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Rockville, MD

Forum Coordinator

Kelly Brooks, MPA
Richmond, VA

August 23, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1768-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1782-P: Medicare Program; 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, and End-Stage Renal Disease Treatment Choices Model

Dear Administrator Brooks-LaSure:


The National Forum of ESRD Networks appreciates the opportunity to comment on the changes proposed in CMS-1782-P. We are aware of the continued importance of the QIP and ETC model in the Advancing American Kidney Health (AAKH) initiative and recognize the intent of the proposed rule to promote excellence. We have primarily limited our comments to those sections of the proposed rule that specifically relate to renal dialysis services insofar as they potentially constrain access to care via the impact on the ESRD Quality Incentive Program (QIP) and via aspects of the ESRD PPS payment as published in the Federal Register on June 30, 2023. Keeping in mind the Department of Health and Human Services' objectives for the Meaningful Measures Initiative 2.0 as a component of the CMS Quality Measurement Action Plan, and the commitment to person-centered care and equity in care, we have highlighted those changes that can be anticipated to affect quality of care and access to ESKD treatment. Below are our comments.

Thank you for your consideration and commitment to person-centered care and equity in care.

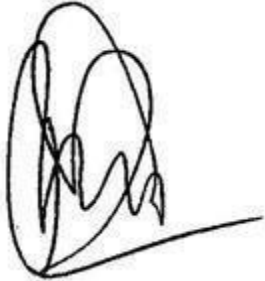
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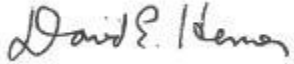
Kam Kalantar-Zadeh, MD, MPH, PhD
President, Forum of ESRD Networks



Daniel Landry, DO
Chair, Forum Medical Advisory Council & President-Elect



Preethi Yerram, MD, MS, FASN
Vice-Chair, Forum Medical Advisory Council



David E. Henner, DO
Immediate Past President, Forum of ESRD Networks



Derek Forfang
Co-Chair, Forum Kidney Patient Advisory Council



Dawn Edwards
Co-Chair, Forum Kidney Patient Advisory Council



Vicki Cash, MBA, BSN, RN
Chair, Forum Executive Director Advisory Council



Mary Albin, BS, CPHQ
Vice-Chair, Forum Executive Director Advisory Council



Andrew Howard, MD, FACP
Past President, Forum of ESRD Networks

1. Proposed Update to the ESRD PPS base rate for CY 2024: The original proposal for CY 2011 was a PPS base rate of \$229.63. We recognize the statutory requirements with which CMS must comply regarding the calculation and determination of reimbursement under the ESRD PPS. The present proposal for CY 2024 is for a base rate of \$269.99. This represents an increase of \$40.36 over a duration of thirteen years. The effects of the COVID-19 PHE dramatically strained systems of healthcare delivery. However, they had and continue to have effects on the provision of dialysis care to patients who represent one of the most vulnerable subpopulations of Medicare beneficiaries. Although many of these impacts have seen significant resolution in other facets of the U.S. economy, they continue to significantly impact the provision of dialysis care. The current proposal for CY 2024 represents a 1.6% increase over the current rate for CY 2023 of \$265.57. We have concerns regarding how this will impact independent and hospital-based dialysis providers. We have witnessed the unprecedented closure of facilities across the country, some of which have occurred in locations that serve the most at-risk beneficiaries leading to further exacerbations of health inequities. Staffing of dialysis facilities has seen challenges at every level given the unique multi-disciplinary team of providers that is necessary to provide excellent care to these most medically complex and vulnerable kidney patients.

ESRD Forum Recommendations:

- Given the proposed PPS base rate of \$269.99 (which is only \$40.36 more than the original rate finalized in 2010 for CY 2011), the recent development of dialysis facility closures outpacing the number of de novo openings, and concerns regarding how access to care has been affected by these closures, the Forum would like to voice its concern that further net closures of facilities may result from the present funding proposal.

