.7	0.5	0.2	0.0	-0.2	-0.5	-0.7	-0.9
	7	1.6	1.4	1.1	0.9	0.7	0.5	0.2	0.0	-0.2	-0.5	-0.7
	8	1.8	1.6	1.4	1.1	0.9	0.7	0.5	0.2	0.0	-0.2	-0.5
	9	2.1	1.8	1.6	1.4	1.1	0.9	0.7	0.5	0.2	0.0	-0.2
	10	2.3	2.1	1.8	1.6	1.4	1.1	0.9	0.7	0.5	0.2	0.0

Therefore, we suggest two-thirds of the weight of the VAT measure topic should go to the catheter measure, with the remaining one-third going to the fistula measure. This would mean that 9 percent of the TPS would apply to the Catheter VAT measure, and 4.5 percent would apply to the Fistula VAT measure. Our analysis suggests that such a differential would result in at most a 2-point change in TPS for any facility. However, this change could be meaningful for facilities near the TPS cut points for payment reductions. Moreover, differential weighting would send an important signal about the importance of reducing catheters.

In addition to making this specific change to the VAT measure weights, KCP also suggests that CMS undertake a more thorough review and update of the measure weights prior to the next annual update of the QIP. Such a review would include opportunity for multi-stakeholder feedback on the importance of the QIP measures and a quantitative analysis of the reliability and improvement opportunity for each measure.

F. KCP is concerned with the significant increase in the proposed payment reductions for PY 2020 (and PY 2021).

KCP continues to support the consistent use of a five-tier penalty system. We strongly believe that patients and caregivers should be able to compare QIP results over time, so maintaining as consistent an appropriate to scoring and assigning penalties is essential to achieving this goal. However, as the preamble to the proposed rule notes CMS projects a significant increase in the average payment penalty to dialysis facilities from PY 2017 to PY 2020 and PY 2021, as illustrated in the table below.

Payment Reduction	PY 2017 Actual		PY 2020 Projected		PY 2021 Projected	
	Count	%	Count	%	Count	%
0.0%	4,961	79.6%	3,174	52.8%	3,469	57.6%
0.5%	970	15.6%	1576	26.2%	1507	25.0%
1.0%	218	3.5%	903	15.0%	754	12.5%
1.5%	50	0.8%	280	4.7%	228	3.8%
2.0%	30	0.5%	81	1.4%	62	1.0%
Totals	6,229	0.13%	6,014	0.38%	6,020	0.33%
% Increase from 2017				292%		254%

We are concerned with this projected increase in the average payment penalty, which is not (to our understanding) a CMS policy goal. If it is a CMS goal to substantially increase payment reductions to dialysis providers, such a goal should be clearly stated and open to public comment. If it is not a goal, then we urge CMS to adjust the QIP payment reduction parameters to maintain more consistent payment levels from one year to the next.

It is difficult to identify why there is such a substantial fluctuation in the number of facilities being penalized in PY 2020 and 2021, when compared to PY 2017. For example, changes in the minimum TPS do not explain the predicted increase in payment reductions. Comparing PY 2017 to PY 2020, the minimum TPS for the two years are 60 and 61. The projected percent of dialysis facilities that will receive at least some payment reduction will jump from 20 percent in PY 2017 to 47 percent in 2020. A 1-point increase in minimum TPS is not enough to explain the jump.

Similarly, the addition of Standardized Hospitalization Ratio (or any single) measure is unlikely to drive a major shift in payment reductions. Since all the measures are scored on a standardized 1-10 scale and that scale is relative to peer performance, the score distribution is roughly the same for all measures. In other words, a single measure is not going to completely disrupt the TPS score distribution.

Additionally, there are no significant changes to measure thresholds during the last two years, which means that the measure thresholds also do not explain why we are seeing such a large shift.

Given the difficulties in explaining these changes, we ask that CMS explain how it determined the percentage of penalties and why there appears to be such a significant change to provide for greater transparency.

