



August 30, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6082-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CM S-1713-P: 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) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

Dear Administrator Verma:

I am writing on behalf of Kidney Care Partners (KCP) to provide comments on the Quality Incentive Program (QIP) provisions of the CY 2020 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and QIP proposed rule (Proposed Rule).¹ I also want to reiterate KCP's appreciation for the Administration's focus on patients living with chronic kidney disease and kidney failure. Since its establishment in the early 2000s, KCP and our members have sought to increase awareness and understanding among policymakers at both the Federal and State levels to improve the lives of kidney disease patients and to try to end the reign of kidney disease as one of the leading causes of death in the United States. We once again support your efforts and want to assist in any way we can help the President, the Secretary, and you achieve the broad goal of turning the page on kidney disease by improving prevention and treatment, increasing the availability of organs for transplant, and encouraging more dialysis patients to make the choice to receive dialysis at home. Simply put, we are pleased that the Administration, in the words of the President, seeks to fight by our side and to be with us every step of the way.

¹84 Fed. Reg. 38330 (Aug. 6, 2019).

As the Centers for Medicare & Medicaid Services (CMS) has recognized, one of the most important ways to improve the lives of any patient, especially patients with a chronic disease such as Chronic Kidney Disease (CKD) or ESRD, is to empower them by providing accurate information about provider performance and to give patients the tools they need to make informed health care choices. We agree with CMS that value-based purchasing programs (VBP), such as the ESRD QIP, are central to achieving this goal.² As the National Quality Forum (NQF) – the Congressionally mandated consensus-based entity upon which CMS relies for evaluating quality measures – has stated in its own report to the Congress, “The presence of high-quality performance measures is essential in providing information and insight on how providers are responding to the needs and preferences of patients and families with regards to healthcare delivery.”³

For VBPs to serve patients and the providers caring for them, VBPs must provide accurate information about the care being provided by the entity or individuals serving the patients. Both CMS and the NQF have recognized that fact and in the words of NQF, “the increased use of performance measures for public reporting and payment purposes underscores the need to ensure that these measures fairly and accurately assess quality.”⁴ CMS recognized this critical principal when, in 2015, it developed the “Principles and Approaches to Enhance Accuracy and Accountability for Value Based Purchasing and Alternative Payment Models.” This project developed an Attribution Model Selection Guide for measure developers and program implementers to enhance accuracy and fairness in assigning accountability for health outcomes.⁵ “The use of measures that are unreliable or invalid undermines confidence in measures among providers and consumers of healthcare.”⁶

In addition to measures being valid and reliable to provide accurate information to patients, the measures being used in VBP must also be meaningful. We applaud CMS’ Measures that Matter initiative’s “focus on core issues that are essential to providing high quality care and improving patient outcomes while reducing the cost and burden associated with quality measurement.”⁷ This effort mirrors the work that KCP has undertaken during the last decade and for which its “Strategic Blueprint for Advancing Kidney Care Quality”⁸ has been an important guiding consensus-based document for the work of the Kidney Care Quality Alliance and KCP’s recommendations to Federal and State policymakers.

²CMS, “Report to the Congress: Identification of Quality Measurement Priorities–Strategic Plan, Initiatives, and Activities” 4 (March 1 2019).

³NQF, “NQF Report of 2018 Activities to Congress and the Secretary of the Department of Health and Human Services” 24 (March 1, 2019).

⁴*Id.* at 17.

⁵CMS, *supra* note 2, at 48.

⁶NQF, *supra* note 3, at 18.

⁷CMS, *supra* note 2, at 1.

⁸The blueprint is available at <https://kidneycarepartners.com/quality-priorities/strategic-quality-blueprint/>.

In light of these shared goals, KCP is pleased to submit comments on the Payment Years (PY) 2022 and 2023 ESRD QIP policies. We also suggest that to the extent possible and, when appropriate, these recommendations apply to prior PYs as well. In sum, KCP asks CMS to:

- Use valid and reliable measures as established through NQF endorsement;
- Adopt endorsed measures when they are available over measures that have not been endorsed;
- Change the status of NQF-endorsed measures when the circumstances under which they were adopted change;
- Remove the two measures that NQF has rejected as part of its endorsement process from the ESRD QIP and the hypercalcemia measure because NQF has assigned it reserve status;
- Avoid modifying NQF-endorsed measures when adopting them for the ESRD QIP;
- Seek NQF endorsement for new measures prior to adopting them in the ESRD or at least use them only as reporting measures while seeking NQF-endorsement;
- Honor its commitment to use rate measures in favor of ratio measures;
- Finalize the proposed updates to the regulatory text;
- Continue to work with stakeholders in a transparent process to identify and address the potential causes that could lead to the penalties increasing when actual performance has improved;
- Work with the community and NQF to develop a better approach to the small numbers problem; and
- Align the ESRD QIP and ESRD DFC/Five Star.

I. Measures

KCP continues to support the ESRD QIP and renews our commitment to working with CMS to address the shortcomings in the current program that create barriers to achieving its goals. We are pleased that CMS appears to have recognized the need for a smaller set of renal dialysis measures for the QIP and has not proposed to add new measures for either PY 2022 or PY 2023. We also wish to echo the comments set forth in KCP's 2018 comment letters (dated August 11, 2019, and August 23, 2019)⁹ on the ESRD QIP through this reference, especially with regard to those policies that have not been modified.

As detailed on Table A, we have outlined an approach to reconsidering the measures for PYs 2022 and 2023, as well as payment years prior to 2022 when appropriate, that seeks to align the use of measures in the ESRD QIP with the statutory requirements outlined in Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), CMS' strategic approach to quality as outlined in its March 2019 Report to the Congress, and the NQF's work as CMS' quality measure contractor. In brief, we considered each measure in terms of the NQF's

⁹Available upon request.

scientifically rigorous measure endorsement criteria and the Administration’s twin goals of putting “Patients over Paperwork” and empowering patients to make informed health care decisions through initiatives such as Measures that Matter (see Appendix A). In light of this analysis, we offer recommendations to CMS as to how the measures can be modified to achieve each of these goals.

A. Using Valid and Reliable Measures as Established through NQF Endorsement

KCP reiterates that measures used in the ESRD QIP should be endorsed by NQF to be consistent with the statutory mandate. Section 1890 of the Social Security Act (SSA) requires CMS to contract with a consensus-based entity for developing measures used in VBPs. The second statutory duty listed for the consensus-based entity, which is currently NQF, is to endorse measures for CMS’ use.