2. Proposal for a POST TDAPA Add-On Payment Adjustment for Existing ESRD PPS Functional Categories: In the CY 2021 ESRD PPS Final Rule, CMS incorporated an adjustment of \$9.93 for the inclusion of calcimimetics in the ESRD-PPS bundled payment. We previously acknowledged the proposal in the CY 2022 ESRD PPS Proposed Rule to increase the ESRD PPS base rate to \$264.09 reflecting the updated wage-index budget neutrality adjustment and the rebased productivity adjusted market basket without any additional adjustment for calcimimetics. In our comments on the CY 2023 ESRD PPS Proposed Rule, the Forum’s Kidney Patient Advisory Council (KPAC) and Medical Advisory Council (MAC) respectfully reiterated that only 20 to 30% of dialysis patients take calcimimetics and these are especially vulnerable patients such as Black American patients, dual-eligible patients, and those with a dialysis vintage longer than 3 years since their first dialysis therapy initiation. The KPAC and MAC remain concerned that lack of any adjustment for oral calcimimetic therapy may lead to the treatment of secondary hyperparathyroidism with either pro-calcemic alternative therapies (e.g., activated vitamin D) or earlier referral for surgical interventions that may carry increased risk for adverse outcome as dialysis companies focus on cost and those for-profit companies on maintaining profits. We are also concerned that patients with kidney failure will not have equal access to the medications that best work for them individually. With intravenous (IV) medications having a substantially higher cost than medications taken by mouth (PO), this may lead many dialysis facilities to utilize the lowest cost medication option. We feel strongly that patients need to have shared decision making with their physician to ensure the medication prescribed works best for them, considering side effects and what is most effective and best tolerated. Providing for medication costs and kidney friendly foods and basic human needs can be difficult. These costs add up and lead to stress, hardship and impact patient wellbeing. We hope CMS will keep this in mind and not increase the cost to patients. We were grateful for the opportunity to comment on the RFI in the CY 2023 ESRD PPS Proposed Rule for a POST-TDAPA Add-On Payment Adjustment for Existing ESRD PPS Functional Categories. The proposal as stated in this year’s CY 2024 Proposed Rule will still present challenges in equitable access to innovative medications for this vulnerable population.

TDAPA supports payment and patient access to new therapies introduced to the ESRD PPS. The Forum appreciates CMS raising of the topic of potential payment adjustments for the post-TDAPA period given an ongoing desire to encourage life-altering drug and biologic innovation while also maintaining a focus on improving equitable access to care. The Forum supports the creation of an add-on payment adjustment for drugs in existing functional categories. We recognize that this would likely require the extension of the TDAPA period beyond two years in order to ensure a thorough review of utilization of drug in the ESRD population as well as up-to-date cost assessment (via Medicare reimbursement as well as facility cost). We would also encourage an annual review of clinical outcomes data in order to ensure the appropriateness of ongoing support for such medications and biologics in an effort for ongoing cost-containment.

ESRD Forum Recommendations:

- Consider adjustment to ESRD PPS bundled payment base rate to help accommodate for the use of emerging medications and technologies (including the specific example of difelikefalin (Korsuva)) that is used for moderate to severe pruritus (itchiness) in dialysis persons once TDAPA coverage concludes on 3/31/2024 (see also below under #4). The Forum recognizes and appreciates the proposal for a post-TDAPA adjustment to this specific agent, however, does also wish to raise a concern that the time frame for adoption of TDAPA agents is limiting when one considers the time required for providers to adopt protocols for utilization and how it may poorly reflect the true patient need for certain agents that are just coming to market. Alternatives to agents such as difelikefalin do not exist currently, and use of other alternatives in an off-label capacity (e.g., antihistamines or gabapentin) has led to significant toxicity to our patients over the years.
- Continue to monitor the usage of calcimimetics including across parenteral vs oral agents.
- Monitor for disparities in access for vulnerable populations.
- Emphasize the importance of shared decision making.

3. TDAPA Definition of Oral-only Drugs: The Forum noted the proposal slated to take effect on 1/1/2025 to change the definition of “oral-only drugs” from a focus on mode of action to end action effect “in the treatment or management of a condition or condition associated with ESRD.” When considering this change in definition, the Forum MAC did note a concern for the future availability of drugs with new mechanisms of action such as daprodustat (Jesduvroq) that has recently been approved by FDA for anemia management in persons on dialysis) if excluded from TDAPA. While we recognize that there is still much to be learned about this specific class of drug, an oral alternative to the current IV only therapeutics has obvious benefits to the workflow of an already busy dialysis facility staff. The Forum also has concerns regarding how such future limitations on oral-only drugs could have adverse effects on our home dialysis population; peritoneal dialysis patients are unable to provide themselves with intravenous iron replacement at home and often have difficulty administering injectable medications at home. Some must travel to dialysis clinics in order to receive these medications. Newer oral therapies could have a dramatic impact for those with limited time and resources.

