KIDNEY CARE PARTNERS

August 21, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1805-P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

Dear Administrator Brooks-LaSure,

On behalf of the nearly 30 organizations working together to advance kidney care through Kidney Care Partners (KCP), I want to thank you for the opportunity to provide comments on the "End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model" (Proposed Rule). This letter focuses on the proposals related to the ESRD QIP. Our comments on the remaining provisions of the Proposed Rule will be provided in separate letters.

Kidney Care Partners is a non-profit, non-partisan coalition of nearly 30 organizations comprising patients, physicians, nurses, dialysis professionals, researchers, therapeutic innovators, transplant coordinators, and manufacturers dedicated to working together to improve the quality of care for individuals living with kidney disease. KCP remains strongly committed to making sure that the ESRD QIP achieves the goals the community and the Congress had when the program was created. We encourage CMS to work with KCP to modernize the program by resolving mis-alignment between the QIP and Facility Compare and reducing the number of measures within the ESRD QIP to increase the value of truly meaningful measures.

I. KCP supports replacing the Kt/V Dialysis Adequacy Comprehensive clinical measure with four separate measures and urges CMS to create greater transparency as to individual facility performance on each of those individual measures.

KCP supports the proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with four separate measures. We agree with CMS's rationale that "[b]y replacing the current Kt/V Dialysis Adequacy Comprehensive clinical measure with four separate measures, [CMS] would be able to assess Kt/V performance more accurately based

on whether the patient is an adult or child and what type of dialysis the patient is receiving."[1] KCP appreciates that the agency has listened to the community's concerns that the comprehensive measure eliminates the ability for patients, care partners, and stakeholders to determine performance on any specific patient population or dialysis modality. It also masks social disparities in terms of adequacy of dialysis.

To further address these concerns, we ask that CMS return to the original QIP reporting requirements that delineated performance at the individual measure level on the posted certificate as opposed to the more aggregated approach used today. We continue to believe that the ESRD QIP should provide patients, care partners, and health care providers with transparency about each facility's performance as the Congress had intended when it included a reporting requirement within the statutory authority creating the program.

KCP also supports weighting the Kt/V measures in total at 11 percent. While we highlight our concerns with the weighting policy below, we agree that this amount appropriately strikes the balance between maintaining a statutorily required measure and assigning more weight to other measures for which there is greater room for improvement.

II. KCP supports the removal of the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure from the ESRD QIP measure set beginning with PY 2027.

KCP remains concerned that the ESRD QIP, which includes nearly 20 measures for a single disease state, fails to meet the intent of the Congress to incentivize high quality care by diluting the impact of the most critical and truly meaningful measures of quality. As noted in more detail below, we reiterate our recommendation that CMS reduce the number of measures in the ESRD QIP. Removing the NHSN Dialysis Event reporting measure is a step in the right direction.

III. KCP remains concerned with regard to the the specifications of many of the remaining measures in the ESRD QIP and urges CMS to adopt the recommendations outlined in this comment letter for each of them.

The chart below summarizes our concerns with the specifications for the specific QIP measures.

	Measure Title and Description	KCP Concerns and Recommendations
1	**In-Center Hemodialysis Consumer Assessment of**	The problems related to the low response rate have yet to be addressed. KCP encourages CMS to review

[1]CMS. "End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model." 89 *Fed. Reg.* 55760 (July 5, 2024).

	Measure Title and Description	KCP Concerns and Recommendations
	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.	the recommendations from recent technical expert panels and the contractor's work to reduce the number of questions in the survey. The survey should also be revised to include home dialysis patients and obtain NQF endorsement of the new measure. To reduce the burden on patients and facilities, we reiterate our request that CMS field the survey once a year and not twice. We also recommend that CMS exclude the homeless to whom the survey cannot be distributed given that facilities are not allowed to provide it directly to patients. Finally, 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 recommended this step.
2	**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.	KCP remains concerned that the SRR is misleading to patients, care partners, and health care providers because it has a relatively wide confidence interval that can lead to facilities being misclassified and their actual performance not being reported. The QIP should use a true risk-standardize rate measure. A ratio that is then multiplied by a national median is not a true risk-standardized rate. In addition, CMS has yet to resolve 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. Also, measure does not support small facilities because it can lead to scores that are highly subject to random variability and/or to update the SFA ranges.