We note that other CMS quality incentive programs – notably the Merit-based Incentive Payment System (MIPS) – are designed to achieve specific payment outcomes. In the case of MIPS, CMS will calibrate provider scores and payment adjustments to achieve net neutral incentive payments to providers. This is very different than the QIP, in which the scoring model is set and then the payment adjustments fall as they may. The current QIP approach increases the volatility of the program. Therefore, we also ask that CMS work with KCP and the kidney care community to consider a policy to adjust the payment reduction thresholds to generate more predictable payment outcomes.

We ask that CMS use these criteria to undertake a more thorough review and update of the measure weights. Such a review would include opportunity for multi-stakeholder feedback on the importance of the QIP measures and a quantitative analysis of the reliability and improvement opportunity for each measure. In the meantime, we ask that CMS emphasize the importance of removing catheters in improving patient outcomes by increasing the weight of this measure.

KCP also asks that CMS fix is an error in Table 5, "Estimated Payment Reduction Scale for PY 2020 Based on the Most Recently Available Data." The last line should read "30-0". As it currently stands, the table does not include Total Performance Scores between 0 and 20.

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

As described earlier in this letter, 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. Additionally, the timeframes and penalties attached to these studies do not provide due process to dialysis facilities required to participate in them.

While understand that the Agency has an interest in auditing quality data submissions to ensure their accuracy at the individual facility level and does so in other programs, CMS has indicated that the effort is <u>not</u> an audit program, but rather a "validation study" of CROWNWeb data submissions and the NHSN Bloodstream Infection Clinical Measure. We remain concerned that CMS has learned from its the yet-to-be-released validation study of CROWNWeb that the data collection tool is not reliable or valid and, as its own data show, the NHSN Bloodstream Infection Measure is not a valid measure.

In terms of CROWNWeb, KCP has formally and informally requested the CROWNWeb validation study under the Freedom of Information Act (FOIA), but so far CMS has not released this study. If CROWNWeb is not validated, then CMS should refrain from using it as part of the ESRD QIP until such validation has been

established. 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 we have noted in previous letters, 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. While this "study" is taking place, CMS should not reduce a facility's QIP TPS since the purpose of the study is to assess future policies to ensure the accuracy of NHSN data.

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

H. KCP continues to recommend changes to the PY 2020 measure set.

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; and[14]
- Pediatric patients (unless the measure is specific to pediatric patients).

1. KCP remains concerned about the use of the pooled 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 composite measures.

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

Further, while the Measure Applications Partnership (MAP) conditionally supported the measure pending NQF endorsement, the NQF Renal Standing Committee has since reviewed the measure and 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.

[14] *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).

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.

2. KCP continues to support the Anemia Management reporting measure.

KCP appreciates that CMS has updated and added miscellaneous clarifying language to the specifications to note the measure relies on a "patient-month" construction. We continue to support the inclusion of this measure in the ESRD QIP.

3. KCP remains concerned that CMS is relying upon topped-out measures to meet the statutory requirement to include a mineral metabolism measures and asks that CMS work with us to develop a more appropriate measure.

Hypercalcemia 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 2020 and PY 2021, 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.

Phosphorus Reporting Measure. KCP continues to support including the Phosphorus Reporting measure in the ESRD QIP, but remains concerned that it is topped-out. Thus, we reiterate our request that CMS to work closely with KCP and the kidney care community to identify a more appropriate measure to meet the statutory requirement.

To the extent CMS maintains this measure, KCP appreciates that CMS includes plasma as an acceptable substrate and recommends that the title be modified to eliminate the word "serum," which is no longer consistent with the inclusion of plasma.

Finally, we are confused and concerned that CMS has removed transient patients from the set of exclusions for this measure. The preamble offers no rationale for this change. We urge CMS to reinstate this exclusion.