ESRD Forum Recommendations:

- Consider further review of proposed changes to “oral-only drug” definition and how such restrictions could affect optimization of patient access to care.

4. POST-TDAPA Add-On Payment for difelikefalin (Korsuva®): The Forum’s MAC members were pleased to see the novel therapy for CKD-associated pruritus (CKDaP), difelikefalin, approved for TDAPA coverage as of 4/1/2022 and notes that coverage under TDAPA will end on 3/31/2024. The Forum recognizes that CKDaP affects a large proportion of our ESRD population and is associated with

a pronounced decline in sleep as well as overall quality of life. We note the proposal for a POST_TDAPA add-on payment for difelikefalin. However, given the proposal to apply the adjustment uniformly to all PPS payments, this would only result in an adjustment of approximately \$0.10 to the PPS base rate payment. We remain concerned that this will result in lack of access to those most in need of such treatment.

ESRD Forum Recommendations:

- The Forum is appreciative of CMS’ recognition of a need for a post-TDAPA add-on payment but feels that the adjustment value will have little impact on making this medication available to those most in need of it. As described above, the Forum is concerned that the TDAPA period used to assess medication utilization is too short and does not accurately reflect the number of patients who have appropriate indication for new, innovative therapies that could impact quality of life and physical well-being.

5. Transitional Add-on Payment for New and Innovative Equipment and Supplies (TPNIES): The Forum’s KPAC and MAC supported and applauded CMS on the creation of the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES). We also supported the substantial clinical improvement (SCI) criteria as the basis of TPNIES eligibility. We agreed that products that qualify for the payment adjustment should be “truly innovative” and emphasize the need for CMS to assess data on patient preferences, patient-reported outcomes, and other patient-centered data when evaluating SCI. We are encouraged by CMS’ effort to continue to make all efforts that reduce patient and care partner burden, improve communication with the care team and improve safety for patients by lower rates of severe adverse events in their considerations. We also felt that it was especially important to consider improving current symptoms and managing symptom burden of dialysis treatments and have treatments that fit better with patients’ lives and improved their health-related quality of life. We felt that taking these concerns into consideration would decrease the high levels of patient and care-partner burnout and issues that currently cause home hemodialysis and peritoneal dialysis patients to transition back to in-center hemodialysis after only few years of home treatments. The high rate of failure to keep patients on home modalities works against the goals of the Administration and the benefits patients receive by improved outcomes by utilizing these home modalities.

ESRD Forum Recommendations:

- With regards to the TPNIES eligibility criteria for applications, the Forum would like to express a concern regarding how CMS proposes to analyze applications in a stepwise, or sequential, manner that eliminates the opportunity to review (or comment on) latter eligibility criteria. We feel that this removes a powerful opportunity for CMS to share input regarding its assessment of a product’s utility while also lacking the flexibility to allow those submitting a product application to better understand areas of need and corrective action that could lead to better innovation of future products and, ultimately, better patient care.
- The Forum also brings to the attention of CMS the example of online hemodiafiltration (HDF) technologies in outpatient dialysis care as a future candidate for TPNIES that could benefit from CMS’ high-quality review and feedback. HDF is a modality that is widely used in many countries in lieu of the preexisting high flux hemodialysis treatment, and has received more attention in the U.S. The recent clinical CONVINCE trial showed a significant survival benefit of HDF versus traditional hemodialysis (N Engl J Med. 2023 Jun 16. doi: 10.1056/NEJMoa2304820. PMID: 37326323.).

6. RFI for Future Modifications to the Low-Volume Payment Adjustment (LVPA): The ESRD Forum is grateful for the opportunity to comment on the RFI concerning the array of proposed future modifications for the LVPA. We see this as having an impact on both access to care and health equity. Based upon the information provided in this year’s CY 2024 proposed rule, 353 facilities received this payment adjustment of 23.9% to the ESRD PPS, as it was originally established in the CY 2011 ESRD PPS Final Rule. We will comment in our response below concerning the proposed modifications to create new exceptions for facilities. Our preference would be to establish a continuous function to adjust LVPA payments with the existing 4,000 treatment upper bound. This would enable those facilities with the lowest volume to receive the highest payment adjustments. This would also eliminate payment cliffs, better aligning payment with resource use and could, potentially, expand eligibility to the greatest number of facilities.

