KIDNEY CARE PARTNERS

August 23, 2018

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

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

Dear Secretary Azar and Administrator Verma:

Kidney Care Partners (KCP) appreciates the opportunity to provide comments on the Proposed Rule entitled "End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS" (Proposed Rule)."[1]

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

In this letter, KCP focuses on the ESRD Quality Incentive Program (QIP) proposals related to the measure specifications and the structural recommendations, including the proposals related to changing the weighting of measures in the ESRD QIP, for Payment Years (PY) 2021 and 2022. We provided a more detailed letter dated August 10, 2018, in which KCP indicated:

- Support for focusing the ESRD QIP on meaningful measures and recommendations for streamlining the ESRD QIP and Dialysis Facility Compare (DFC) to reduce administrative burden and improve transparency for patients, caregivers, and consumers.
- Support for the effort to assess and account for social risk factors in the ESRD QIP program through adjusters and other mechanisms.
- Recommendations that CMS revise the proposed regulatory text to align with the statute and current policies.

[1] 83 *Fed. Reg.* 34304 (July 19, 2018)
[2] A list of KCP members is provided in Appendix A.

- General support for the Retirement Factors outlined in the Proposed Rule, but also recommendations for refining them.
- The need for clarification about the projected increase in QIP payment penalties.
- Recommendations for changes to the PYs 2021 and 2022 measures sets based on previous KCP comments and consistent with the recommendations to streamline the QIP and DFC.

Our comments on the ESRD PPS are in a separate letter as well.

I. CMS should ensure that measure specifications for the same focus precisely align. Different specifications for the "same" measure can introduce performance score variance for the same facility, which potentially affects discordance between QIP penalties and star ratings.

KCP has analyzed the specifications for measures used across the Agency's quality programs, specifically the QIP, Five Star, ESCOs, Fistula First, and Survey & Certification. In multiple cases, KCP has identified instances where measure specifications in one program do not align with what has been implemented in another. For example, the current catheter measure used in the QIP has several exclusion variations when compared to the measure used in Five Star. Specifically, three exclusions are present in the specifications for the QIP measure that are not on the Five Star version (Facilities that treat <11 eligible patients during the performance period; Patients <18 years; Patients not on hemodialysis) and the Five Star version has an exclusion not present in the QIP version (Patients on ESRD treatment <91 days).

There is simply no justification for CMS to use different specifications for the same measure focus (e.g., long-term catheter use, dialysis adequacy). Such an approach can mean a facility's scores on the measure differ slightly between the QIP and Five Star, thereby confusing patients when results from each program are publicly reported. Different specifications also can contribute to discordance in a facility's penalty status and star ratings. KCP has previously provided CMS with data on the impact that different specifications for dialysis adequacy appear to contribute to a lack of penalty, yet low star rating and vice versa. In addition to providing conflicting and confusing results to patients, facilities cannot prioritize whether or how to improve performance when presented with different results for the "same" measure.

Appendix B summarizes these differences, and Appendix C presents redlined details. KCP strongly urges that CMS immediately align the specifications for measures that purport to address the same focus.

II. KCP recommends that CMS refrain from finalizing the proposed weighting changes and instead establish weights for measures that are based on the clinical importance of the measures.

As we have noted in previous letters, KCP believes that the weighting of measures should be aligned to their clinical value and importance to patients. As we reviewed the proposed recommendations for the new weights, our members expressed great concerns about the weighting generally and about the influence that the STrR and ICH CAHPS would have in skewing the total performance score (TPS). This impact is particularly troubling given the validity issues with both measures. In addition, we believe that CMS should weight the catheter measure greater than the fistulas. In previous letters, we have highlighted the fact that the equal weighting and lack of a graft measure has led to patients having to endure attempts to place AV fistulas when clinically inappropriate. The evidence is overwhelming that AV fistulas and AV grafts are preferable for improved outcomes. Weighting the catheter more heavily supports a "catheters last" approach to improve quality in this critical area.

KCP also suggests that CMS undertake a more thorough review and update of the measure weights prior to the next annual update of the QIP. Such a review would include opportunity for multi-stakeholder feedback on the importance of the QIP measures and a quantitative analysis of the reliability and improvement opportunity for each measure. Therefore, KCP recommends that CMS not finalize the proposed weights and instead work with the kidney care community in the coming months to develop weights that reflect the basic principles of clinical value and importance to patients.

A. Analysis of proposed weights shows they would distort facility performance and privilege problematic measures over valid, reliable, actionable measures that matter to health care professionals and patients; KCP recommends in particular that CMS substantially lower the weights for the STrR and ICH CAHPS measures.

Discern Health, a consultant to KCP, analyzed the proposed weights by quantifying how the proposed changes in weighting and movement of measures between categories in the ESRD QIP could impact TPS and potential penalties/reimbursement classifications. To do so, Discern used the most recent data available (PY2018) to compare what the TPS distribution curve would be using the proposed and current weighting systems (see Appendix D). Discern generated a calculator to simulate aggregate-level effects on TPS with PY2018 data and the current (PY2019) and proposed (PY2021) methodologies. On an aggregate level, it appears that the proposed weighting system would result in a slightly lower median TPS. In addition, the area under the curve would increase to the left which indicates an increasing number of individual facilities with a decrease in TPS.

To understand variability in individual facility TPS, Discern quantified how many facilities would change payment reduction tiers if the new weighting schema were to be applied to PY2018 data (see Table 1). Under the 2021 payment methodology, most facilities would either remain in the initial reduction tier applied or be expected to fall into a higher reduction tier. The number of facilities expected to shift reduction tiers are colored in either shades of green (positive change) or red (negative change). Those not expected to change are shaded grey. The proposed methodology for 2021 would result in more facilities previously in the "No and Lower" Reduction tiers moving into the higher rates of reduction tiers.

Table 1. Effects of the Proposed PY2021 Weighting Schema on PY2018 data*

		2021 Status					
		No Reduction	0.50% Reduction	1.00% Reduction	1.50% Reduction	2.00% Reduction	Total
2018 Status	No Reduction	3139	1326	851	295	26	5637
	0.50% Reduction	18	95	190	239	104	646
	1.00% Reduction	0	11	28	64	82	185
	1.50% Reduction	0	1	4	18	44	67
	2.00% Reduction	0	0	0	0	21	21
	Total	3157	1433	1073	616	277	6556

*Does not include facilities that did not receive a TPS and for which no reduction tier could be calculated.

CMS's proposed retirement of multiple measures (of which three are topped out) could result in changes in the future minimum TPS. However, without the most recent measure performance data, Discern was unable to replicate CMS' methodology or calculate these impacts.