(2) ENDORSEMENT OF MEASURES.—The entity shall provide for the endorsement of standardized health care performance measures. The endorsement process under the preceding sentence shall consider whether a measure—

(A) is evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level; and

(B) is consistent across types of health care providers, including hospitals and physicians.

(3) MAINTENANCE OF MEASURES.—The entity shall establish and implement a process to ensure that measures endorsed under paragraph (2) are updated (or retired if obsolete) as new evidence is developed.¹⁰

When the Congress established the ESRD PPS, it was even more specific in its mandate to use NQF endorsed measures.

(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

¹⁰SSA § 1890(b)(2) & (3).

given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.¹¹

CMS has described the statutorily-mandated role of the NQF as follows:

The NQF endorsement process is designed to ensure measures meet rigorous standards, including these measure evaluation criteria: importance to measure and report; scientific acceptability of measure properties; feasibility; and usability and use. Comparison with similar measures, endorsed or new, helps to ensure that measures of similar topics and specifications do not inappropriately burden health care providers. This process encourages innovation, harmonization, and selection of superior measures.¹²

1. CMS should adopt endorsed measures when they are available over measures that have not been endorsed.

For PYs 2022 and 2023, only five of the 14 adopted measures have received NQF endorsement. While we note below that some of these measures should be revised and submitted for NQF endorsement with modifications because of changes in the data or circumstances since their first review, we generally support CMS' decision to use these measures that have been endorsed by NQF.

A corollary to the requirement to use NQF-endorsed measures is that when CMS considers adopting a measure that has not been endorsed by the NQF and a measure in the domain has been endorsed by NQF, CMS should use the NQF-endorsed measure. For example, we are unclear why CMS in the Proposed Rule has indicated that the **Ultrafiltration** measure is no longer the NQF-endorsed # 2701: Avoidance of Utilization of High Ultrafiltration Rate (>13 ml/kg/hour) for PYs 2022 and 2023. Historically, CMS has stated in other proposed rules it had planned on using the endorsed measure's specifications as the basis for the reporting measure. Table 3 in the Proposed Rule, however, indicates that there is no applicable NQF-endorsed measure for the ultrafiltration measure. In last year's rulemaking, CMS indicated that it was using the specifications for the Kidney Care Quality Alliance measure (NQF #2701) as the basis for a utilization reporting measure. The Proposed Rule no longer references the NQF endorsed measure and CMS has not provided specifications for review. Therefore, we ask that CMS clarify that it is using the endorsed measure #2701 specifications, without any changes, for the ultrafiltration reporting measure in PY 2022 and subsequent years.

In addition, if CMS were to return to the NQF-endorsed measure, the denominator should be patient-months, rather than facility months, to be consistent with NQF #2701's construction. The patient-months measure construction in the endorsed measure was carefully

¹¹SSA § 1881(h)(2)(B) (emphasis added).

¹²CMS, *supra* note 2, at 10.

and deliberately selected by KCQA when developing the measure so that patients receiving care at a given facility for fewer than 12 months would still be captured and counted in measure calculations and would contribute to the facility score in accordance with the number of months they received care there. This specific—and intended—construction was supported by the NQF Renal Standing Committee when it endorsed the measure in 2017 and should, accordingly, be adopted by CMS for use in the QIP.

We also ask that when scoring the measure, CMS avoid imposing a double penalty on facilities by counting a missed Kt/V measure both for the Kt/V measures and the ultrafiltration measure. We ask as well that CMS apply the transient flag consistently between ultrafiltration and Kt/V measures. Specifically, if a patient is enrolled as transient in CROWNWeb, CMS does not require the facility to submit a Kt/V value, but it is requiring one for the ultrafiltration measure. This inconsistency should be resolved.

2. KCP supports CMS' decision to change the status of NQF-endorsed measures when the circumstances under which they were adopted change.

CMS is right to re-evaluate existing endorsed measures when data show there may be problems with validity and reliability. As CMS has stated in its recent report to the Congress, "Reliable and meaningful quality measurement that focuses on outcomes important to patients is an essential prerequisite for achieving high-quality, safe, and affordable health care."¹³

For example, after NQF endorsed the **Standardized Transfusion Ratio (STrR)** measure, it became clear during implementation that the codes used in the measure were not accurately capturing a sufficient percentage of blood transfusions to ensure validity of the measure. KCP appreciates that CMS has recognized the problem and supports the decision to convert the STrR to a reporting measure while it is examining the problem. This is a clear example of when a measure needs to be re-evaluated and its role in the ESRD QIP changed, despite NQF endorsement. In addition, we highlight in the section addressing the standardized ratio measures generally, that there are other changes CMS should consider for this measure to promote the empowerment of patients and putting patients over paperwork.

In addition, KCP continues to recommend that rather than rely on the STrR, CMS should replace it with an hemoglobin (Hgb) threshold measure, such as the Hgb < 10 g/dL measure. We are aware that such a measure is not currently endorsed by NQF, but believe NQF's updated evidence algorithm would provide a path for its consideration anew, and that the Hgb < 10g/dL measure, stewarded by CMS, represents a framework to which updated specifications, exclusions, and business rules could be applied.

¹³*Id.* at 1.

Consistent with its review of the STrR measure, KCP asks CMS to eliminate the **NHSN Blood Stream Infection (BSI)** measure while it determines how to revise the specifications so that the validity problems with the measure can be resolved and the NQF has the opportunity to review the measure. As CMS reported in last year's ESRD PPS proposed rule for CY 2019 stated, CMS data shows that as many as 60-80 percent of dialysis events may be under-reported with the NHSN BSI measure. In a follow-up TEP, CMS and other HHS agency officials indicated that the percentage was slightly lower, but TEP members raised concerns that the percentage remains unacceptably high. In light of these data, it is clear that the measure does not meet the criterion of validity for endorsement. This fact means that the measure in many instances may incorrectly report that a facility has a low number of blood stream infections when, in fact, the facility has a higher number. Given the understandable importance that patients place on a facility's ability to manage blood stream infections, a measure that fails to accurately represent the facility's performance deprives patients of their ability to make informed health care decisions. It also unfairly penalizes facilities that diligently pursue and report the hospital infection data necessary for a full picture of infection rates.