ESRD Forum Recommendations:

- The Forum favors establishing a continuous function to adjust LVPA with the existing 4,000 treatment upper bound in an effort to maintain budget neutrality and avoid any reduction to the ESRD PPS base rate.

7. Proposal for an Exception to the Current LVPA Attestation Process for Disasters/Emergencies:

In response to the unprecedented Public Health Emergency due to COVID-19, CMS enacted a policy in the ESRD PPS CY 2021 Final Rule, that a facility would be held harmless from increases in treatment counts due to temporary patient shifting as a result of the PHE. As noted in this year’s Proposed Rule, natural disasters can have similar impacts impacting both transient increases in treatment counts and the need for temporary closure of a facility with subsequent reopening. The two proposed changes to the current LVPA attestation process would create a new exception to the LVPA treatment threshold for ESRD facilities that accept patients from an ESRD facility affected by a disaster or emergency if it causes that facility to temporarily exceed the LVPA threshold. The second proposed exception would allow a facility currently receiving the LVPA to close and reopen in response to a disaster or emergency and still be eligible to receive the LVPA.

ESRD Forum Recommendations:

- The Forum is very appreciative of the creation of an exception to the current LVPA attestation process for disasters/emergencies and fully supports this proposal.

8. Proposal to Measure Patient-Level Utilization – “Time on Machine”: Several of our members participated in the TEPs held in both December 2018 and December 2020 when this issue was discussed, and the responses gathered used to inform this proposal. We understand that this data would be used as a proxy to apportion facility-level Composite Rate Costs by more accurately attributing labor related costs to each patient receiving in-center hemodialysis by reporting minutes receiving hemodialysis. We also acknowledge that this proposal, if incorporated into the Final Rule would not impact the ESRD PPS base rate, however, may be used for future refinements to the existing adjusters which were last updated in the CY 2016 ESRD PPS Final Rule, and these would impact the ESRD PPS base rate. We understand that this information would be used to try and ameliorate health equity disparities. We are concerned that collection of this information could become an unfunded burden on facility staff who are already struggling to provide safe care that is of the highest quality.

ESRD Forum Recommendations:

- While the Forum does agree with any premise or proposal to improve the equitable provision of healthcare to our patients, but do not see this proposal as being feasible in the current strained

environment of limited dialysis unit staffing. If it were to be implemented, the proposed start date of 1/1/2024 is not seen as tenable given our above concerns.

9. Proposal for a Transitional Pediatric ESRD Add-On Payment Adjustment (TPEAPA): This is a proposal to establish a new add-on payment adjustment to the ESRD PPS base rate effective in CY 2024 and continuing through CY 2026 that was informed by the RFI in the CY 2023 ESRD PPS Proposed Rule. As we understand the proposal, 30% of the per treatment amount would be added to all renal dialysis services furnished to pediatric ESRD patients. Although budget neutrality is not required for this proposed adjustment, the stated proposal does include a budget neutrality adjustment factor of 0.999532, which when included in the calculation of the ESRD PPS base rate would lead to a reduction of \$0.12 for every treatment. We also understand that propensity score matching will be used to analyze cost report data resulting from this modification during the 3-year period.

ESRD Forum Recommendations:

- The Forum is very much in favor of efforts to support the added care burden of managing pediatric dialysis but is not in favor of such fiscal support coming at the expense of the base rate when budget neutrality is not mandated in such a situation.

10. Proposal for Unused/Discarded Amounts of Renal Dialysis Drugs/Biologicals Paid for Under the ESRD PPS: Medicare currently authorizes payment for the unused and/or discarded amount of a drug or biological and the dose administered for single-use vials. Renal dialysis drugs or biologicals paid for under the ESRD PPS are not separately billable. The use of the JW modifier to capture the discarded drug not administered is currently applied under the ESRD PPS. The current proposal would require the use of both the JW modifier along with the JZ modifier on all claims to indicate that no drug was wasted or not administered. This would enable CMS to track the discarded amounts of single-vial or single package renal dialysis drugs or biologicals currently paid for under the ESRD PPS. We understand that this information would not be used to alter current payments, however, may inform future payment policies.

ESRD Forum Recommendations:

- The Forum respectfully declines to support such a measure that places an unfunded burden on dialysis facilities currently under significant strain with other data collection mandates while struggling to maintain adequate staffing. Once again, we find that those facilities most at risk are those caring for the most vulnerable of patients.