	Measure Title and Description	KCP Concerns and Recommendations
		We continue to encourage CMS to transition the measure and use the underlying readmission rate that could then be appropriately risk adjusted in the same manner CMS had done with the standardized mortality ratio. The confusion around the ratio measure and misclassification of facilities create an unnecessary burden on facilities. It also misleads patients for whom a readmissions metric is a critically important factor in making health care decisions. As CMS has acknowledged in previous rulemaking, rate measures are more transparent and easier for patients and caregivers to understand.
3	**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.	Patients continue to prioritize anemia management as an important factor in making health care decisions. Transfusions also place patients at risk of becoming ineligible for transplant. As noted already, KCP recommends that CMS use rate measures because they are more transparent and easier for patients and caregivers to understand. KCP also remains concerned that the STrR measure lacks validity. While we appreciate that CMS has acknowledged this concern, we are troubled that CMS has not addressed the very low reliability, especially for small facilities. Penalizing facilities for performance due to random chance is not appropriate. In particular, the review should examine the problems with hospital coding data. For the same reasons noted in our discussion of the SRR measure, we recommend that CMS transition the measure to a true rate and appropriately risk adjust it using race/ethnicity. Yet, 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.

	Measure Title and Description	KCP Concerns and Recommendations
4	**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.	KCP continues to support this measure as currently specified.
5	**Hypercalcemia** (reporting measure): Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.	We understand that CMS maintains this measure because of its view that the statute mandates its inclusion; however, as we have noted in previous letters with the inclusion of an IV calcimimetics in the bundle, the statutory basis for including the measure is no longer binding. Thus, CMS should retire the measure. Including this measure dilutes the value of the other measures that are part of the QIP. Moreover, it is not meaningful to patients or providers.
6	**Standardized Hospitalization Ratio (SHR)** (clinical measure): Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.	Consistent with our comments on the SRR and STrR measures, KCP remains concerned about including the SHR measure in the QIP because it is not reliable for small dialysis facilities. Nearly half of a facility's score is attributable to random noise and not signal. Penalizing facilities for performance due to random chance is not appropriate. Once again, we urge CMS to adopt a true risk-standardize hospitalization rate measure to avoid mis-classifying facilities and misleading patients. 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. Thus, the measure provides inaccurate information upon which they are then asked to make health care decisions.
7	**Clinical Depression Screening and Follow-Up** (reporting measure): Facility reports in EQRS one of four conditions for each	Unfortunately, CMS has changed the specifications from those that the consensus-based organization endorsed. These changes invalidate the endorsement. If CMS continues to retain this

	Measure Title and Description	KCP Concerns and Recommendations
	qualifying patient treated during performance period.	measure, it should submit it to the consensus-based organization for a complete review. To achieve the goal of the QIP containing a parsimonious set of meaningful measures, KCP recommends removing this measure from the QIP program and including it in the Facility Compare program. In addition, we ask CMS to identify a standardized ESRD-specific tool to be used with this measure.
8	**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.	Research conducted by the CDC (the measure's developer) and others, including CMS, show that the measure is neither valid nor reliable. As a result, the measure is not reporting accurate data to patients or providers. A measure that incorrectly reports a facility as having a low number of BSIs when in fact it does not distorts the ability of patients, care partners, and other providers to make an informed health care decision. 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 consensus-based organization. Research suggests that the underreporting may be due to the fact that 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.
9	**Percentage of Prevalent Patients Waitlisted (PPPW)** (clinical measure): Percentage of patients at each dialysis facility who were	KCP recommends that CMS remove this measure from the ESRD QIP because the consensus-based organization failed to endorse it. We suggest that CMS work with dialysis facilities to test and submit