STrR Sub-Analysis. KCP is deeply concerned about the proposal that beginning in PY2021, the STrR measure will account for 22 percent of a facility's TPS score, the highest weighting of any measure, yet on a measure where concerns about coding and validity have been identified. If a facility fails to report any other measures and weights are accordingly distributed, the STrR will account for even more of a facility's TPS. Because of the STrR measure's increased importance, Discern sought to analyze measure performance trends and potential impact on facilities. It has been previously noted that the transition from ICD-9 to ICD-10 coding is impacting how transfusions are coded and this is impacting performance. (Please see extensive comments in August 10, 2018, KCP Letter)

Unfortunately, public data for facility-level performance on the STrR are only available through CY 2016 (PY 2018), which does not allow sufficient time for trends to emerge post-ICD-10 implementation. With the data that are available, while the standard transfusion ratios appear similar between years (see Appendix E), it is clear that the number of transfusions in claims is decreasing overall (see Appendix F) and the ICD-10 coding has affected transfusions when the hospital claims data are analyzed. Besides the weighting question for STrR, KCP also emphasized in its August 10, 2018, letter, that the unresolved technical issues will affect the measure's reliability. Thus, KCP recommends that CMS substantially reduce the weight of the STrR measure to reflect these problems with the measure.

ICH CAHPS Sub-Analysis. Similarly, KCP remains concerned that the low response rates for CAHPS resulting in facilities not receiving an ICH CAHPS score. At 15 percent of a facility's TPS (the second highest overall weight), this measure in particular has the potential to exacerbate other weighting problems. For instance, for home clinics where CAHPS is not part of QIP and the vascular access type measure topic is not included, STrR would rise to be weighted at 28 percent. This would increase further if other additional measures are not reported.

Discern examined the implications of facilities not receiving a CAHPS score and having the measure's weight proportionally redistributed (see Appendix G). Using the previously-generated calculator on PY2018 data (redistributing the weights of SHR, NHSN Event Reporting, Ultrafiltration, and ICH CAHPS), analysis shows this would shift the TPS distribution curve to the right, indicating general TPS improvement.

However, this is likely due to PY2018 CAHPS performance showing wide variation, with more facilities scoring 0-6 than 7-10 (see Appendix H). When the CAHPS weight is redistributed, the STrR measure is the largest beneficiary of increased weight. In PY2018, the STrR performance was fairly high and much better than CAHPS (see Appendix I). Therefore, in the aggregate-level simulation with PY2018 data, a failure to report CAHPS would positively impact TPS, but a decrease in STrR performance overall could result in large TPS shifts.

This analysis highlights the precarious nature of the STrR measure's new proposed weighting, as well as concerns for facilities that are not able to report ICH CAHPS, since the STrR weighting would increase in greater magnitude than proposed due to score distribution rules. If CMS were to adjust the STrR benchmark and the measure performance distribution were to become more normal (as Discern has previously shown is the trend with other measures), facility-wide TPS could react by falling dramatically. This increasing importance being assessed through weighting on the STrR is exceedingly problematic when paired with previously raised concerns about the validity of the measure. Considering the possibility of a portion of the CAHPS weight being reassigned to STrR, KCP recommends that CMS postpone any plans to adjust the STrR weight until the

identified issues with the validity of the measure are fully assessed and rectified and a more global consideration of how unreported measure weights should be handled is completed.

B. KCP recommends that CMS adopt criteria for assessing the weights of measures.

As in previous years, KCP urges CMS to consider additional criteria to adjust weights for the various QIP measures to emphasize the measures that have the greatest benefit to patient care. While KCP has made these recommendations in previous comment letters, we are unclear why CMS has not adopted them for determining the weights of measures in the ESRD QIP. We believe if applied along with the existing CMS criteria, these recommended criteria, if applied, would have avoided the problems that the proposed weights in the Proposed Rule would create.

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

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

- Opportunity for Improvement. The actual variation between excellent and poor performers on a measure matters. The coefficient of variation (Standard Deviation÷Mean) is one method to measure variation. Using such a weighting criterion would have the advantage of reducing weight gradually as measures become more topped-out, making the decision to retire such measures less disruptive to overall scores.

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

Given the complexities of the measures and the KCP recommendations outlined in the August 10, 2018, letter suggesting significant changes to the measures used in the ESRD QIP, we suggest that CMS first not change the current weights for PY 2022. Next, it should reduce the QIP to the set of measures KCP recommends in the August 10, 2018 letter. Then, it could seek comments from stakeholders on the specific weights that meet the criteria it has set forth along with the three criteria recommend in this letter. Thus, for the next

rulemaking cycle, CMS would be in a better position to propose the appropriate weights for the QIP measures and address the problems Discern has identified with the current proposals.

III. Reorganization of Domains and Resulting Impacts on Eligibility

KCP is also concerned about the reorganization of the domains and recommends that CMS not finalize these changes. Again, consistent with our comments on establishing a parsimonious set of measures for the ESRD QIP, we believe CMS should take that step first and then address the domains.

The proposed rule indicates "that to be eligible to receive a TPS, a facility must be eligible to be scored on at least one measure in any two out of the four domains in the ESRD QIP measure set." CMS indicates this proposal is warranted due to the proposed removal of the Reporting Domain and increase in the number of domains from 3 to 4. In addition, the Agency posits that the proposal would maximize the number of facilities that can participate in the QIP. This is a change from the way TPS eligibility was determined in the past, where "a facility must be eligible to be scored on at least one measure in the Clinical Measure Domain and at least one measure in the Reporting Domain."

Discern assessed the impact of this proposed eligibility adjustment. In the PY2018 data, 276 facilities did not receive a TPS (see Table 2). Of those, 276 facilities that did not receive a TPS, 142 facilities did not receive a score on any measure and 95 facilities received a score for exactly one measure. Those facilities would remain ineligible to receive a TPS under the recent proposed changes. 47 facilities reported at least two measures and of those 47, 41 reported at least two measures in at least two different domains (the remaining 6 facilities reported at least two measures, but they were in the same domain and would thus remain ineligible to receive a TPS).

Table 2. PY 2018 TPS eligibility

	Number of Facilities (% of total facilities)
Facilities that did not receive a TPS	276 (4.04%)
Facilities with no measures scored	142 (2.08%)
Facilities with 1 measure scored	95 (1.39%)
Facilities with 2+ measures scored	47 (0.68%)
Facilities with 2+ measures scored in 2+ domains	41 (.060%)

If CMS's proposal to change how TPS eligibility is determined would have been applied in PY2018, 41 more facilities (0.60 percent of total facilities) could have received a TPS. Based on the CMS rationale that this eligibility adjustment will maximize eligibility, we agree that an additional number of facilities will receive a TPS; however, the impact will be minor.

B. CMS should place the Medication Reconciliation (MedRec) Measure in the Care Coordination Domain to be consistent with the Meaningful Measures Initiative.

As indicated in the Measures section of the QIP comment memo, CMS is currently proposing to add a Medication Reconciliation measure to the QIP for PY2022. Although the proposal language includes a discussion of the process of Medication Reconciliation being an important safety construct for ESRD patients, it is also mentioned that it is a function of medication management. The Meaningful Measures initiative would suggest as a medication management focus, the measure would belong in the Care Coordination domain. CMS is proposing to add to the Safety domain, which seems to conflict with Meaningful Measures priorities.

The following assessment was undertaken to understand how measure weights could be impacted if CMS were to revise the domain assignment to correspond to Meaningful Measures. Past policy indicates, CMS would reduce weights of other measures in a domain versus promoting the domain weight.

As it is currently written in the proposed rule, the measure is slated to receive 4 percent weight of a facility's total TPS. Table 3 shows how CMS proposes to include MedRec in the Safety domain beginning in PY2022.