11. RFI on the Development of a New Payment Adjustment Based on Geographic Isolation: The Forum acknowledges CMS' comments "*Our preliminary analysis found that, in general, low-volume facilities that are rural, isolated, or located in low demand areas did not have higher costs than low-volume ESRD facilities overall.*". We also appreciate CMS' description of Local Dialysis Need (LDN) methodology, and the possibility of using this in conjunction with a modified LVPA. However, the Forum is concerned about the potential negative impact such a change might have on the access to dialysis services for vulnerable dialysis patients who reside in rural areas. Even if many of these facilities do not have higher cost than low-volume ESRD facilities overall, as described in the proposed rule, with the possible changes in modified LVPA, many of these facilities might experience a significant decrease in reimbursement. Furthermore, even if the cost of staffing in these facilities is similar to non-rural low volume ESRD facilities, it is still very difficult to staff these facilities if staff must travel further to get to work, and if staff need to travel further for training.

ESRD Forum Recommendations:

- The Forum would caution CMS against eliminating the rural adjustment and replacing it with the LDN methodology. We are concerned this will likely lead to closure of more rural dialysis facilities, or closure of shifts leading to worse health equity for the patients residing in these rural areas.
- The Forum recommends maintaining the rural adjustment and implementing the modified LVPA according to our comments above under #6.

12. Measures for PY2026: The ESRD Forum acknowledges the proposal for several changes in the measures for PY 2026 in this year's Proposed Rule to include the removal of the Ultrafiltration Rate Reporting measure and the Standardized Fistula Rate Clinical measure, the addition of the Facility Commitment to Health Equity Reporting measure, the conversion of the Clinical Depression Screening Reporting measure to a Clinical measure and the modification of the COVID-19 Vaccination Coverage Among HCP Reporting measure.

As we have previously noted, we gratefully acknowledge the ongoing commitment to maintain a meaningful Quality Payment Program for ESRD and have previously commented that the ESRD QIP is in the vanguard of the CMS initiatives for this endeavor to build value-based care in our healthcare system.

We wish to emphasize that reduction in the regulatory burden and the unique burden of maintaining multiple different reporting requirements each intended to ensure the same quality of care and incentivize excellence, will enhance the ability of all providers to work with the ESRD networks to fulfill their work on behalf of CMS and of the patients, to further enhance quality. Additionally, we wish to emphasize that this central task of the ESRD networks is critically dependent on reliable, accurate, and timely data. Optimizing the parsimonious collection of data to serve multiple purposes will enable achievement of the highest fidelity of the data and allow for timely interventions. We have learned from our experience with dealing with the COVID-19 pandemic, the importance of data to meet both acute and continuing challenges to the safe, effective, and unbiased care of ESRD patients. Such data is also key to identifying disparities in the delivery of care and sources of such disparity and informing prospective measures to correct these disparities and their impact on patient outcomes. Good data is central to an honest effort to achieve the goals of the AAKH initiative on health equity.

ESRD Forum Recommendations:

- We urge CMS to be cognizant of the unfunded regulatory burden on dialysis facilities to track and monitor these many measures, especially independent and hospital-based facilities because they do not often have data managers, or the individuals working for large dialysis organizations that can assist with these functions. The burden for compliance often results in taking dialysis staff away from critical direct patient care activities to perform this extra work. We recommend aligning measures in the QIP with those in DFR, DFC, Core Survey, Network QIAs and the Advancing American Kidney Health initiative to the extent possible. Although the data sources for most of these programs are the same, the burden on facility staff to enter this data into EQRS, and to track all of these measures is quite significant.

Furthermore, our comments with regards to specific proposed changes are as follows:

a. Removal of the Ultrafiltration Rate (UFR) Reporting Measure: This measure was adopted in the CY 2017 ESRD PPS Final Rule and was intended to guard against risks associated with high rates of ultrafiltration to achieve a desired target weight through fluid removal. We note the data included by

CMS in this year's Proposed Rule and their conclusion that this measure may not indicate the quality of a given session of hemodialysis and may influence decision making regarding a given treatment. The proposal is to remove this measure under measure removal factor 2 which states that performance or improvement does not result in better or the intended outcomes.