In the short-term, removing the clinical measure and using the Dialysis Event Reporting Measure alone would let patients know whether a facility is reporting such infections while allowing CMS and the community to fix the problems. Once a new measure is specified, CMS should submit it to NQF for endorsement before adopting it as a clinical measure for the ESRD QIP.

Another example of an NQF-endorsement measure that should be re-examined is the **ICH-CAHPS** measure. KCP continues to support its inclusion, but as noted in Table A and in our 2018 comment letter, CMS' own data demonstrate that the increasingly lower response rates threaten the validity of ICH-CAHPS as an accountability measure. While the measure itself is sound, the problem is that the manner in which it is fielded exhausts patients and discourages them from completing the survey. Understanding the patient's perspective and incorporating it into health care decision-making is critical.

Rather than be a barrier to the Administration's goal of achieving that outcome, ICH-CAHPS should be administered to patients once a year (not twice) to reduce burdens on patients. When asking patients to complete the survey, the contractor should divide the survey into the three validated section and field each one. Then, while a facility would be surveyed on the complete tool, any one patient would have to complete only one-third of the questions. CMS should exclude the homeless to whom the survey cannot be distributed, given that facilities are not allowed to provide the survey directly to patients.

In addition, we reiterate our outstanding request that the survey be revised to include home dialysis patients and that CMS obtain NQF endorsement of the new measure, which MedPAC and others in the community also have consistently requested. We appreciate that

CMS has completed some work on the tool, but given the Administration's strong desire to incentivize home dialysis, having an in-center only tool seems to contradict that position.

Finally, it is important that CMS allow facilities and patients to use the ICH-CAHPS survey results to improve care. Patients and physicians participating in the recent TEP on patient-outcomes measures raised concerns multiple times that the fact that facilities never see the results and cannot communicate with patients about the results leaves patients feeling as if they had wasted their time completing the survey. Patients want to be heard. As currently administered, ICH-CAHPS has the opposite effect.

3. CMS should remove the two measures that NQF has rejected as part of its endorsement process from the ESRD QIP; similarly, CMS should remove the hypercalcemia measure because NQF has assigned it reserve status.

Just as CMS is right to re-evaluate existing endorsed measures when data show there may be problems with validity and/or reliability, CMS should not use measures that have failed NQF's scientific criterion. The NQF has formally rejected one measure, the **Percentage of Prevalent Patients Waitlisted (PPPW)**, concluding that it lacks validity. Lacking validity means that the PPPW measure does not accurately measure its facility performance. Part of the problem is that the measure fails to measure actions taken by dialysis facilities. "Fair and accurate attribution is essential to the success of value-based purchasing and alternative payment models."¹⁴ If patients or other stakeholders were to use it to make medical decisions, they would be using invalid information. Given that reality, CMS should not use the measure so as to ensure that the ESRD QIP is not misleading patients. In this case, CMS should work to develop a measure that will provide accurate information related to transplantation and empower patients in their decision-making. As we have recommended in previous letters, we encourage CMS to work with the community to develop a referral and first appointment measure to which facilities could be directly held accountable. CMS has referenced in the "Advancing American Kidney Health" initiative that it is working on a referral measure; KCP supports the efforts and asks to work directly with CMS on this project.

Although NQF had endorsed a distinct composite dialysis adequacy measure, it has since reviewed the **(Kt/V) Dialysis Adequacy Comprehensive** measure. The NQF Renal Standing Committee reviewed the measure and recommended against endorsement. Importantly, the 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. Using a pooled measure approach is problematic as well because it results in all patients from the four dialysis populations (adult and pediatric/peritoneal and hemodialysis) being pooled into a single denominator. The scores are calculated as would be done for a single measure. This approach

¹⁴NQF, *supra* note 3, at 13.

eliminates the ability to see performance on any specific patient population. NQF has endorsed other measures in the domain of dialysis adequacy. They are:

- NQF #0249 Delivered Dose of HD Above Minimum;
- NQF #0318 Delivered Dose of PD Above Minimum;
- NQF #1432 Minimum spKt/V for Pediatric HD Patients
- NQF #2704, Minimum Delivered PD Dose;
- NQF #2706, Pediatric PD Adequacy—Achievement of Target Kt/V

CMS should use these measures instead of the rejected measure, not only to be consistent with the statutory mandate, but also to ensure that patients have the ability to understand each facility's actual performance on the different dialysis modalities. This approach is especially important given the Administration's emphasis on increasing the number of patients selecting home dialysis.

Similarly, the **Hypercalcemia** measure should no longer be used in the ESRD QIP because it is based on NQF #1454, which the NQF has placed in reserve status. In addition, in its 2016 report, the Measure Applications Partnership (MAP) did not support the measure. Historically, CMS has stated that it is required to use the hypercalcemia measure under the statutory provision requiring the adoption of measures for oral-only drugs (which is distinct from the provision related to bone mineral measures). That oral-only requirement, however, applied only when there was an oral-only calcimimetic. Now that Parsavib[®], an IV calcimimetic, is being reimbursed through the ESRD prospective payment system, the statutory provision is no longer relevant to the status of the hypercalcemia measure. Therefore, CMS should retire it.

In addition, KCP reiterates that it would be appropriate, for purposes of having a bone mineral metabolism measure, to use the serum phosphorous measure as a reporting measure in the QIP. Even though the measure is in reserve status, physicians still rely upon the serum phosphorous measure to make clinical decisions.

4. CMS should avoid modifying NQF-endorsed measures when adopting them for the ESRD QIP.

Several of the measures on the list for PYs 2022 and 2023 are "based on" NQF-endorsed measures, but have not been endorsed by NQF because some aspects of the measure have been changed, making the measure different than the one NQF reviewed under the scientific measure evaluation criteria. Modifying a measure after it has been endorsed changes the measure without providing NQF and its expert panels with the opportunity to evaluate whether those changes impact the endorsement criteria, such as reliability and validity.

Therefore, we ask that CMS indicate in the final rule that it will either adopt the measures as endorsed by NQF without modification or, if the Agency believes a modified

version is necessary for the ESRD QIP, that it will submit the modified version to NQF for endorsement while using it as a reporting measure in the QIP until the measure is endorsed. Given the topics of some of these measures, we understand that CMS may believe it is not appropriate to remove the measure from the QIP while seeking NQF endorsement. To that end and in this instance only, we have suggested when allowing the measure to remain in the QIP may be appropriate. However, we encourage CMS on a going forward basis not to skip the NQF endorsement step and to adhere to the statutory requirements set out in MIPPA.