Table 3. Medication Reconciliation in the Safety Domain

Care Coordination Measure Domain		
SRR measure	40.00%	12.00%
SHR measure	40.00%	12.00%
PPPW measure	13.33%	4.00%
Clinical Depression and Follow-Up reporting measure	6.67%	2.00%
Total: Care Coordination Measure Domain	100% of Care Coordination Measure Domain	30% of TPS
Safety Measure Domain		
MedRec measure	26.67%	4.00%
NHSN BSI clinical measure	53.33%	8.00%
NHSN Dialysis Event reporting measure	20.00%	3.00%
Total: Safety Measure Domain	100% of Safety Measure Domain	15% of TPS

If CMS were to move MedRec to the Care Coordination Domain, CMS would have to decide how to reduce the measure weights within the Care Coordination domain and increase the measure weights within the Safety domain. Table 4 shows how this would play

out if MedRec were to retain 4 percent of TPS weight and the reweighting done proportionally (a rationale CMS currently employs).

Table 4. Medication Reconciliation in the Care Coordination Domain

Measures/Measure Topics by Subdomain	Measure Weight Within the Domain (PY2022)	Measure Weight as percent of TPS (PY2022)
Care Coordination Measure Domain		
SRR measure	34.67%	10.40%
SHR measure	34.67%	10.40%
PPPW measure	11.57%	3.47%
Clinical Depression and Follow-Up reporting measure	5.77%	1.73%
MedRec measure	13.33%	4.00%
Total: Care Coordination Measure Domain	100% of Care Coordination Measure Domain	30% of TPS
Safety Measure Domain		
NHSN BSI clinical measure	75.83%	11.37%
NHSN Dialysis Event reporting measure	24.17%	3.63%
Total: Safety Measure Domain	100% of Safety Measure Domain	15% of TPS

However, based on the preamble to the Proposed Rule, it is unclear how CMS would choose to reweight measures should MedRec be moved from the Safety to the Care Coordination domain. In light of the comments questioning the placement of the MedRec measure in the Safety Domain, we ask that CMS clarify how it determines the weighting of measures generally and more specifically how it would align the MedRec measure with the Meaningful Measures Initiative and according adjust the weight.

IV. KCP supports the proposals to maintain the other current structural aspects of the ESRD QIP.

With the caveat outlined in the KCP August 10, 2018, letter raising questions about why the TPS penalties have increased so substantially without a change in the underlying structural methodology, KCP supports the continued use of the benchmarks, attainment and improvement standards, as well as the penalty tiers. As we have noted in pervious letters, we believe having a consistent structure allows for patients to compare facility performance over time in a consistent and meaningful manner.

V. KCP strongly supports efforts to increase patient modality choice, including home dialysis and increasing the number of transplants; however, current ESRD PPS payment policies (including the Conditions for Coverage (CfCs)) are not the barrier to achieving these goals.

As we have noted other letters on the CY 2019 Proposed Rule, KCP continues to support efforts increase dialysis modality options for patients and ensure equal access to them, as well increase opportunities for transplant. Achieving these goals is one of the reasons KCP advocated for aligning the home and in-center dialysis payments and was pleased when CMS adopted our recommendation to do so. KCP has also supported the current requirements in the CfCs and our members take them very seriously.

As MedPAC has noted, there has been a steady rise in the use of home dialysis since these changes were implemented. However, as MedPAC also recognized shortages in the solution used for PD has flattened that growth. Home hemodialysis has growth has been slower than anticipated because of the uncertainties associated with the payment policies around more frequent dialysis. Noridian's decision to pay for only three sessions and the recent Local Coverage Determinations (LCDs) issued by the Medicare Administrative Contractors (MACs) to restrict more frequent dialysis, will likely exert downward pressure on the future expansion of this modality. As KCP has commented to the MACs, medically justified more frequent dialysis leads to improved clinical outcomes and supports the use of HHD. CMS could help address both of these issues by: (1) developing a process with the FDA to address fluid shortages more quickly in the future; and (2) promoting a policy that support more frequent dialysis.

Another policy CMS could refine to improve modality selection is the Kidney Disease Education (KDE) benefit. As the 2015 GAO report noted, the KDE benefit is not effective today, in large part because of its inadequate payment rate. CMS should ensure adequate payment for the benefit and emphasize modality education as part of it. Also, while dialysis facilities are well equipped with the interdisciplinary beneficiary teams to provide the benefit, current law excludes them. CMS should address this problem by piloting a KDE benefit program that allowed dialysis facilities to provide and be reimbursed for KDE services and evaluate its impact on the number of beneficiaries who select home dialysis.

We also recommend that CMS eliminate the pooled Kt/V measure in the ESRD Quality Incentive Program (QIP) and return to the individual in-center and home dialysis measures of dialysis adequacy. The pooled measure hides facilities' performance on home dialysis from patients and consumers. Having the individual Kt/V measures, as originally used in the ESRD QIP, would incentivize the use of home dialysis by creating appropriate transparency in terms of the quality of care being provided. The lack of a home dialysis tool for measuring patient satisfaction also reduces transparency. Consistent with our ongoing work on the ICH CAHPS measure, KCP recommends moving more quickly to adapt the current measurement tool to support home dialysis patient surveys. Having a home

dialysis CAHPS tool would also be an important step to addressing the weighting problems with the current QIP that penalize facilities providing home dialysis only.

Similarly, in the area of transplant it is important to include a transplant measure in the QIP that is actionable by dialysis facilities, as well as that would meet the other scientifically based criteria used to evaluate measures. While CMS has proposed two transplant measures in the QIP, the National Quality Forum (NQF) has rejected both measures as not meeting these criteria. Thus, if adopted, they will not incentivize transplant because they are so poorly designed that they do not measure what they were intended to assess. As noted in our April 10, 2018, comment letter on the ESRD QIP, KCP recommends that CMS prioritize developing an appropriate transplant measure that is actionable by dialysis facilities. A measure that recognizes what is actionable by facilities would better support the Meaningful Measures Initiative priority area of increased focus on effective communication and coordination. The problem is not with facility assessment and evaluation, but with the criteria hospitals set for the waitlists. We recognize the need to avoid a "check-box measure," but believe that a transplant measure must be actionable for it to have a true impact on patient access to transplant.

We additionally recommend that CMS work closely with transplant programs to find a way to align and streamline the waitlist criteria. There is no centralized set of criteria and patients have to register with multiple transplant centers to improve their chances of finding a match. CMS may want to develop a pilot program to help patients navigate the complexities of the waitlist process as well. CMS should also carefully examine how transplant centers are evaluated in terms of outcomes and eliminate any metrics that encourage cherry-picking among patients.

CMS should consider the experience of the C.W. Bill Young Cell Transplantation Program, which is the national bone marrow and cord blood registry for the United States. Lessons learned from this highly successful program could be applied to improve matching with living donors, especially.

We also recommend that CMS work with the Congress to address the very real problem that many Medicare beneficiaries experience. Transplant centers will not include them on the waitlist unless they can prove they can pay for their immunosuppressive drugs post-transplant. Current law limits the length Medicare will cover these drugs for kidney transplants, which is a barrier to transplant.