ESRD Forum Recommendations:

- The Forum acknowledges that equipoise is required when considering the balance between an association of high ultrafiltration rates and myocardial ischemia versus the risks of inadequate volume removal in those patients with low body mass. The Forum ultimately agrees with CMS' assessment that the measurement of UFR may not indicate the quality of a given hemodialysis session, can lead to unintended consequences to the patient, and should therefore be removed as a reporting measure. The Forum supports a more individualized approach to such clinical decision-making when it comes to volume removal on hemodialysis.

b. Removal of the Standardized Fistula Ratio (SFR) Clinical Measure: This measure was adopted in the CY 2018 ESRD PPS Final Rule. The Forum has advocated for revision of this measure and gratefully acknowledges the recognition by CMS in this year's Proposed Rule that some patients may exhaust their options for an AVF and an AVG may be preferable. It is of note, that this change was incorporated into the determination of an Optimal Start in the voluntary Kidney Care Choices models as one of the quality measures. The Forum has championed the KDOQI's 2019 guidance for a patient-centered approach to dialysis access. The proposal in this year's Proposed Rule is to remove this measure under measure removal factor 3 as this no longer aligns with current clinical guidelines and practice. The proposal further assigns the total weight of the previous Vascular Access Type Measure of 12% of the TPS to the Long-Term Catheter (LTC) Clinical measure.

We do agree that reduction in catheter use in hemodialysis patients overall is beneficial to most dialysis patients, and that Nephrologists play an important role in helping to educate patients and refer patients for appropriate vascular access. We acknowledge the exclusions of patients on Peritoneal Dialysis, patients under hospice care, patients with metastatic cancer, patients with end stage liver disease, and patients with coma or anoxic brain injury in the past 12 months.

Both the Kidney Patient Advisory Council (KPAC) and Medical Advisory Council (MAC) of the National Forum of ESRD Networks expressed concern that patient choice is not incorporated into this measure, and in keeping with the Meaningful Measures Initiative concept of patient-centered measures that are meaningful to patients, we believe that patient choice can and should be incorporated into this measure. We believe that the life goals of patients need to be considered when considering which type of vascular access to pursue. At a certain age or time in a patient's life, she/he just may not wish to go through the process of evaluation or await the maturation of an arteriovenous (AV) fistula (AVF) and/or associated multiple revisions in some cases, or for valid clinical reasons may not wish to pursue an AV access including AVF or AV graft (AVG). Furthermore, patients who have been on dialysis for many years and have had many vascular access surgeries may be suffering and choose not to pursue any more vascular surgery. We healthcare providers and payers all should respect our patients'/beneficiaries' life goals and choices.

Also, when considering patient-centered care that safeguards the public, we believe that patients that have exhausted all possible sites for potential AVF or AVG placement be excluded from these measures. In addition, we believe that patients that have suffered significant complications from AVF or AVG placement in the past, including steal syndrome affecting the partial or complete use of a limb, should be excluded from this measure. In many of these cases, further attempts of AVF or AVG placement may

jeopardize the health of our patients, and we don't believe the CMS should incentivize facilities to pursue further potentially harmful interventions for these patients. Keeping our patients safe is one of our primary goals, and we also feel that avoiding unnecessary or potentially dangerous vascular access surgeries in some patients is best for certain beneficiaries and should be considered in the measure. For example, in patients with severe cardiovascular disease, in whom the risk of undergoing AV access surgery exceeds the possible benefit, patients should be excluded from this measure. In addition, there are patients in whom the vascular surgeon has determined there are no viable vessels for AV access. In these patients, attempting to place AV access may lead to unnecessary and preventable harm to beneficiaries. There are also many patients with medical or psychiatric contraindications to having AV access used on dialysis, such as some patients with schizophrenia or other psychiatric disorders in which use of an AV access on dialysis could potentially be dangerous. In these patients, a catheter may be the safest option.

In general, we believe that well informed patient choice is critical when considering placement of AV accesses. The appropriate access needs to be individualized for each patient based on both patient choice, and the safest option. The recently released KDOQI guidelines also focus on choosing the most appropriate vascular access for each patient.