While Table 3 in the Proposed Rule suggests a different set, based on previous rules and the specifications available at the CMS website, the ESRD QIP measures that are “based on” the NQF-endorsed measure are listed below with the KCP recommendations of how to address each one.

- **STrR, based on NQF #2979**
 - As described above and below, CMS should evaluate the validity concerns raised by hospital coding concerns and use a true risk-standardized rate measure that would be submitted to the NQF for endorsement.
 - As noted below, KCP also recommends that CMS apply the “partial credit” approach proposed for the NHSN Dialysis Event measure also should be applied to the STrR reporting measure.
- **Hypercalcemia, based on NQF #1454**
 - CMS should retire the measure, as noted elsewhere in this comment letter.
- **Clinical Depression Screening and Follow-Up, based on NQF #0418**
 - CMS should seek NQF endorsement and work with the community to develop a standardized tool.
- **NHSN Bloodstream Infection (BSI) in Hemodialysis Patients, based on NQF #1460**
 - As described above, CMS should eliminate the NHSN BSI measure and rely upon the NHSN dialysis event reporting measure while CMS convenes a TEP to identify the problems with the BSI measure. Once it has revised the measure, CMS should submit the revised measure, which would meet the validity requirements of endorsements, to the NQF.
- **Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), based on NQF #2988**
 - CMS should revert to the NQF-endorsed specifications.
 - KCP strongly objects to the proposed change to the specifications to use “facility-months.” The previous calculation using the patient-months construction comports with the NQF-endorsed measure and should be used. We do not understand the statement in the Proposed Rule that one reason for the change is that reporting measures use a “facility-months” construction because it simply is not true. For example, the STrR reporting measure relies upon the related “patient-years” at-risk construction.

As noted above and in previous rules, CMS has indicated that the **Ultrafiltration** measure was based on NQF #2701, but Table 3 in the Proposed Rule suggests otherwise. If the intent remains to use NQF #2701, we ask that CMS use the measure as specified when endorsed by NQF.

5. CMS should seek NQF endorsement for new measures prior to adopting them in the ESRD or at least use them only as reporting measures while seeking NQF-endorsement.

KCP has supported the **NHSN Dialysis Event** measure as a reporting measure, but has asked for CMS to eliminate the recent addition of a set of subjective factors to the measure because these factors do not support the purpose of the measure. Given the statutory requirement to use NQF-endorsed measures, it is unclear why CMS has not yet submitted this measure for NQF review. Therefore, we also ask that CMS submit the measure to NQF for review in the next cycle.

KCP supports the proposed change to remove the exclusion of facilities with fewer than 12 eligible reporting months, beginning with PY 2022, and to assess successful reporting based on the number of months facilities are eligible to report the measure. Under the new proposal, facilities would receive credit for scoring purposes based on the percentage of months they successfully report data out of the number of eligible months. KCP agrees with CMS that providing the partial credit is a useful proposal. We also recommend that CMS apply the “partial credit” approach proposed for the **NHSN Dialysis Event** measure also should be applied to the STrR reporting measure.

B. CMS should honor its commitment to use rate measures in favor of ratio measures.

KCP appreciates that CMS has recognized that it can be difficult for patients to understand ratio measures and apply the information from them in a way that allows for meaningful decision-making. NQF has also raised concerns that ratio measures have relatively wide confidence intervals that can lead to facilities being misclassified and their actual performance not being reported. To address these issues, KCP has recommended that the QIP use a true risk-standardized rate in place of the standardized ratio measures. A ratio that is then multiplied by a national median is not a true risk-standardized rate.

In addition, CMS, Assistant Secretary for Planning and Evaluation (ASPE), and NQF have recognized the importance of risk-adjusting certain measures. KCP supports CMS’ decision to risk adjust the Standardized Mortality Ratio (SMR) measure using race/ethnicity. This adjustment should also be used with the other three standardized ratio measures adopted in the ESRD QIP. Consistent with the NQF’s 2018 renal dialysis report and the ongoing work of the

NQF and the ASPE report, KCP asks CMS to develop socio-demographic adjusters for these measures as well.

This approach would be consistent with the work CMS has asked NQF to undertake and that NQF described in its recent report to the Congress.

...healthcare outcomes are not solely the result of the quality of care received and can be influenced by factors outside a provider's control, such as a patient's comorbid conditions or severity of illness. Because patients are not randomly assigned to providers, performance measures should account for these underlying differences in patients' health risk to ensure performance measures make fair conclusions about provider quality....Risk adjusting outcome measures to account for differences in patient health status and clinical factors (e.g., comorbidities, severity of illness) that are present at the start of care is widely accepted. However, there is a growing evidence base that a person's social risk factors (*i.e.*, socioeconomic and demographic factors) can also affect health outcomes.¹⁵

KCP understands that it may take some time to develop the appropriate socio-demographic adjusters, but encourages CMS to use the existing rates for each of the QIP standardized ratio measures, add the race/ethnicity adjustment, and submit the updated measures to NQF for endorsement. If CMS were to take these steps this fall, these measures could arguably be reviewed and ideally endorsed before PY 2022 begins.

II. Structure

KCP appreciates the engagement with CMS during the past several years as the ESRD QIP has evolved. These discussions have resulted in the ESRD QIP helping patients and providers move toward a payment system that incentivizes high-quality performance. As the ESRD QIP nears the 10 year milestone, we look forward to continued engagement.

A. KCP supports the proposed updates to the regulatory text.

One of the policies that KCP has consistently supported with regard to the ESRD QIP is the fact that the measures, as well as benchmarks for improvement and achievement thresholds, have been finalized in advance of the performance years. Therefore, KCP supports the proposal to codify in the regulatory text that the baseline period and performance period for each payment year will be adopted automatically by advancing each payment period by one year from the baseline and performance period that were adopted for the previous payment

¹⁵*Id.* at 15.

year. This step will provide predictability and avoid CMS having to provide notice and stakeholders having to comment on this policy each year.

Similarly, KCP supports the predictability of codifying the long-standing policy that facilities must submit measure data to CMS on all measures for calculating measure scores. We also support codifying requirements for the Extraordinary Circumstances Exception (ECE) process, including the new option for facilities to reject an extraordinary circumstance exception granted by CMS under certain circumstances.