	Measure Title and Description	KCP Concerns and Recommendations
	on the kidney or kidney -pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.	the measure set developed by the Kidney Care Quality Alliance (KCQA) which are available at this link. This measure set addresses the underlying problems with the PPPW measure by including both a transplant referral and waitlisting rate with a percent waitlisted among the patients referred rate. This structural approach will more accurately assess dialysis facility performance and provide the information patients and their care partners need to make informed health care decisions.
10	**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.	KCP continues to support the medication reconciliation measure, but requests that CMS return to the original specifications endorsed by the consensus-based organization. Moreover, we agree with the recent discussions within the consensus-based organization that there should be more substantive changes to the specifications. We support CMS in this effort and would welcome the opportunity to work closely with CMS as it updates the measure. To achieve the goal of the QIP containing a parsimonious set of meaningful measures, KCP recommends removing this measure from the QIP program and including it in the Facility Compare program.
11	**NHSN COVID-19 Vaccination Coverage among Healthcare Personnel** (reporting measure): Percentage of months for which the facility successfully reports National Healthcare Safety Network (NHSN) COVID-19 vaccination data for eligible healthcare personnel (HCP) in the CDC's NHSN system.	KCP supports this measure for use in the QIP, but continues to urge CMS to seek review and endorsement by the consensus-based organization.
12	**Facility Commitment to Health Equity** (reporting measure): This structural measure assesses facility commitment to health equity using	KCP continues to support the efforts of CMS to address health care inequities; however, we are concerned that the consensus-based organization has not had a chance to review and consider the

	Measure Title and Description	KCP Concerns and Recommendations
	a suite of equity-focused organizational competencies aimed at achieving health equity for racial and ethnic minority groups, people with disabilities, members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, individuals with limited English proficiency, rural populations, religious minorities, and people living near or below poverty level.	measure for endorsement. We also encourage CMS to address the MAP's concern that a simple attestation measure such as this one will not effectively drive improvement in health equity. To achieve the goal of the QIP containing a parsimonious set of meaningful measures, KCP recommends removing this measure from the QIP program and including it in the Facility Compare program.
13	**Screening for SDOH** (reporting measure): The Screening for Social Drivers of Health measure assesses the percentage of patients, aged 18 years and older, screened for health-related social needs (HRSNs) (specifically, food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) during established care in dialysis facilities.	As with the facility commitment to health equity measure, KCP is concerned that CMS has not submitted this measure for review by the consensus-based organization. To achieve the goal of the QIP containing a parsimonious set of meaningful measures, KCP recommends removing this measure from the QIP program and including it in the Facility Compare program.
14	**Screen Positive Rate for Social Drivers of Health** (reporting measure): The Screen Positive Rate for Social Drivers of Health is a structural measure that provides information on the percent of patients that were screened for all five HRSNs, and who screen positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety. For ESRD QIP, facilities will receive credit for reporting 'Yes' or 'No' (non-missing) responses.	As with the screening for SDOH measure, KCP is concerned the consensus-based organization has not had the opportunity to review this measure. We also believe that to achieve the goal of the QIP containing a parsimonious set of meaningful measures, CMS should place this measure in the Facility Compare program and remove it from the QIP for the reasons noted above.

	Measure Title and Description	KCP Concerns and Recommendations
15	**Adult Hemodialysis Kt/V Adequacy** (clinical measure): Percentage of all adult hemodialysis (HD) patient-months for patients whose delivered dose of dialysis was greater than or equal to 1.2 during the reporting period.	KCP supports this measure.
16	**Adult Peritoneal Dialysis Kt/V Adequacy** (clinical measure): Percentage of all adult peritoneal dialysis (PD) patient-months for patients whose delivered dose of dialysis was greater than or equal to 1.7 during the reporting period.	KCP supports this measure.
17	**Pediatric Hemodialysis Kt/V Adequacy** (clinical measure): Percentage of all pediatric in-center hemodialysis (HD) patient-months for patients whose delivered dose of dialysis was greater than or equal to 1.2 during the reporting period.	KCP supports this measure.
18	**Pediatric Peritoneal Dialysis Kt/V Adequacy** (clinical measure)**:** Percentage of all pediatric peritoneal dialysis (PD) patient-months for patients whose delivered dose of dialysis was greater than or equal to 1.8 during the reporting period.	KCP supports this measure.