In the end, we believe that the current CfCs are appropriate and being implemented by the vast majority of dialysis facilities in a manner that helps patients navigate the complexities of modality selection and transplant. However, there are very real barriers that patients face in both of these areas that are outside of the control of the dialysis facility and need to be addressed to see improvement beyond the margins.

VI. Conclusion

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

Sincerely,

Allen Nissenson
Chairman
Kidney Care Partners

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

Appendix A: List of KCP Members

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

APPENDIX B: ESRD MEASURE SPECIFICATIONS COMPARISON SUMMARY TABLE

QIP (Reference Specs)	Five Star	ESCOs	Fistula First	Surveys & Certification
SAFETY				
NHSN BSI Clinical Measure	—	—	—	—
NHSN Dialysis Event Reporting Measure	—	—	—	—
Medication Reconciliation for Patients Receiving Care at Dialysis Facilities	—	—	—	—
—	—	**Medication Reconciliation Post-Discharge**	—	—
PATIENT AND FAMILY ENGAGEMENT				
ICH CAHPS Clinical Measure	Yes; there will be a separate CAHPS 5-Star rating determined using a clustering model beginning in 2018.	Yes, but ESCO adjusts survey results for mode and patient-mix effects "as needed" and includes a facility weighting approach.	—	Yes; patient satisfaction and grievances reported and analyzed for trends using ICH-CAHPS or other survey.
—	—	**KDQOL**	—	Yes; psychosocial status and Health Outcomes and Physical and Mental Functioning assessed by standardized tool, e.g.KDQOL-36 survey or age appropriate survey.
CARE COORDINATION				
SRR	Yes, but 5-Star includes flagging rules and p-values and Ci definitions.	—	—	—
SHR	Yes, but 5-Star includes flagging rules and p-values and Ci definitions.	—	—	—
Clinical Depression Screening and Follow-Up	—	Yes, but several numerator and exclusion variations from QIP.	—	—
Percentage of Prevalent Patients Waitlisted (PPPW) (PY 2022 onward)	?	—	—	—

QIP (Reference Specs)	Five Star	ESCOs	Fistula First	Surveys & Certification
Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) (PY 2024 onward)	?	—	—	—
CLINICAL CARE				
STrR	Yes, but 5-Star includes flagging rules and p-values and Ci definitions.	—	—	—
—	**SMR**	Yes, but ESCO includes a facility weighting approach.	—	—
Adult HD Adequacy (through PY 2018)	Yes, but several exclusion variations from QIP.	—	—	Yes, but several exclusion variations from QIP.
—	—	—	—	**Adult HD Adequacy: Standardized Kt/V**
Adult PD Adequacy (through PY 2018)	Yes, but several exclusion variations from QIP and requires Kt/V to be in range (<=8.5) for numerator inclusion.	—	—	Yes, but several exclusion variations from QIP.
Pediatric HD Adequacy (through PY 2018)	Yes, but several exclusion variations from QIP and requires spKt/V to be in range (<=5) for numerator inclusion.	—	—	Yes, but several exclusion variations from QIP.
Pediatric PD Adequacy (through PY 2018)	Yes, but several exclusion variations from QIP.	—	—	Yes, but several exclusion variations from QIP.
Kt/V Dialysis Adequacy Comprehensive Measure (PY 2019 onward)	—	—	—	—
UFR Reporting Measure (PY 2020 onward)	—	—	—	—
—	—	—	—	**Functional AVF or AVG**
VAT: AVF Clinical Measure (through PY 2020)	Yes, but several exclusion variations from QIP.	—	—	Yes, but several exclusion variations from QIP.
VAT: Catheter >=90 Days (through PY 2020)	Yes, but several exclusion variations from QIP.	—	—	Yes, but several exclusion variations from QIP.
VAT: Standardized Fistula Rate (PY 2021 onward)	—	—	—	—

QIP (Reference Specs)	Five Star	ESCOs	Fistula First	Surveys & Certification
VAT: Long-Term Catheter Rate (PY 2021 onward)	—	—	—	—
—	—	—	**Incident Patients: Access Type AVF Only**	—
—	—	—	**Incident Patients: Access Type AVG Only**	—
—	—	—	**Incident Patients: Access Type Catheter for >=90 Days**	—
—	—	—	**Incident Patients: Access Type Catheter for >=90 Days**	—
—	—	—	**Prevalent Patients: Access Type AVF Only**	—
—	—	—	**Prevalent Patients: Access Type AVG Only**	—
—	—	—	**Prevalent Patients: Access Type Catheter for >=90 Days**	—
—	—	—	**Prevalent Patients: Access Type Catheter for >=90 Days**	—
Hypercalcemia Clinical Measure	Yes, but several exclusion variations from QIP.	—	—	Yes, but several exclusion variations from QIP.
—	—	—	—	**Hyperphosphatemia**
—	—	—	—	**Albumin**
—	—	—	—	**Average UFR**
—	—	—	—	**Transplant Waitlist**
—	—	—	—	**Hemoglobin <10**
SCREENING/REPORTING MEASURES				
Mineral Metabolism Reporting (through PY 2019)	—	—	—	—
Serum Phosphorus Reporting (PY 2020 only)	—	—	—	—
Anemia Management Reporting (through PY 2020)	—	—	—	—
Pain Assessment and Follow-Up (through PY 2020)	—	—	—	—
NHSN Healthcare Personnel Influenza Vaccination	—	—	—	—

QIP (Reference Specs)	Five Star	ESCOs	Fistula First	Surveys & Certification
(through PY 2020)				
—	—	**Diabetic Care: Eye Exam**	—	—
—	—	**Diabetic Care: Foot Exam**	—	—
—	—	**Tobacco Use: Screening and Cessation Intervention**	—	—
—	—	**Falls: Screening, Risk Assessment, and Plan of Care to Prevent Future Falls**	—	—
—	—	**Advance Care Plan**	—	—
VACCINATION MEASURES				
—	—	**Influenza Immunization in the ESRD Population**	—	Yes, but defines eligible timeframe as August 1-March 31 rather than July 1-March 31 as in ESCO measure and excludes patients with ESRD <30 days.
—	—	**Pneumococcal Vaccination Status**	—	Yes.
—	—	—	—	**Hepatitis B Vaccination Status**

APPENDIX C: KCP MEASURES SPECIFICATION TABLE

	Measure	NQF Number	Applicable Programs		QIP	DFC Five Star	ESCOs	Fistual First Catheter Last	Survey & Cert
* QIP specfications are used as "reference" specifications. Departures from those reference specifications in other programs are indicated by red text.									
**Most current version of specifications used as source when multiple years published. (E.g., PY2018 is used when available, rather than PYs 2019, 2020, 2021, etc.)									
1	NHSN BSI Clinical Measure	Based on NQF 1460	QIP only, PY2018 onward.	Source(s)	ESRD QIP Proposed Rule Technical Specifications (July 2018); CMS ESRD Measures Manual V2.5 (October 2017).				
				Description	The Standardized Infection Ratio (SIR) of Bloodstream Infections (BSI) will be calculated among patients receiving HD at outpatient HD centers.				
				Numerator	The number of new positive blood culture events based on blood cultures drawn as an outpatient or within 1 calendar day after a hospital admission.				