B. KCP encourages CMS to continue to work with stakeholders in a transparent process to identify and address the potential causes that could lead to the penalties increasing when actual performance has improved.

As NQF and others have indicated, VBP measures should measure the performance of providers fairly and accurately.¹⁶ Historically, the ESRD QIP's structure has provided a consistent platform for achieving that goal. While KCP has expressed concern about certain measures not providing fair and/or accurate information, the structure has been for the most part an exemplar of how VBP structures should work.

Thus, KCP was surprised and concerned during the last few rulemakings, when CMS projected a substantial increase in the number of facilities being penalized under the ESRD QIP even though the actual performance of dialysis facilities was improving. In addition to being penalized, facilities will be required to report publicly to their patients that under the QIP their quality is lower, even though that result is not factually correct. This non-sequitur would undermine the trust in, and integrity of, the ESRD QIP.

KCP continues to believe that quality is not relative and that any program that requires public reporting and penalizes providers should reflect the actual quality of care being provided. To that end, KCP reiterates that we would prefer the Total Performance Score (TPS) cut points and the benchmarks and thresholds for attainment and improvement to be based on objective goals. We remain concerned that setting a fixed number of facilities in any of the five TPS categories distorts quality and eliminates transparency. It results in a pre-determined number of facilities being labeled as providing poor quality, when in reality there may actually be a greater or lesser number of facilities that should fall into the lowest quintile based on their actual performance. If this approach were taken, the results projected by earlier rulemakings should not have occurred.

While we appreciate CMS' engagement with KCP and our consultants during the past year, we ask that CMS provide in the final rule the reason it believes that the projections led to

¹⁶*Id.* at 17.

the inverted result and why when the STRR measure is shifted to a reporting measure the problem is substantially lessened.

We believe this problem can be addressed in a way that promotes the integrity of the QIP and allows it to achieve the goals that CMS, the Congress, and the kidney care community have defined for it.

C. KCP continues to encourage CMS to work with the community and NQF to develop a better approach to the small numbers problem.

KCP remains concerned that CMS' decision to include facilities with 11 or more cases as the basis for measure applicability instead of the more widely accepted 25 or more cases that commercial insurers and other private quality programs typically apply. Allowing so few cases undermines the statistical reliability of the measure results. We appreciate the work CMS has done on the small facility adjuster, but as Discern Health analyses have repeatedly shown (which we have provided in several of the previous KCP comment letters), the current policy unfortunately does not eliminate the random results associated with small numbers.

In addition, we have been encouraged by the work that NQF undertook in the rural context that recognizes that it remains important for small entities to report quality measures. NQF has identify ways to developed measures that can be used without small numbers negatively impacting the outcomes reported, as well.¹⁷

Given that the problem has not yet been resolved for the ESRD QIP, we ask that CMS work with KCP before the next rulemaking cycle to review options that could be part of the next rulemaking process.

III. Alignment of ESRD Quality Programs

Finally, KCP renews our commitment to work with CMS to eliminate the inconsistencies and conflicts that have arisen among the various Medicare ESRD quality programs. In our comment last year, KCP offered one approach that would allow the DFC and QIP to achieve the independent goals CMS has identified for each and that would preserve the Congressional intent for the ESRD QIP. Under this model, KCP recommended that the DFC focus on meaningful measures that are not used in the ESRD QIP and provide patients with the data about each measure on its website in a way that allows patients to prioritize the measure results they want to see. The ESRD QIP would be a smaller set of meaningful measures that ensure that each measure has substantial weight to avoid any one measure being diluted by the others. Because the Congress mandated that the QIP be a public reporting program, we suggested that CMS shift the star ratings to the QIP TPS scores.

¹⁷*Id.* at 6.

We recommended the following initial set of measures for each program, based upon the measures that are in the programs today.

ESRD QIP Measures	ESRD DFC Measures
Standardized hospitalization rate measure (current ratio measure modified to a true risk-standardized rate)	KCQA UFR Measure
Standardized readmissions rate measure (current ratio measure modified to a true risk-standardized rate)	KCQA Medication Reconciliation (MedRec) Measure
Catheter > 90 Days Clinical Measure	NHSN Healthcare Personnel Influenza Vaccination Reporting Measure
Bloodstream infection measure (not the current measures, but one that is valid and reliable and meets other NQF criteria)	Kt/V Dialysis Adequacy Comprehensive Clinical Measure (modified to return to individual dialysis adequacy measures)
Patient Experience of Care: In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Clinical Measure (modified per historic recommendations)	Fistula measures (Current AV measure; future standardized fistula rate)
Hgb < 10 g/dL	Clinical Depression Screening and Follow-Up Reporting Measure
Serum phosphorous	Standardized Mortality Rate measure (current ratio measure modified to a true risk-standardized rate)
Transplant referral measure, including assistance with first visit	Patient Reported Outcome Measure (when developed and endorsed)

We also would ask that each of these measures be refined based on KCP recommendations for the specific measures.

In other letters, we have also suggested that CMS could align the two programs by ensuring that the DFC and QIP measures have the same specifications and the same scoring mechanism.

We encourage CMS to carefully review these proposals and would welcome the opportunity to identify ways of better aligning the ESRD QIP and DFC so that patients could use both programs for decision-making, but each one would be supportive of the other rather than conflicting as they are today.

The Honorable Seema Verma

August 30, 2019

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IV. Conclusion

KCP appreciates the opportunity to provide comments on the Proposed Rule. Kathy Lester, our counsel in Washington, will be in touch to schedule a meeting. However, please feel free to contact her at any time if you have questions about our comments or would like to discuss any of them in further details. She can be reached at klester@lesterhealthlaw.com or 202-534-1773. Thank you again for considering our recommendations.