IV. To achieve the goal of the QIP containing a parsimonious set of meaningful measures, KCP recommends removing several measures from the QIP program and including them in the Facility Compare program.

The chart below sets forth the KCP's recommendations as to which measures are best suited to be in the ESRD QIP value-based purchasing program and which measures should be available through Dialysis Compare to avoid inconsistencies in the two programs, create a parsimonious set of meaningful measures for the penalty-based QIP program, and better promote patient decision-making.

KCP Recommendations for Distributing Measures Across the QIP and DFC

QIP	Dialysis Compare
Bloodstream Infection in HD Patients Rate Clinical Measure (replaced with one that is valid and reliable)	Medication Reconciliation Reporting Measure
ICH-CAHPS Clinical Measure (with suggested modifications and including home dialysis questions)	Clinical Depression Screening and Follow-Up Reporting Measure
Standardized hospitalization rate measure (current ratio measure modified to a true risk-standardized rate)	COVID-19 Vaccination Coverage Among Healthcare Personnel
Standardized readmissions rate measure (current ratio measure modified to a true risk-standardized rate)	Facility Commitment to Health Equity Reporting Measure
Transplant referral and percentage of referred patients waitlisted measure set	Screening for Social Drivers of Health Reporting Measure
Hgb < 10 g/dL	Screen Positive Rate for Social Drivers of Health Reporting Measure
Long-Term Catheter Rate Clinical Measure	
Adult Hemodialysis Kt/V Adequacy Measure	
Adult Peritoneal Dialysis Kt/V Adequacy Measure	
Pediatric Hemodialysis Kt/V Adequacy Measure	
Pediatric Peritoneal Dialysis Kt/V Adequacy Measure	

The measures recommended for the QIP program address critical aspects of care that are particularly meaningful to patients and should be prioritized in terms of weighting and assessing penalties. The measures recommended for Facility Compare focus on aspect of care that are also important to patients, but can be assessed and addressed through the Compare program without diluting the more critical measures assigned to the ESRD QIP.

V. KCP remains concerned that the weights assigned to the domains and individual measures do not focus the program on meaningful measures.

One of the reasons KCP continues to urge CMS to reduce the measures included in the penalty-based QIP is because including nearly 20 individual measures within the programs leads to each measure having very little impact on the overall score. We appreciate that CMS has established groups of measures (domains) that have some groupings receive more weight than others, but this alone will not address the problem.

For example, in the area of care coordination, the hospital admission measure has the same weight as the depression screening measure. Given the critical importance patients place on staying out of the hospital and the overwhelming costs to the Medicare program when dialysis patients are hospitalized, it would seem that a penalty-based value-based purchasing program should be incentivizing efforts to reduce hospitalizations at a greater level than efforts to administer a depression screening tool. Yet, the QIP does not.

In previous letters and in Section IV of this letter, KCP has highlighted measures in those area of care that we believe are best suited for the QIP program. In addition, we encourage CMS to engage with KCP prior to the next rulemaking cycle to identify potential modifications to the weighting of the individual measures so that a more robust, clinically-driven approach could be proposed during the CY 2026 rulemaking cycle.