	Measure	NQF Number	Applicable Programs		QIP	DFC Five Star	ESCOs	Fistual First Catheter Last	Survey & Cert
				Denominator	Expected number of positive blood culture events in maintenance in-center HD patients treated in the outpatient HD unit on the first 2 working days of the month.				
				Exclusions	Facilities that do not offer in-center HD.				
					Facilities with a CCN open date after January 1, 201X.				
					Facilities that treat <11 patients during the performance period.				
					Facilities with approved Extraordinary Circumstances Exception.				
					Included in Measures Manual only: Facilities that do not offer in-center HD as of December 31 of the performance period.				
				Minimum Data	12 months.				

	Measure	NQF Number	Applicable Programs		QIP	DFC Five Star	ESCOs	Fistual First Catheter Last	Survey & Cert
				Risk Adjustment	None.				
2	**NHSN Dialysis Event Reporting**	**Not endorsed**	QIP only, PY2019 onward.	Source(s)	ESRD QIP Proposed Rule Technical Specifications (July 2018); CMS ESRD Measures Manual V2.5 (October 2017).				
				Description	Number of months for which facility reports NHSN Dialysis Event data to the CDC.				
				Numerator	Not specified.				
				Denominator	Not specified.				
				Exclusions	Facilities treating <11 in-center HD patients.				
					Facilities with a CMS open date on or after January 1, 201X.				
					Facilities with approved Extraordinary Circumstances Exception.				
					Included in Measures Manual only: Facilities that do not offer in-center HD as of December 31 of				

	Measure	NQF Number	Applicable Programs		QIP	DFC Five Star	ESCOs	Fistual First Catheter Last	Survey & Cert
					the performance period.				
				Risk Adjustment	None.				
3	**Medication Reconciliation for Patients Receiving Care at Dialysis Facilities**	**Based on NQF 2988**	QIP only, PY2022 onward.	Source(s)	ESRD QIP Proposed Rule Technical Specifications (July 2018).				
				Description	The percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.				
				Numerator	Number of patient-months in the denominator for which the facility reported the following required data in CROWNWeb: Type of clinician who completed the medication reconciliation/ personnel identifier; and Date of the medication reconciliation.				

	Measure	NQF Number	Applicable Programs		QIP	DFC Five Star	ESCOs	Fistual First Catheter Last	Survey & Cert
				Denominator	Total number of eligible patient-months for all patients assigned to a dialysis facility during the reporting period.				
				Exclusions	In-center patients who receive <7 HD treatments in the facility during the reporting month.				
4	**Medication Reconciliation Post-Discharge**	**Not endorsed**	ESCOs only.	Source(s)			CMS Comprehensive ESRD Care Model Technical Specifications for Quality Measures for CY2017 (November 2017).		
				Risk Adjustment			Percentage of discharges from January 1 to December 1 of the measurement year for ESCO aligned beneficiaries for whom		

	Measure	NQF Number	Applicable Programs		QIP	DFC Five Star	ESCOs	Fistual First Catheter Last	Survey & Cert
							medications were reconciled on the date of discharge through 30 days after discharge (31 total days).		
				Numerator			Medication reconciliation conducted by a prescribing practitioner, clinical pharmacist, or registered nurse on the date of discharge through 30 days after discharge (31 total days). Documentation in the medical record must include evidence of medication reconciliation and the date when it was performed.		

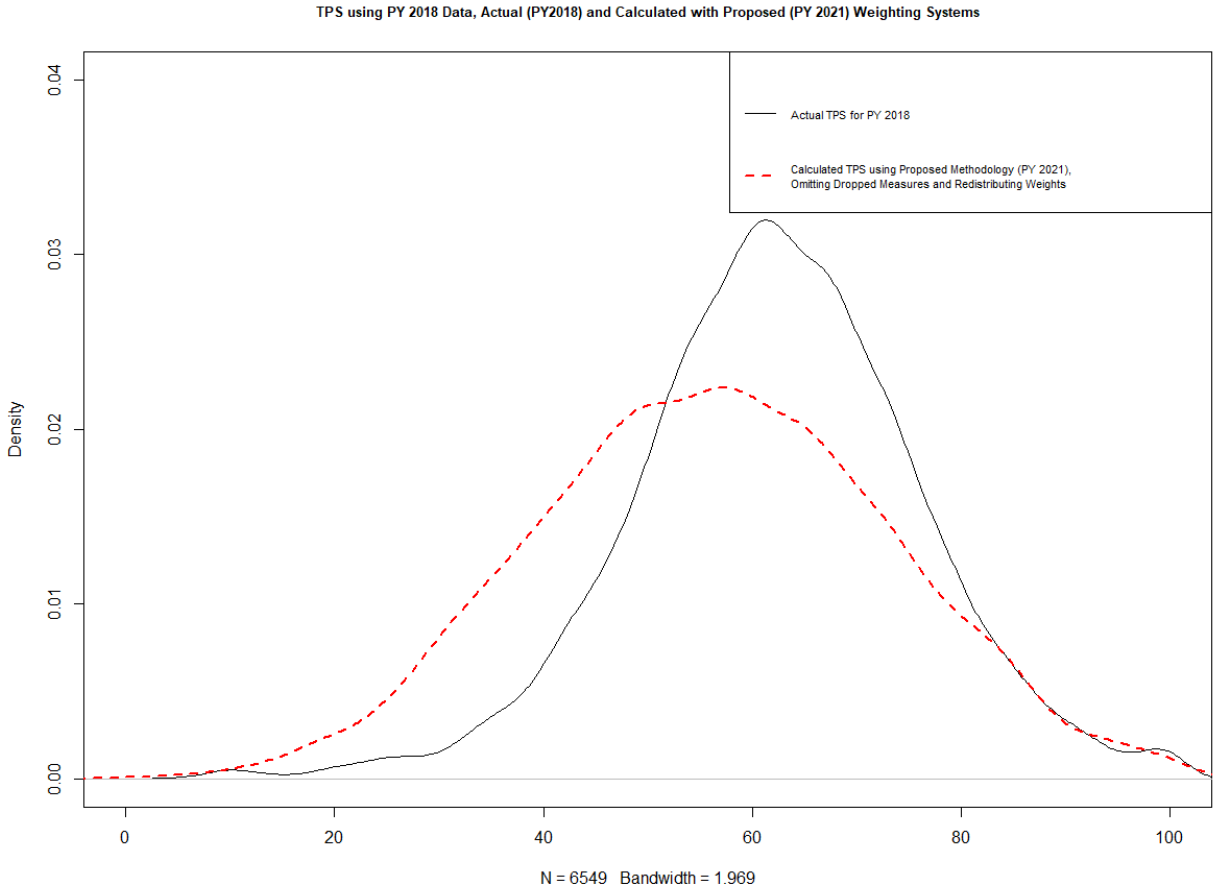
	Measure	NQF Number	Applicable Programs		QIP	DFC Five Star	ESCOs	Fistual First Catheter Last	Survey & Cert
							Any of the following meets the evidence criteria: -- Documentation that the provider reconciled the current and discharge medications. -- Documentation of the current medications with a notation that references the discharge medications (e.g., no changes in medications since discharge, same medications at discharge, discontinue all discharge medications). -- Documentation of the		