Sincerely,

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

Allen Nissenson
Chairman
Kidney Care Partners

cc: Dr. Kate Goodrich, Director and CMS Chief Medical Officer
Dr. Michelle Schreiber, Director Quality Measurement and Value-Based Incentives Group
Dr. Reena Duseja, Chief Medical Officer for Quality Measurement
James M. Poyer, Director, Division of Value, Incentives and Quality Reporting

Table A: Measure Recommendations and Summary Analysis

	NQF Status	Measure Title and Description	KCP Concerns and Recommendations
1	0258	<p>In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration (clinical measure): Measure assesses patients’ self-reported experience of care through percentage of patient responses to multiple testing tools.</p>	<p>Concern: CMS data show that the response rate is low and continues to drop. The Patient-Reported Outcomes TEP suggested that the low response rate is due to patient fatigue.</p> <p>CMS should also align the specifications with those that AHRQ relied on when it tested the measure to ensure the accuracy of its fielding and make sure that patient contact information is updated.</p> <p>Recommendation: KCP suggest maintaining the measure as a <u>reporting</u> measure until the response rate is improved. In previous letters, KCP has offered suggestions as to how to address the problem of fatigue by dividing the survey into the three validated section and fielding each one. Then, while a facility is surveyed on the complete tool, any one patient has to complete only a third of the questions. The survey should also be revised to include home dialysis patients and obtain NQF endorsement of the new measure.</p> <p>Burden reduction: To reduce administrative burden, CMS should field the survey once a year and not twice to reduce burdens on facilities and patients. CMS should exclude the homeless to whom the survey cannot be distributed given that facilities are not allowed to provide it directly to patients.</p> <p>Patient Empowerment: To empower patients, CMS should allow facilities to see the results of the surveys so they can respond to the specific patient concerns. Patient members of the TEPs have</p>

			<p>recommended this step. KCP has consistently recommended extending the survey to include questions related to home dialysis patients. Given the Administration’s Advancing Kidney Care Initiative, CMS should prioritize adding these questions to the survey and seeking NQF endorsement of the new measure.</p>
<p>2</p>	<p>2496</p>	<p>Standardized Readmission Ratio (SRR) (clinical measure): Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.</p>	<p>Concern: The QIP should use a true risk-standardized rate measure, because the ratio measure has relatively wide confidence intervals that can lead to facilities being misclassified and their actual performance not being reported. A ratio that is then multiplied by a national median is not a true risk-standardized rate.</p> <p>In addition, there is unnecessary 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. Also, current policies do not prevent small facilities from having scores that are highly subject to random variability.</p> <p>Recommendation: CMS could use the underlying readmission rate and appropriately risk adjust it using race/ethnicity (as is done with the standardized mortality ratio). It should also build off of its contracted work with NQF and develop socio-demographic adjusters, consistent with KCP’s 2018 comment letter recommendations. While CMS submits the new measure to the NQF for endorsement, it could use this improved readmissions rate measure in the QIP.</p> <p>Burden Reduction: The confusion around the ratio measure and misclassification of facilities create</p>

			<p>an unnecessary burden on facilities, as well as patients who are interested in understanding the actual performance of facilities and cannot.</p> <p>Patient Empowerment: Readmissions is an important factor in making health care decisions for patients. CMS has acknowledged in previous rulemaking that rate measures are more transparent and easier for patients and caregivers to understand. CMS should act quickly to establish a meaningful readmissions measure for the QIP.</p>
<p>3</p>	<p>Based on NQF 2979</p>	<p>Standardized Transfusion Ratio (STrR) (a clinical measure): Risk-adjusted STrR for all adult Medicare dialysis patients. Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected</p>	<p>Concern: The STrR measure lacks validity; KCP is pleased that CMS has acknowledged this concern and proposed reviewing the problem. NQF found the STrR measure to have very low reliability, especially for small facilities.</p> <p>CMS data show that the STrR measure is not reliable for small dialysis facilities; 43 percent of a facility’s score is attributable to random noise and not signal. Penalizing facilities for performance due to random chance is not appropriate. Until it is reliable for all facilities, the measure should not be used in the ESRD QIP. This is similar to the concerns CMS is reviewing for the STrR measure.</p> <p>Recommendation: Consistent with the recommendations of the NQF to address gaps in the renal measure set and the concerns CMS acknowledged in the Proposed Rule, KCP supports the review of the measure and urges CMS to have NQF review the measure in light of the hospital coding data. Until that data can be collected, KCP supports using the STrR as a reporting measure with the changes noted below.</p>

		<p>The QIP should use a true risk-standardized rate measure, because the ratio measure has relatively wide confidence intervals that can lead to facilities being misclassified and their actual performance not being reported. A ratio that is then multiplied by a national median is not a true risk-standardized rate.</p> <p>CMS could use the underlying transfusion rate and appropriately risk adjust it using race/ethnicity (as is done with the SMR). It should also build off of its contracted work with NQF and develop socio-demographic adjusters, consistent with KCP's 2018 comment letter recommendations. While CMS submits the new measure to the NQF for endorsement, it could use this improved transfusion rate measure as a reporting measure in the QIP.</p> <p>In the 2018 comment letter, KCP suggested a 4-year look-back period, which would result in a minimum of two-thirds of the variance in both measures in all three groups would be due to actual differences between facilities and would align the measures with the Standardized Mortality Ratio (SMR) used in Dialysis Facility Compare (adhering to CMS' principals for alignment among various quality programs).</p> <p>Despite these points and given that physicians and hospitals, not dialysis facilities, control whether or not a patient receives a transfusion, KCP once again urges CMS to adopt a more appropriate anemia management measure. KCP volunteers to work with CMS to develop such a measure. Once an appropriate measure is develop, KCP asks that CMS submit it to NQF for endorsement.</p>
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			<p>Burden Reduction: Shifting to a more appropriate anemia management measure for dialysis facilities would reduce burden, because any transfusion measure (including a rate measure) requires dialysis facilities to chase paperwork created by other providers who also experience the burden on having to provide the data/documentation of providing the transfusion.</p> <p>Patient Empowerment: Patient Empowerment: Anemia management is an important factor in making health care decisions for dialysis patients. Transfusions also place patients at risk of becoming ineligible for transplant. CMS has acknowledged in previous rulemaking that rate measures are more transparent and easier for patients and caregivers to understand. CMS should act quickly to establish a meaningful transfusion rate measure for the QIP.</p>
<p>4</p>	<p>NQF endorsed different measure and has rejected the pooled measure</p>	<p>(Kt/V) Dialysis Adequacy Comprehensive (clinical measure): A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.</p>	<p>Concern: Using a pooled measure approach results in all patients from the four dialysis populations (adult and pediatric/peritoneal and hemodialysis) to be pooled into a single denominator and in scores being calculated as would be done for a single measure. This approach eliminates the ability to determine performance on any specific patient population or dialysis modality.</p> <p>The pooled measure also disincentivizes home dialysis. Home facilities will have lower adequacy scores under the pooled measure, which will make them more likely to be penalized.</p> <p>Recommendation: To promote transparency in dialysis performance and the adoption of home dialysis by patients in their facilities, KCP suggests using the distinct adult HD and PD adequacy adult and</p>