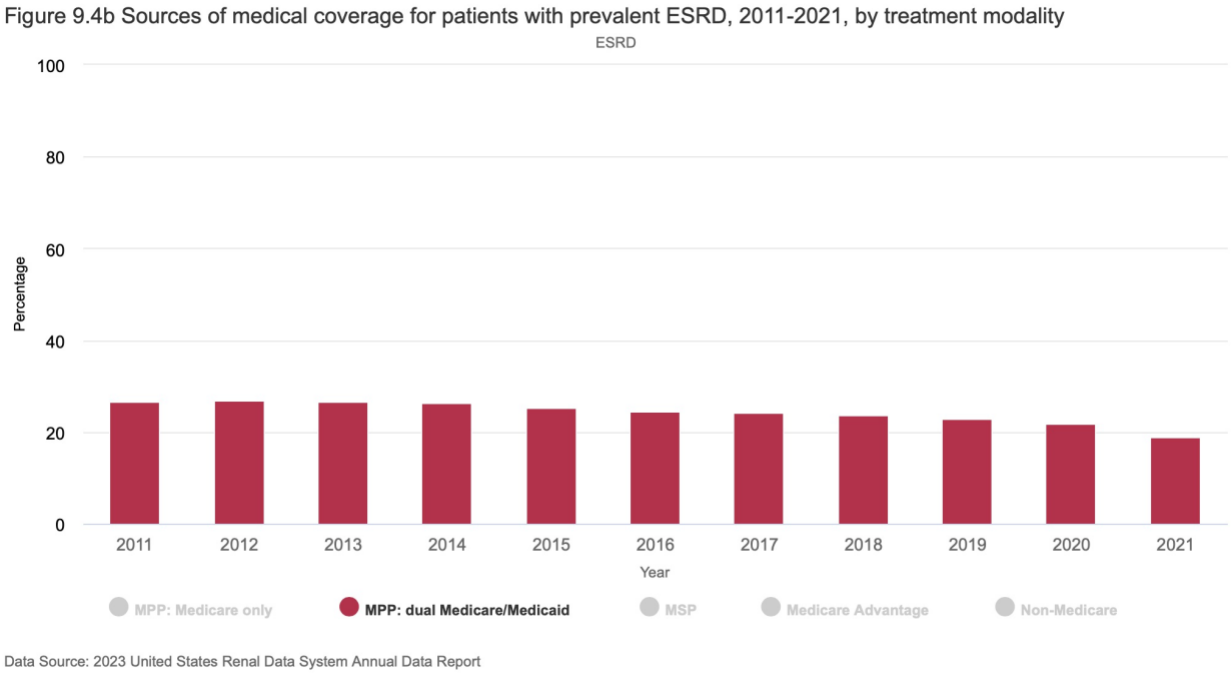
VI. KCP supports the continued application of the ESRD methodology.

KCP remains supportive of the QIP methodology and supports the proposal outlined in the Proposed Rule.

VII. KCP supports adding a health equity adjustment to support facilities that treat patient populations with higher proportions of health-related social needs and offers a potential framework for designing the adjustment.

As CMS has recognized, the Medicare ESRD patient population is disproportionately low-income. According to the U.S. Renal Data System (USRDS), 18.9 percent of prevalent

ESRD patients were dually eligible for Medicare and Medicaid in 2021.[2] In 2019, 22.3 percent of prevalent ESRD patients were dually eligible,[3] while more than a quarter of all ESRD prevalent patients were dually eligible in 2011.[4]



As the Assistant Secretary for Planning and Evaluation (ASPE) has reported dual eligibility status is one of the most significant predictors of negative health outcomes.[5] These patients often present with greater medical complexity than their counterparts.

CMS has recognized in the inpatient and skilled nursing facility (SNF) settings that providers with a disproportionately higher dual-eligible patient population often find meeting quality performance improvement and attainment benchmarks more challenging. CMS has also recognized the impact on dual-eligibility status in the ESRD Treatment Choices (ETC) model. In each of these instances, CMS has adopted a health equity adjustment to provide support for those providers with a higher percentage of dually eligible patients.

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[2]USRDS. Annual Data Report. Ch. 9 "Healthcare Expenditures for Persons with ESRD." (2023). Available at: https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd.

[3]*Id.*

[4]*Id.* at Chart 9.4b.

[5]Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. Available at: *https://aspe.hhs.gov/reports/second-report- congress-social-risk-medicares-value-based- purchasing-programs*.

KCP welcomes the opportunity to work with CMS to develop a health equity adjustment (HEA) for the ESRD QIP program. We believe it would be valuable to support providers and patients. We also appreciate the opportunity to provide a potential framework based on some of the existing HEAs CMS has adopted in other programs. A 60-day comment period is not sufficient to consider fully all of the potential options or ramifications of an HEA. To that end, we offer these initial suggestions for consideration and request the opportunity to engage in a meaningful dialogue with CMS during the next few months to support a more robust set of policy options that could be included in future rulemaking.