4. KCP supports the inclusion of the new VAT measures, but seeks clarification regarding the specifications.

AV Fistula Measure (NQF #2977). KCP supports the inclusion of the AV Fistula (AVF) measure as endorsed by NQF (#2977) in the ESRD QIP. CMS indicates in the Proposed Rule that it concurred with the recommendation of KCP and the 2015 Vascular Access Technical Expert Panel (TEP) that the measure specify that the AVF must use two needles (or an approved single-needle device). This revision is reflected in the methodology report, but not the specifications. We are pleased that the flowchart in the methodology report specifies AVF only with two needles or an approved single-needle device, but continue to recommend that the numerator specifications also should explicitly state that the patient must be on maintenance HD "using an AVF with two needles and without a dialysis catheter present" to emphasize clarity and avoid ambiguity.

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.

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.

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

KCP recommends that CMS use a risk-standardized rate measure for all of the standardized ratio measures, including the 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 the NQF bases its evaluation of measures and more generous than the literature.[15] 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."

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[15] 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.

Finally, 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.

6. KCP continues recommend that CMS address the low reliability of the STrR measure and adopt a rate rather than a ratio measure.

KCP remains concerned that CMS has included a modified version of the STrR measure that differs significantly from the one endorsed by the NQF (#2979). Because the statute requires CMS to use NQF endorsed measures if available, we ask that CMS comply with the statutory requirement and use the actual NQF-endorsed measure.

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).

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 reliability[16] (IUR) for facilities with sample sizes below 46 patients was about 0.4, suggesting that 60 percent of inter-facility difference was due to random noise and not underlying performance. IURs increase as a function of sample size. Therefore, smaller samples would be associated with lower IURs. Based on the NQF documentation 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.[17] 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, 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.

7. 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

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[16] 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.
[17] J.L. Adams, "The reliability of provider profiling: A tutorial." *RAND Health* (2009).

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 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.

8. 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.[18] We have heard during recent TEPs that this amount might be slightly lower, but still remains

[18] 81 *Fed. Reg.* 77834, 77879.

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.[19]

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.[20]

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

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

demonstrably valid and reliable.[21] 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.

9. KCP continues to support including the NHSN Healthcare Personnel Influenza Vaccination measure as a <u>reporting</u> measure, but asks CMS to align the performance period with the CDC guidelines.

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. However, we continue to be concerned that the performance period is not aligned with the CDC's guidelines and disadvantages facilities that follow them. The specifications should be aligned to comport with the NQF's standard specifications for influenza immunization

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

measures and NHSN's own protocol. 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. CMS has not explained why Medicare providers should not follow these guidelines. Therefore, we ask that CMS align the performance period in the final rule.

We also ask that CMS work expeditiously with the kidney care community to allow for batch submission to NHSN for this measure to reduce the burden associated with reporting it.

10. KCP supports using the KCQA NQF-endorsed Ultrafiltration measure, but asks for clarification as to how it will be weighted.

KCP continues to believe that fluid management is an important quality area, which is why it funded the Kidney Care Quality Alliance (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).*

We also request clarification with regard to the measure's weight because no weight was included in the Proposed Rule.

11. 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 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.[22] 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 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.

12. KCP continues to seek clarification about the Pain Assessment measure.

KCP recognizes that pain assessment should be part of the evaluation of every patient. As we have noted, it is important to distinguish between chronic and

[22] *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).

immediate pain. Therefore, we again request that CMS clarify that this metric seeks to measure the facility's assessment and follow-up of immediate pain that relates to the care being provided in the dialysis facility.

13. KCP asks that CMS work with it to establish a standardized ESRD-specific depression screening tool in light of the inclusion of the Clinical Depression Screening and Follow-Up measure in the ESRD QIP.

KCP continues to support the current approach to use *Clinical Depression Screening and Follow-up* as a reporting measure, but encourages CMS to work with the kidney care community to establish a standardized ESRD-specific tool.

IV. PY 2021

A. KCP reiterates its concerns described in Section III.H. and urges CMS to adopt these recommendations before simply maintaining PY 2020 Measures for PY 2021.

As described in detail in Section III.H, KCP supports many of the measures in the ESRD QIP for PY 2020. However, we remain concerned that there are too many measures, which dilute the ability of critically important measures, such as removing catheters, to drive quality outcomes. In addition, we ask that CMS review the comments in Section III.H for our recommendations on the specific measures.