	Measure	NQF Number	Applicable Programs		QIP	DFC Five Star	ESCOs	Fistual First Catheter Last	Survey & Cert
							beneficiary's current medications with a notation that the discharge medications were reviewed. -- Documentation of the current medication list, a discharge medication list, and notation that both lists were reviewed on the same date of service. --Evidence that the beneficiary was seen for post-discharge hospital follow-up with evidence of medication reconciliation or review. -- Documentation in the discharge summary that		

	Measure	NQF Number	Applicable Programs		QIP	DFC Five Star	ESCOs	Fistual First Catheter Last	Survey & Cert
							the discharge medications were reconciled with the current medications. There must be evidence that the discharge summary was filed in the outpatient chart on the date of discharge through 30 days after discharge (31 total days). --Notation that no medications were prescribed or ordered upon discharge. Only documentation in the outpatient chart meets the intent of the measure, but an outpatient		

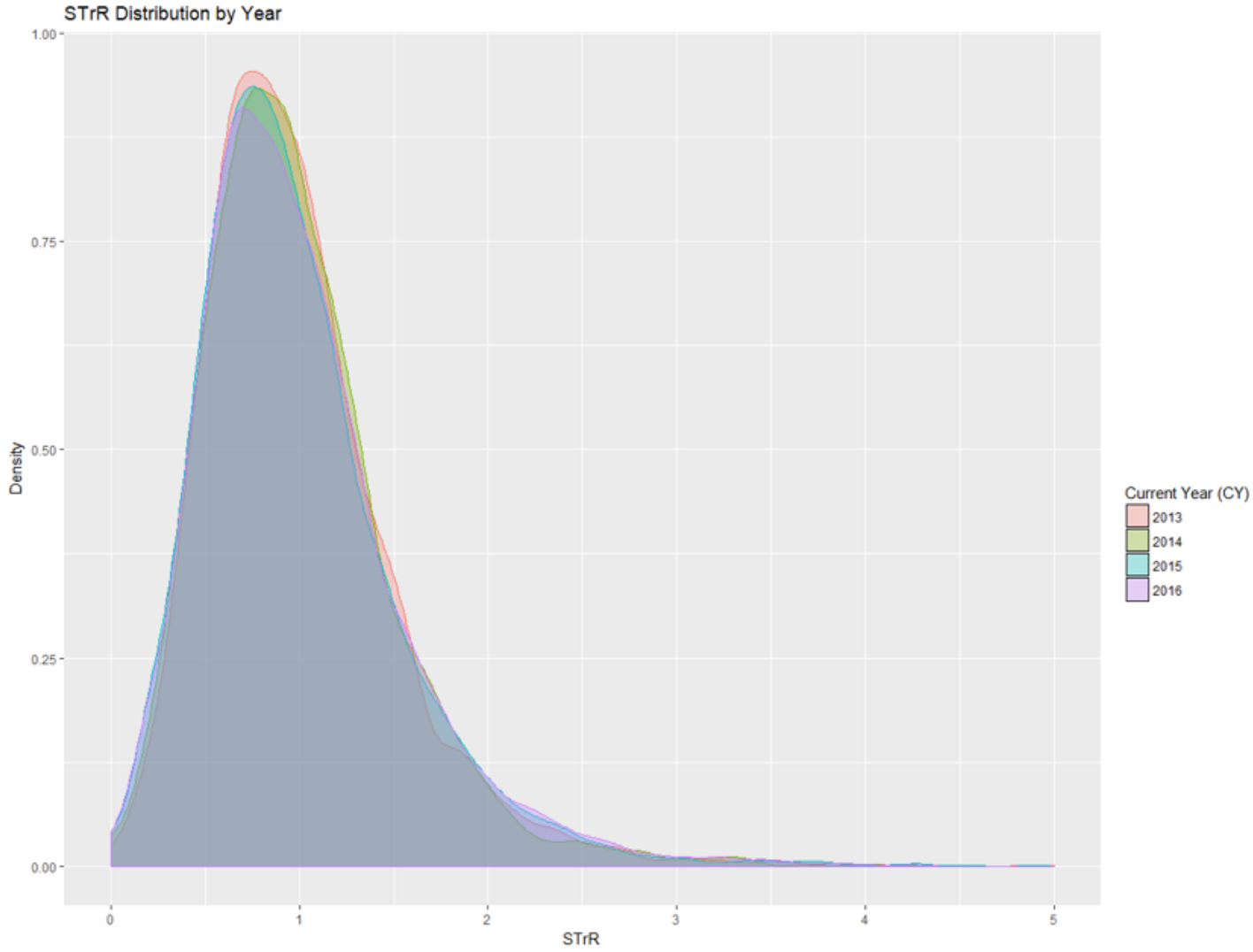
	Measure	NQF Number	Applicable Programs		QIP	DFC Five Star	ESCOs	Fistual First Catheter Last	Survey & Cert
							visit is not required.		
				Denominator			A systematic sample of inpatient discharges drawn from the eligible population.		
				Exclusions			None.		