A. KCP believes a HEA would be valuable to the ESRD QIP.

KCP supports developing and implementing an HEA tailored to the ESRD program for many of the same reasons CMS has adopted this type of adjuster in other programs. We agree with the findings of a recent study in *JAMA Forum* noted that a HEA can serve as "an important strategy to ensure that value-based payment programs are more equitable."[6] Without such an adjustment, the ESRD QIP could widen disparities in care by reducing the resources available to those providers serving more complex and often more vulnerable dual eligible patients. In the inpatient hospital setting, the HEA is predicted to result in safety-net hospitals experiencing payment adjustment increases. We believe that adding an HEA in the ESRD QIP program could also help to mitigate the disproportionate reduction in payments to facilities that care for a greater proportion of dually eligible patients.[7]

B. KCP suggests that CMS consider a modified version of the hospital inpatient PPS (IPPS) HEA for the ESRD program.

In considering options, KCP has reviewed the IPPS, SNF, and ETC Model HEAs. As a threshold, all three of these policies are based on awarding bonus points when a provider has a certain percentage of dual-eligible (or in the case of the ETC Model, LIS beneficiaries). KCP supports adopting a bonus-scoring option for a potential ESRD QIP HEA as well. Consistent with the policy today, the application of an HEA should not be budget neutral. In other words, implementation of an HEA bonus should not leave facilities that do not qualify for the bonus worse off than they otherwise would have been. Because the QIP is not a budget neutral program, applying the HEA would likely result in a reduction in the number and size of the QIP penalties imposed. CMS should not seek to increase the overall QIP penalties through other policy changes.

Of the IPPS and SNF policies, one of the differences appears to be that the IPPS policy bonus is calculated based on the performance on each of the domains, whereas the SNF policy bonus is calculated at the measure level. As an initial approach to further this

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[6]Liu M, Sandhu S, Joynt Maddox KE, Wadhera RK. Health Equity Adjustment and Hospital Performance in the Medicare Value-Based Purchasing Program. JAMA. 2024;331(16):1387–1396. doi:10.1001/jama.2024.2440.
[7]Qi AC, Butler AM, Joynt Maddox KE. The role of social risk factors in dialysis facility ratings and penalties under a Medicare quality incentive program. Health Affairs. 2019 Jul 1;38(7):1101-9.

discussion, KCP has focused on the IPPS policy as a starting point because it seems closer to the design of the ESRD QIP and could be adapted more easily to support ESRD patients and facilities.

We also want to emphasize that while the IPPS policy seems to be directionally appropriate, a 60-day comment period is too short of a time to develop a complete set of recommendations around a policy as critically important to patients and providers as the HEA. Therefore, we reiterate our commitment to engaging in a meaningful dialogue with CMS in the coming months before an HEA policy or policy options are proposed to allow for a refined and more robust set of recommendations.

In our review, KCP has made the following observations that we hope will be helpful to CMS as it considers the HEA policy for the ESRD QIP.

- There are many more facilities than hospitals, so CMS might want to use quartiles or quintiles rather than tertiles.
- Bonus points should be based on the percentage of dual-eligibles (and low-income subsidies as in the ETC Model) treated at the facility and applied to the facilities TPS.
- To support facilities serving more dually eligible patients, the bonus should be awarded to allow facilities to move from a greater penalty tier to a lesser penalty tier.
- CMS should work with the community to establish the appropriate number of points given the difference between the ESRD QIP and other value based purchasing programs. We would want to consider, among other things, adopting a sufficient number of points to allow facilities with a substantial proportion of dually eligible patients to move to a lesser penalty tear, but also potentially allowing facilities with high quality and a substantial proportion of dual eligible beneficiaries to move into the zero penalty tier as well.
- As noted above, the adoption of an HEA should not leave facilities that do not qualify for the bonus worse off than they otherwise would have been. By introducing a bonus into a penalty program, CMS should be prepared to collect fewer penalties overall.
- The proportion of dually eligible patients should be calculated among both Medicare fee for service and Medicare Advantage patients to accurately represent the proportion of patients with dually eligible served by the dialysis facility (versus only using the proportion of Medicare fee for service dually eligible patients).