B. KCP appreciates the clarifications to the STrR measure, but these clarifications do not address the underlying concerns with the measure.

KCP continues to have significant concerns about the inclusion of the Standardized Transfusion Ratio (STrR) measure in the ESRD QIP. 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 continue to look forward to seeing CMS's evaluation promised in last year's rulemaking about the impact of the STrR on access to care. Moreover, if CMS is unclear about whether these measures will have a positive or negative impact on dialysis patients and the care they receive, the Agency should not use these measures until it has such clarity.

As noted in Section III.H., we remain concerned that NQF found the STrR measure to have very low reliability, especially for small facilities. The inter-unit

reliability[23] (IUR) for facilities with sample sizes below 46 patients was about 0.4, suggesting that 60 percent of inter-facility difference was due to random noise and not underlying performance. The current small facility adjustment only raises the scores for small facilities and does not adequately offset the substantial effect of random variation for small sample sizes.

In the analysis in Appendix A, Discern determined that this problem could be resolved by using longer look-back periods, which would result in a significant increase in reliability for the STrR measure (as well as for the SHR measure). For small facilities in the STrR measure, the 1-year IUR 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. With a 3-year look-back period, the IURs for small facilities is 0.68.

Moreover, to the extent this domain is important to improving the care patients receive, KCP recommends that CMS develop a true risk-standardized rate measure, which would more transparent and useable by all stakeholders. A ratio that is then multiplied it to a national median is not a true risk-standardized rate.

C. KCP recommends that CMS weight the catheter reduction measure greater than the fistula placement measure.

While KCP appreciates the revisions to the VAT measures, we continue to believe that CMS should align the weighting and the scoring of these measures in a manner that places greater emphasis on the reduction of catheters greater.

D. KCP supports the proposed performance period, but once again asks that CMS align the performance period for the NHSN Healthcare Personnel Influenza Vaccination Reporting Measure with clinical and federal guidelines.

KCP supports setting CY 2019 as the Performance Period for PY 2020. However, we remain concerned that CMS proposes the performance period for the NHSN Healthcare Personnel Influenza Vaccination Reporting Measure as October 1 through March 31. KCP strongly objects to these parameters and instead asks that the Agency comport with the NHSN protocol upon which the measure is based, as well as with NQF's standardized influenza immunization specifications. Both define the acceptable immunization period as commencing on "October 1 or when the vaccine became available." Penalizing providers when practicing according to

[23] 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.

established clinical guidelines will place patients at increased risk early in the influenza season. Per the CDC, approximately two weeks are required after vaccination for sufficient antibody production to protect against infection; early vaccination is recommended to protect patients before the virus begins spreading through the community. Vaccine shipments typically begin in August, and we believe the measure should be specified to allow for this fact.

E. KCP supports the proposed performance standards, achievement thresholds, and benchmarks for the PY 2021 ESRD QIP

KCP continues to support relying upon the same basic methodology year-over-year for the ESRD QIP. Thus, we support the continuation of the previous policy of setting the Performance Standard, Achievement Threshold, and Benchmark at the 50th, 15th and 90th percentile respectively in PY 2021.

F. KCP supports the scoring the PY 2021 ESRD QIP

KCP supports the proposal to use the existing methodology for scoring in PY 2021, as has been finalized in previous rulemakings.

G. KCP recommends that CMS apply the recommended criteria in PY 2021 to increase the weight of the catheter reduction measure in the Vascular Access Topic area.

As described in Section III.E., KCP encourages CMS to adopt three criteria to adjust the weights for the various QIP measures. Using these criteria would allow CMS to assign a greater weight to the measures that have the greatest benefit to patient care. These criteria are: (1) strength of evidence (taking into account the extent to which a measure is supported by either suggestive clinical or epidemiological studies or theoretical rationale, and endorsement by the NQF); (2) opportunity for improvement (addressing the variation between excellent and poor performance on a measure that would reduce the weight of measures gradually as they become more topped-out); and (3) clinical significance (focusing on the number of patients affected by measure compliance and the impact that measure compliance has on patient outcomes, allowing measures that significantly affect outcomes for large numbers of patients to receive a higher weight).