			<p>pediatric measures endorsed by the NQF. KCP volunteers to work with CMS to address the small numbers problem for pediatric facilities and suggests building on the lessons learned from the NQF's rural health project in which small numbers were addressed through other means than pooling measures.</p> <p>Burden Reduction: The confusion created by pooling the adequacy measures creates an unnecessary burden on facilities, as well as on patients who are interested in understanding the actual performance of facilities and cannot.</p> <p>Patient Empowerment: To make informed decisions about modality choice, patients need to understand a facility's actual performance on the different modality types. The pooled measure hides this information from patients.</p>
<p>5</p>	<p>2977</p>	<p>Hemodialysis Vascular Access: Standardized Fistula Rate (clinical measure): Measures the use of an AV fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.</p> <p>.</p>	<p>Concern: The QIP should use a true risk-standardized rate because the ratio measures have relatively wide confidence intervals that can lead to facilities being misclassified and their actual performance not being reported. A ratio that is then multiplied by a national median is not a true risk-standardized rate.</p> <p>Recommendation: CMS could use the underlying fistula rate measure. While CMS submits the new measure to the NQF for endorsement, it could use the current measure in the QIP.</p> <p>CMS may also wish to work with the community to determine if insurance status prior to receiving dialysis should be a risk adjuster for this measure.</p> <p>Burden Reduction The confusion around the ratio measure and misclassification of facilities create</p>

			<p>an unnecessary burden on facilities, as well as patients who are interested in understanding the actual performance of facilities and cannot.</p> <p>Patient Empowerment: Vascular access may be the most important measure for patients making decisions about dialysis facilities in the ESRD QIP, with catheter reduction being the most important of the two access measures. CMS has acknowledged in previous rulemaking that rate measures are more transparent and easier for patients and caregivers to understand. CMS should act quickly to make this a rate measure.</p>
6	2978	<p>Hemodialysis Vascular Access: Long-Term Catheter Rate (clinical measure): Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.</p>	<p>Concern: Generally, KCP supports this measure.</p> <p>Recommendation: CMS may wish to work with the community to determine if insurance status prior to receiving dialysis should be a risk adjuster for this measure.</p> <p>Burden Reduction: None</p> <p>Patient Empowerment: Vascular access may be the most important measure for patients making decisions about dialysis facilities in the ESRD QIP, with catheter reduction being the most important of the two access measures.</p>
7	Based on 1454, which NQF has placed in reserve status; the Measure Applications Partnership (MAP) did not support the measure	<p>Hypercalcemia (clinical measure): Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.</p>	<p>Concern: The measure is not used to make clinical decisions and is topped out.</p> <p>Recommendation: CMS should retire the measure; the previous statutory requirement that CMS identified as the basis for maintaining this measure no longer exists, because an IV option for calcimimetics is now available.</p>

	<p>in its 2016 report</p>		<p>Burden Reduction: Reporting a measure that has provides neither clinical value nor differentiates among facilities imposes a burden without providing benefit.</p> <p>Patient Empowerment: Given the topped out nature of this measure, there is no significant benefit for patients.</p>
<p>8</p>	<p>1463</p>	<p>Standardized Hospitalization Ratio (SHR) (clinical measure): Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.</p> <p>.</p>	<p>Concern: CMS data show that the SHR measure is not reliable for small dialysis facilities; 43 percent of a facility’s score is attributable to random noise and not signal. Penalizing facilities for performance due to random chance is not appropriate. Until it is reliable for all facilities, the measure should not be used in the ESRD QIP. This is similar to the concerns CMS is reviewing for the STRR measure.</p> <p>The QIP should use a true risk-standardized rate because the ratio measures have relatively wide confidence intervals that can lead to facilities being misclassified and their actual performance not being reported. A ratio that is then multiplied by a national median is not a true risk-standardized rate.</p> <p>Recommendation: In the 2018 comment letter, KCP suggested a 4-year look-back period, which would result in a minimum of two-thirds of the variance in both measures in all three groups that would be due to actual differences between facilities and would align the measures with the Standardized Mortality Ratio (SMR) used in Dialysis Facility Compare (adhering to CMS’ principals for alignment among various quality programs). However, KCP would also support shifting the SHR to a reporting measure as CMS has proposed with the STRR as it reviews the validity problems.</p>

			<p>CMS could use the underlying hospitalization rate and appropriately risk adjust it using race/ethnicity (as is done with the SMR). It should also build off of its contracted work with NQF and develop socio-demographic adjusters, consistent with KCP's 2018 comment letter recommendations. While CMS submits the new measure to the NQF for endorsement, it could use this improved hospitalization rate measure in the QIP.</p> <p>Burden Reduction: The confusion around the ratio measure and misclassification of facilities create an unnecessary burden on facilities, as well as patients who are interested in understanding the actual performance of facilities and cannot.</p> <p>Patient Empowerment: Hospitalization rates are critical indicators of quality performance for both patients and providers. The lack of reliability for the SHR means that the measure is not accurately reflecting the performance of small facilities. Thus, the measure provides inaccurate information upon which patients are then asked to make health care decisions.</p>
<p>9</p>	<p>Based on NQF #0418</p>	<p>Clinical Depression Screening and Follow-Up (reporting measure): Facility reports in CROWNWeb one of six conditions for each qualifying patient treated during performance period.</p>	<p>Concern: CMS has changed the specifications making the measure different than the one that NQF endorsed. These changes mean that the QIP measure has not been reviewed or endorsed by NQF.</p> <p>Recommendation: If it were to remain in the QIP, KCP continues recommending that CMS use it as a reporting measure, but encourages CMS to work with the kidney care community to establish a standardized ESRD-specific tool.</p>