Appendix D

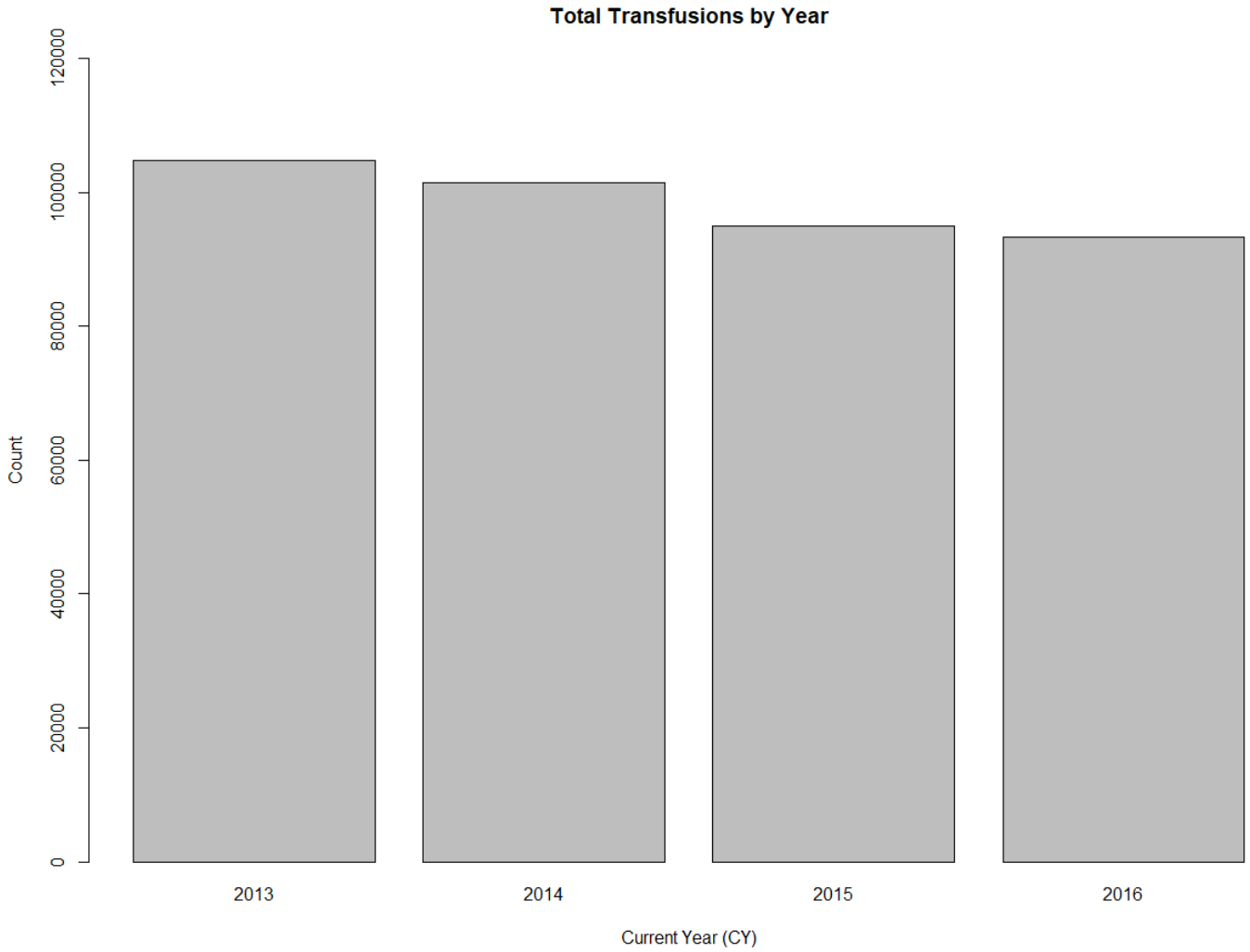


Note: Calculated scores with 2021 methodology exclude the Ultrafiltration, NHSN Event Reporting, and SHR measures, as they were unscored in PY2018. The missing measure weights (23%) were redistributed using the proposed new methodology. Additionally, all facilities were considered eligible for the purposes of this analysis, as eligibility requirements shifted between years.

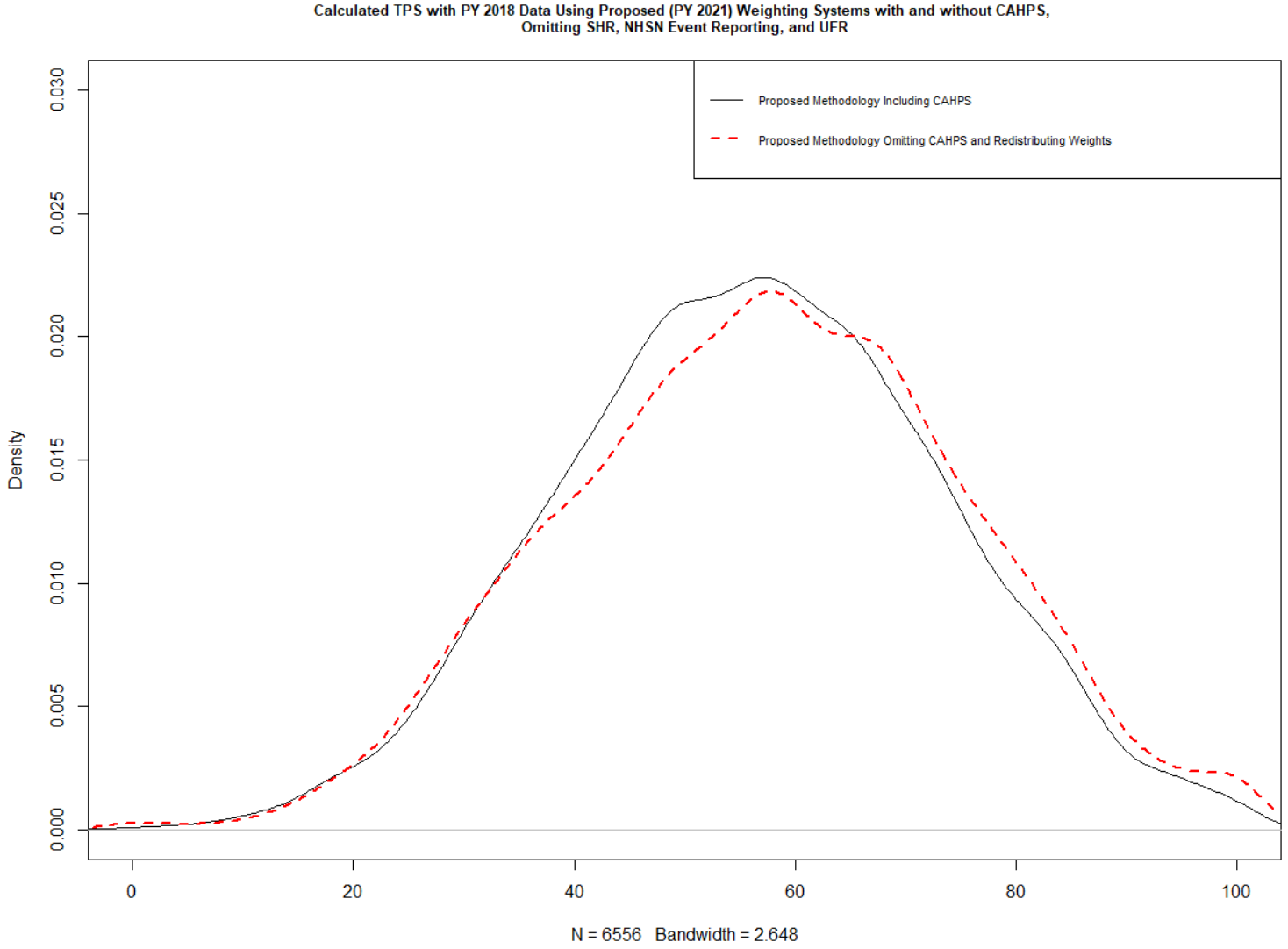
Appendix E.


STrR Distribution by Year
Density
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
STrR
Current Year (CY)
2013
2014
2015
2016