H. KCP continues to recommend that CMS eliminate the small facility adjustment process and adopt a minimum sample size of 26 patients scoring measures.

As noted in Section III.B., we remain concerned that CMS continues to rely sample sizes a small as 11. This approach is inconsistent with measurement best practices and exposes the QIP to random results not fully compensated by the small

sample size adjustment. It is also inconsistent with Principal 6 of the National Quality Strategy; trying to compensate after the fact for the inevitable random effects of small sample sizes is not consistent with the NQS goal of applying consistent approaches to measuring quality. Therefore, KCP recommends that CMS eliminate the small facility adjustment process and adopt a minimum sample size of 26 patients scoring measures.

I. KCP is concerned about the substantial change in the number of payment reductions and seeks clarification.

As described in detail in Section III.F., KCP is extremely concerned about the significant increase in the number of facilities that are projected to receive a payment reduction in PYs 2020 and 2021. In our review of the Proposed Rule, KCP and our consultant Discern Health can find no changes in the methodology or measures that would explain the substantial fluctuation. For example, changes in the minimum TPS does not predict the change. The addition of any single measure is also unlikely to drive a major shift in payment reductions. Finally, there are no significant changes to the measure thresholds that would explain the large shift. We urge CMS to adjust the QIP payment reduction parameters to maintain more consistent payment levels from one year to the next. Therefore, we also ask that CMS work with KCP and the kidney care community to consider a policy to adjust the payment reduction thresholds to generate more predictable payment outcomes.

V. Conclusion

KCP appreciates the opportunity to provide comments on the ESRD QIP. We look forward to working with the Secretary and Administrator 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,

Frank Maddux, M.D.
Chairman
Kidney Care Partners

Appendix A: KCP Members

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

Appendix B: Discern Analysis

Discern Health conducted an analysis of the reliability of the Standardized Hospitalization Ratio (SHR) and Standardized Transfusion Ratio (STrR) measures in use in the Dialysis Facility Compare (DFC) program by the Centers for Medicare & Medicaid Services (CMS). This analysis compares the reliability of SHR and STrR measures with a 1-year "look-back" period to versions of the measures with longer look-back periods.

Methods

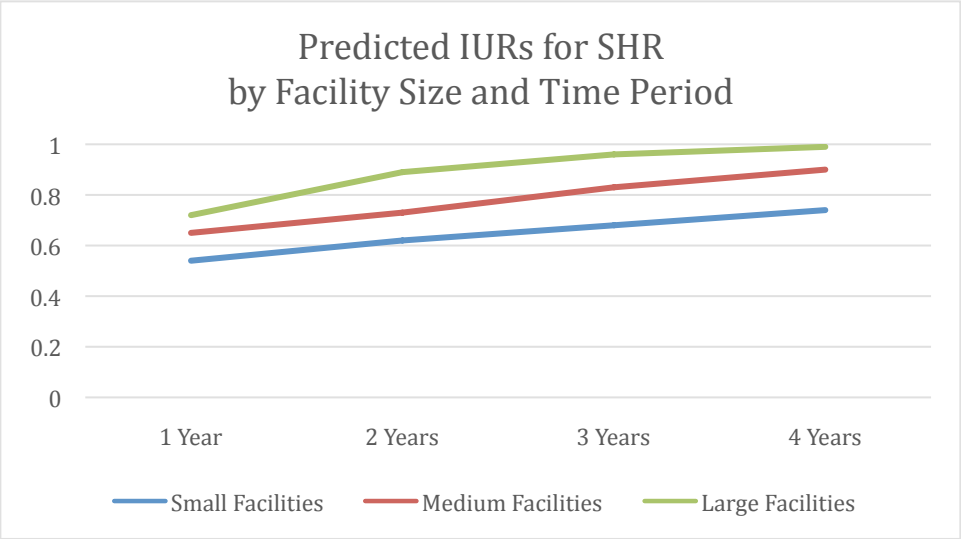
Discern utilized dialysis facility-level data[24] and SHR and STrR methodology reports[25,26] from the University of Michigan Kidney and Epidemiology Cost Center (UM KECC) for this analysis. The definitions of the three facility size groups – small, medium, and large – were taken from the methodology reports. Based on the definitions, the facility-level data were used to calculate mean yearly patient population size figures for the three facility size groups for both SHR and STrR. Probit regression models were used to estimate the relationship between patient population size and the interunit-reliability (IUR) for both SHR and STrR. IURs for versions of the measures with 1-year look-back periods were taken from the UM KECC methodology reports. In the model, mean patient population size was the independent variable and 1-year IUR was the dependent variable. Probit regression models were chosen because they are appropriate for situations in which a dependent variable has values between 0 and 1.