While we have highlighted considerations related to the potential parallels between the IPPS and ESRD programs, we also welcome considering other potential options that could support facilities serving a greater proportion of dually eligible patients.

VIII. KCP agrees that the data validation program should be updated and offers a set of recommendations.

KCP agrees with CMS that an important aspect contributing to the success of the ESRD QIP "is ensuring that the data submitted to calculate measure scores and [Total Performance Scores] are accurate."[8] We appreciate the opportunity to provide suggestions on ways CMS could update the data validation policy to encourage accurate, comprehensive reporting of ESRD QIP data.

As a threshold matter, we encourage CMS to revise the data validation system both for the EQRS and the NHSN. The current system is incredibly burdensome. While larger facilities may have the resources to dedicate teams of people to respond the two different surveys, smaller facilities have neither the staff nor the resources to undertake such efforts. As a result, it may be more economical for these facilities to accept the penalty for not reporting than to try to comply. This is the wrong incentivize for the program to create. We encourage CMS to hold a stakeholder meeting to allow for meaningful dialogue among the CMS EQRS, CDC NHSN, and dialysis facilities teams to identify specific ways to reduce the burden created by the current data validation program. Solutions could include shifting the time of the surveys away from the end of the year, providing more than the current 60 days for facility to respond to requests, allowing for more time between the survey requests, providing a more predictable schedule for survey requests, and allowing facilities that meet a certain benchmark of successful validation to reduce the number of times they are surveyed during a specified period of time.

In addition, KCP asks that CMS provide greater transparency with regard to the results of the data validations surveys. The results should be published and brought to the CMS EQRS workgroup, and potentially other similar groups, to help facilities understand what might need to be improved and identify ways to achieve that goal. This greater transparency could also support targeted educational efforts to assist facilities that may have had challenges identified during the surveys.

KCP would also support a bonus for facilities that perform above an established reporting or data accuracy threshold if the funding for such bonus were new money and not obtain by reducing payments to ESRD facilities. It could be funded in part from the penalties collected under the QIP. It is difficult to provide meaningful comments on what an appropriate threshold for such a bonus might be because the results of previous surveys have not been shared. While we understand from conversations with CMS that overall accuracy for facilities may be greater than 95 percent, we have not seen the results of the studies published. Before CMS establishes a threshold, it should share the results of previous studies and seek additional comments from stakeholders.

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[8] *Supra* note 1 at 55822.

Finally, we also wish to reiterate that as CMS notes in the Proposed Rule the purpose of the data validation program is to ensure the accuracy of data that facilities submit. This is similar to the purpose of claims review, which is to ensure the accuracy of claims submitted for payment. Both are efforts by CMS to audit information being submitted by facilities/providers. Thus, we believe that the data validation program should provide the same due process protections available to providers through other audit programs that CMS operates. For example, we have heard concerns from facilities that one problem they face under the NHSN validation program is that facilities are penalized not because of problems with the accuracy of the data submitted, but rather because of how the data are interpreted. Having a robust due process policy would allow for such issues to be addressed in a systematic and consistent manner.

KCP looks forward to continuing to work with CMS – and the CDC – to revise the data validation program.

IX. Conclusion

KCP appreciates the opportunity to provide the comments outlined in this letter and our ongoing working relationship with the CMS quality teams. Please do not hesitate to reach out to our counsel in DC, Kathy Lester, if you have any questions or would like further detail about the recommendations outlined in this letter.

Sincerely,

Mahesh Krishnan MD MPH MBA FASN
Chairman
Kidney Care Partners

Appendix: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Society of Nephrology
American Society of Pediatric Nephrology
Ardelyx
Atlantic Dialysis
Baxter
Centers for Dialysis Care
Cormedix
CSL Vifor
DaVita
Diality
Dialysis Care Center
Dialysis Patient Citizens
Fresenius Medical Care
GlaxoSmihKline
Greenfield Health Systems
Kidney Care Council
NATCO
Nephrology Nursing Certification Commission
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
The Rogosin Institute
U.S. Renal Care
Unicycive