ESRD Forum Recommendations:

- The Forum supports CMS' proposal to remove the Standardized Fistula Ratio (SFR) measure as stated.
- In addition, the Forum would recommend excluding patients from the denominator that have exhausted most to all potential sites for AVF or AVG placement, or in whom there are no viable vessels for AVF or AVG placement from these measures. We believe that facilities can report such patients in EQRS (formerly known as CROWNWeb) if a checkbox to indicate such patients was added.
- We recommend excluding patients from the denominator that have suffered severe steal syndrome affecting the partial or complete use of a limb. We also recommend excluding patients with conditions such as severe congestive heart failure, severe psychiatric illness, or other conditions in which the risk of surgery to place AV access, or use of AV access on dialysis is deemed to be unacceptable by their Physician. We believe that facilities can report such patients in EQRS if a checkbox to indicate such patients is added.
- We recommend excluding patients from the denominator that refuse consideration of AVF or AVG placement or use, despite >2 attempts spanning a 3-month period at education on the risks of catheters and benefits of AVF or AVG by their Nephrologist and RN. Educational attempts should be documented by having the patients sign forms indicating that they have been informed and decline that option after repeated education has been completed. The patient's declination should be indicated by documentation in EQRS. We believe that facilities can report such patients in EQRS if a checkbox to indicate patient refusal was added.
- For such patients that would be excluded from the denominator due to the patient's informed decision not to have an AV access, we also recommend requiring facilities to continue attempts at education on the risks of catheters and benefits of AVF or AVG by their Nephrologist and RN at least annually. This ongoing education attempt could be indicated by an additional checkbox in EQRS.
- We believe including the above exclusions would help achieve the goal of making these measures more patient-centered and meaningful and would help to safeguard the health of ESRD patients.
- Our recommendations align with the updated KDOQI Vascular Access Guidelines, which emphasize that a patient's access needs stem from the creation of an individualized ESKD life-

plan. Rather than a “fistula-first, catheter-last” approach, the guideline reflects that the “right” vascular access is different for every patient.

c. Addition of the Facility Commitment to Health Equity Reporting Measure: The ESRD Forum provided comments in the CY 2022 ESRD PPS Proposed Rule concerning the RFI on the CMS framework for Health Equity. This year’s proposed rule states that the “...*commitment of dialysis facility leadership to health equity would result in a reduction of health disparities in the ESRD population.*” This is the basis for the proposal to adopt an attestation-based structural reporting measure across five domains that is identical to the Hospital IQR program. As we understand the proposal, for a facility to attest “yes” to a domain, the facility must engage in all activities included in the domain. 2 points would be given for attesting “yes” to a given domain with a maximum of 10 points since there are five domains. Data will be required to be submitted annually using EQRS by the end of the December data reporting month. This measure would have an individual weight of 2% equivalent to the other four measures remaining in the Reporting domain for PY 2026.

ESRD Forum Recommendations:

- The Forum supports the premise of engaging in any and all efforts to help reduce health disparities for our dialysis patients, but again must raise concerns regarding the added burdens being placed on dialysis facilities and staff in addition to the relative short amount of time allotted to begin such reporting. We note that this new reporting requirement is complex and may require detailed interviews with individual patients and/or identifying data that may not be part of the routine electronic EMR on these patients. This requirement would introduce an additional opportunity for substantial error in the collection and reporting of the data required to complete this measure. We believe that, in order to ensure accurate data collection, substantial training and additional staff support will be required. The risk of error in data reporting is accentuated given the current environment in which there is a high turnover of dialysis facility social workers, the individuals who are best positioned to complete this task.
- In addition, the Forum raises concerns regarding how the placing responsibility on dialysis leadership and their staff to document the numerous social inequities of their patients will result in a reduction of these inequities unless that data goes into more patient-centered programs (e.g., state and federal level programs to assist patients with safe housing, utilities, nutritional assistance, and transportation). In the current climate of dialysis staffing shortages and closing clinics, we worry that such reporting will ultimately take away from providing the best dialysis-directed patient care possible.

d. Conversion of the Clinical Depression Screening and Follow-Up Reporting Measure to a Clinical Measure: This measure was originally adopted in the CY 2015 ESRD PPS Final Rule to begin in PY 2018. The proposal in this year’s proposed rule is to convert this from a reporting measure to a clinical measure with an overall weight of 6% of the TPS as part of the Care Coordination domain. Facilities are currently required to report one of six conditions for each eligible patient and in the current proposal, credit would be awarded for the following four conditions: screen positive with follow-up documented, screen positive with no follow-up documented (patient ineligible), screen negative with follow-up not required or screen not documented (patient ineligible). No credit would be given for the following two responses: screen positive with no follow-up documented (no reason provided) or screen not documented (no reason provided).