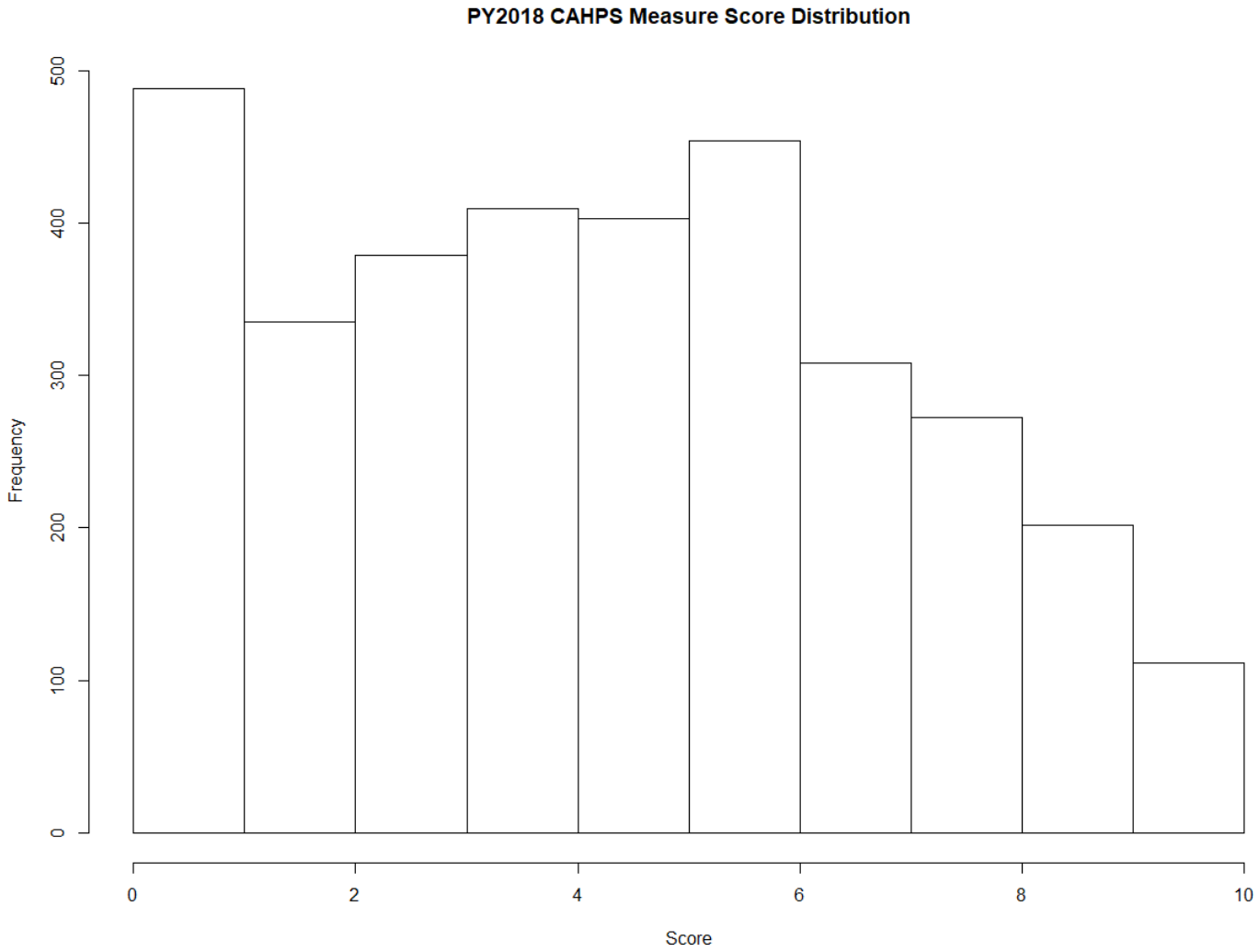
Appendix F.


Total Transfusions by Year
Count
0
20000
40000
60000
80000
100000
120000
2013
2014
2015
2016
Current Year (CY)

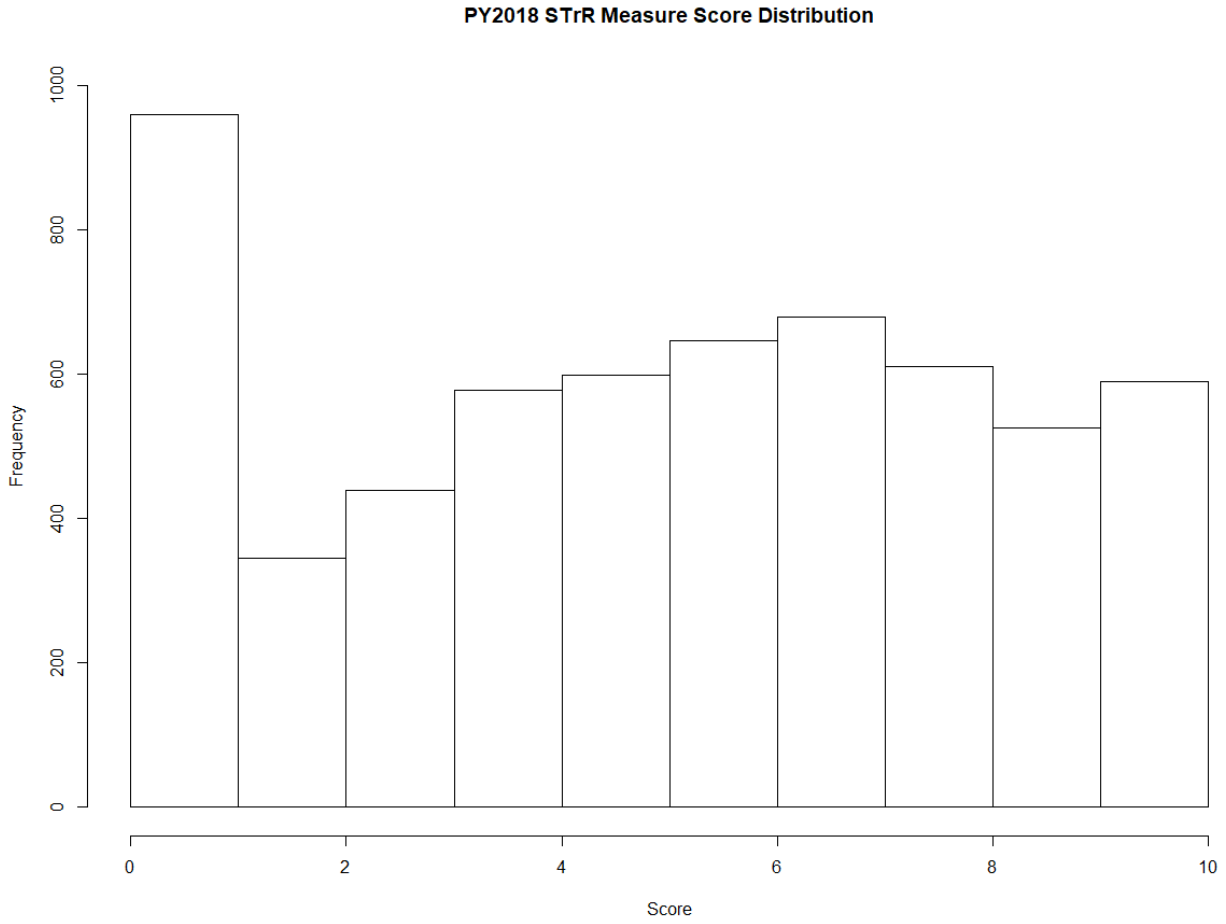
Appendix G.


Calculated TPS with PY 2018 Data Using Proposed (PY 2021) Weighting Systems with and without CAHPS, Omitting SHR, NHSN Event Reporting, and UFR
Proposed Methodology Including CAHPS
Proposed Methodology Omitting CAHPS and Redistributing Weights
Density
0.000
0.005
0.010
0.015
0.020
0.025
0.030
0
20
40
60
80
100
N = 6556 Bandwidth = 2.648

Appendix H.


PY2018 CAHPS Measure Score Distribution
Frequency
0
100
200
300
400
500
0
2
4
6
8
10
Score

Appendix I.


PY2018 STrR Measure Score Distribution
Frequency
0
200
400
600
800
1000
0
2
4
6
8
10
Score