The regression model resulted in a function that can be used to predict an IUR for any given patient population size. Patient population sizes for the small, medium, and large group at 2-year, 3-year, and 4-year periods were calculated by simply multiplying the mean patient population sizes for the 1-year measures taken from the facility level data. These population figures were entered into the regression model post-estimation to predict IURs for each facility group by time period as a function of the patient population size. The results of this analysis are presented in the tables below.

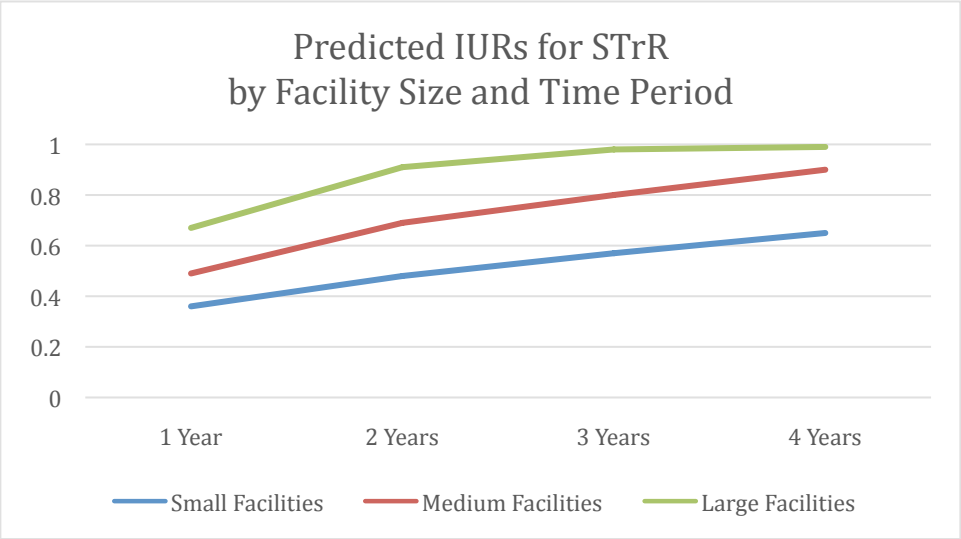
Results

Standardized Hospitalization Ratio (SHR)				
	1-Year	2-Year	3-Year	4-Year
Small Facilities	0.54	0.62	0.68	0.74
Medium Facilities	0.65	0.73	0.83	0.90
Large Facilities	0.72	0.89	0.96	0.99

[24] https://dialysisdata.org/content/esrd-measures
[25] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/SHR-Methodology-Report.pdf
[26] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/MeasureMethodologyReportfortheProposedSTrRMeasure.pdf



Standardized Transfusion Ratio (STrR)				
	1-Year	2-Year	3-Year	4-Year
Small Facilities	0.36	0.48	0.57	0.65
Medium Facilities	0.49	0.69	0.80	0.90
Large Facilities	0.67	0.91	0.98	0.99



Discussion

This analysis 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, 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.