			<p>Burden Reduction: When CMS changes the specification of an NQF-endorsed measure, it creates burden on facilities because they are reporting a measure that may or may not meet measure development criteria and if it does not reporting the information does not provide any value. Patients are burdened by having to figure out on their own whether or not the measure is accurately reporting on a facility's performance.</p> <p>Patient Empowerment: Clinical Depression is an important component in managing patients living with kidney failure. However, this measure is better suited for the Dialysis Facility Compare program so that a facility's performance on the measure is not diluted by other measures, making it difficult for patients to use it to make decisions. CMS has indicated that the purpose of DFC is specific to this task.</p>
<p>10</p>	<p>CMS is using a non-NQF endorsed measure, but NQF has endorsed NQF 2701: Avoidance of Utilization of High Ultrafiltration Rate (>13 ml/kg/hour)</p>	<p>Ultrafiltration Rate (reporting measure): Number of months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.</p>	<p>Concern: CMS is using a measure that has not been endorsed by NQF when an NQF-endorsed measure exists.</p> <p>We ask for CMS to use KCQA's NQF-endorsed measure, 2701: Avoidance of Utilization of High Ultrafiltration Rate (>13 ml/kg/hour).</p> <p>Recommendation: CMS should use the NQF-endorsed measure without changes.</p> <p>Burden Reduction: When CMS changes the specification of an NQF-endorsed measure, it creates burden on facilities because they are reporting a measure that may or may not meet measure development criteria and if it does not reporting the information does not provide any value. Patients are burdened by having to figure out on their own whether or not the measure is</p>

			<p>accurately reporting on a facility's performance.</p> <p>Patient Empowerment: 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 in KCP's Strategic Blueprint for Kidney Care Quality.</p>
<p>11</p>	<p>Based on NQF #1460</p>	<p>NHSN Bloodstream Infection (BSI) in Hemodialysis Patients (clinical measure): The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.</p>	<p>Concern: Research conducted by the CDC (the measure's developer) and others, including CMS, show that the measure is not valid or reliable.</p> <p>CMS data shows that as many as 60-80 percent of dialysis events may be under-reported with the NHSN BSI measure.¹⁸ TEP members have been told the percentage is slightly lower, but the TEP members continued to raise concerns that the percentage is unacceptably high. There is a problem with the measure that results in it not meeting the rigorous criterion of validity. As a result, the measure is not reporting accurate data to patients or providers.</p> <p>Recommendation: In previous comments, KCP has suggested that CMS convert the NHSN BSI measure to a reporting measure while it convenes a TEP to identify the problem with the measure, propose solutions, and submit a measure that would meet the validity requirements of endorsement to the NQF.</p> <p>Burden reduction: Research suggests that the underreporting may be due to the fact that</p>

¹⁸2018 Proposed Rule Display Copy 90.

			<p>hospitals, not dialysis facilities, have the data. It is a burden on hospitals to provide the data to facilities and on facilities to chase hospitals for the data. Addressing this problem through a valid measure would reduce unnecessary burden on the hospitals and facilities.</p> <p>Patient Empowerment: This measure topic area is critically important to patients. A measure that incorrectly reports a facility as having a low number of BSI when in fact it does not distorts the care being provided and misleads patients in a way that disrupts their ability to make an informed health care decision.</p>
12	N/A	<p>NHSN Dialysis Event (reporting measure): Number of months for which facility reports NHSN Dialysis Event data to CDC.</p>	<p>Concern: CMS has not submitted this measure to NQF for endorsement, which is inconsistent with the intent of the Congress for CMS to use NQF endorsed measures in the QIP (see SSA § 1881(h)(2)(B)).</p> <p>Without the rigor of endorsement, the reliability and validity of the measure remain uncertain and the specification have been allowed to morph so that there are now several subjectively interpreted signs of infection (<i>e.g.</i>, swelling, redness) being included.</p> <p>Recommendation: CMS should remove the subjective factors and seek NQF endorsement of the measure.</p> <p>Burden Reduction: The expansion of the reporting protocol to be highly subjective is extremely burdensome and does not contribute to the measure’s underlying premise—to identify BSIs verified by positive blood cultures. Eliminating the subjective factors would help reduce the burden of this measure.</p>

			<p>Patient Empowerment: It is important to patients and KCP that facilities are appropriately monitoring BSI. However, the information reported should be objective and serve the purpose of identifying patients at risk for BSI so they can receive appropriate treatment. The subjective factors added to the measure specifications last year do not achieve this goal.</p>
13	Rejected by NQF	<p>Percentage of Prevalent Patients Waitlisted (PPPW) (clinical measure): Percentage of patients at each dialysis facility who were on the kidney or kidney - pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.</p>	<p>Concern: NQF has rejected the PPPQ measure as lacking validity.</p> <p>Recommendation: KCP stands ready to develop an appropriate transplant-related measure with CMS and others in the kidney care community that meets the endorsement criteria of NQF and the intent of the Congress.</p> <p>Burden Reduction: Collecting and submitting data on the PPPW measure when it does not provide an accurate view of dialysis facility quality is a burden without benefit.</p> <p>Patient Empowerment: Making sure that facilities are doing everything within their scope to promote transplants (e.g., educating patients about transplant options, protecting patients from infection, referring patients to transplant centers, etc.) is important to patients, the community, and the Administration. However, using a measure that is not accurately reporting on facility action misleads patients and forces them to make health care decisions based on false data.</p>
14	Based on NQF 2988	<p>Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) (reporting measure): Percentage of patient-months for which medication reconciliation was performance and documented by an eligible professional.</p>	<p>Concern: CMS has changed the specifications from those that NQF endorsed. Specifically, the QIP revisions delete specific items that must be addressed in the medication reconciliation (e.g., medication name, dosage, etc.).</p>

			<p>These changes mean that NQF has not reviewed or endorsed the new measure.</p> <p>Recommendation: KCP supports using the MedRec measures in the QIP and asks that CMS uses the specifications as endorsed by the NQF.</p> <p>Burden Reduction: When CMS changes the specification of an NQF-endorsed measure, it creates a burden on facilities because they are reporting a measure that may or may not meet measure development criteria and, if it does not, reporting information that has questionable value. Patients are burdened by having to figure out on their own whether or not the measure is accurately reporting a facility's performance.</p> <p>Patient Empowerment: TEPs have consistently endorsed the adoption of a MedRec measure. To be consistent with CMS' own principles and those of experts like NQF, the measure used should be reliable and valid so that patients can use the information to make informed decisions. Changing the specifications calls the new, revised measure's validity and reliability into question.</p>
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Appendix A: Kidney Care Partner Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
Ardelyx
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
AstraZeneca
Atlantic Dialysis
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Cara Therapeutics
Centers for Dialysis Care
Corvidia Therapeutics
DaVita
DialyzeDirect
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
Medtronic
National Renal Administrators Association
Nephrology Nursing Certification Commission
Otsuka
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care