ESRD Forum Recommendations:

- The Forum commends the CMS effort to add weight to important metric by elevating the clinical depression screening to a clinical measure. Several members of our own KPAC have been

involved in recent research indicating the need to better identify and treat this often-overlooked condition (Clin J Am Soc Nephrol. 2023 Jun 1;18(6):689-690. PMID: 37071607).

e. Modification of the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP)

Reporting Measure: This measure was adopted in last year’s CY 2023 ESRD PPS Final Rule for PY 2025. CMS is now proposing to continue this measure, however, to replace the term “complete vaccination course” with the term “up to date” in the vaccine definition. The justification for continuing to use the updated measure is provided in this year’s proposed rule with the statement that the “...*PHE expired on May 11, 2023; however, HHS has stated that the public health response to COVID–19 remains a public health priority with a whole of government approach to combatting the virus, including through vaccination efforts.*” The current proposal would update the numerator to specify the time frames within which a HCP (defined as employees, Licensed Independent Practitioners, students, volunteers or other contract personnel) is considered up to date with recommended COVID-19 vaccines including booster doses. The denominator remains unchanged as do the previously specified reporting requirements.

ESRD Forum Recommendations:

- The Forum has concerns regarding how enforceable staff vaccination will be when it is no longer mandated. Many facilities may suffer from substandard measurement scores despite the fact that enforcing such vaccination is out of their control.

13. Measures for PY2027: The ESRD Forum acknowledges the proposal for the inclusion of two new measures under the reporting domain to include the Social Drivers of Health (SDOH) Reporting measure and the SDOH Screen Positive Rate Reporting measure. Our comments concerning these two proposals are as follows:

a. Adoption of the Screening for Social Drivers of Health (SDOH) Reporting measure: This proposed measure was included in the RFI in last year’s CY 2023 ESRD PPS Proposed Rule and has been adopted in the FY 2023 IPPS/LTCH Final Rule along with being incorporated into the SNPs and MIPS program. CMS states that inclusion of this measure in the ESRD QIP would “...*enable facilities to identify patients with HRSNs, who are known to experience the greatest risk of poor health outcomes...and increased health care utilization...*”. Facilities will be permitted to choose a screening tool to assess the percentage of patients ≥ 18 years old who were screened for five Health-Related Social Needs (HRSNs) to include: Food Insecurity, Housing Instability, Transportation Needs, Utility Difficulties and Interpersonal Safety. CMS recommends consideration for using the American Health Communities (AHC) HRSN Screening Tool. Exclusions will include patients who opt-out or are unable to complete the screening. There will be a requirement for annual reporting of this information and the measure would have a weight of 1.43% equivalent to the other six measures in the Reporting domain for PY 2027.

ESRD Forum Recommendations:

- In principle, the Forum wholeheartedly supports all efforts to better understand and qualify the Social Drivers of Health in our dialysis population, but again, must offer pause when it comes to more unfunded facility burden to collect such important data. The Forum therefore recommends either added training and funding to support such data collection efforts in dialysis clinics, or a commitment to withhold such data collection until a time when this support is available to ensure accurate and useful information to guide such health equity efforts.

b. Adoption of the Screen Positive Rate for Social Drivers of Health (SDOH) Reporting measure:

Identical to the Screening for SDOH Reporting measure, this proposed measure was included in the RFI in last year's CY 2023 ESRD PPS Proposed Rule and has been adopted in the FY 2023 IPPS/LTCH Final Rule along with being incorporated into the SNPs and MIPS program. Exclusions would be identical to those for the Screening for SDOH Reporting measure. The numerator would include the number of eligible patients that a facility reports screening results for all five HRSNs during the performance period with the denominator being the total number of eligible patients screened for all five HRSNs during the performance period. There will be a requirement for annual reporting of this information and the measure would have a weight of 1.43% equivalent to the other six measures in the Reporting domain for PY 2027.

ESRD Forum Recommendations:

- The Forum respectfully offers similar concerns as to those conveyed regarding the SDOH reporting measure and believes that such important data collection efforts should have adequate support for dialysis clinics and staff prior to implementation.

14. End-Stage Renal Disease Treatment Choices Model (ETC) Proposed Changes:

a. Clarify the Ability of the CMS Administrator to Review Targeted Review Determinations

Current: An ETC participant may request a targeted review of the MPS calculation and CMS has 90 days to review this request

Proposed: An ETC participant may escalate the targeted review determination for final administrative review by the CMS administrator to ensure accountability. The CMS administrator may within 45 days of the request:

- Decline to review the targeted review request determination made by CMS
- Render a final decision based on the review
- Take no action

ESRD Forum Recommendations:

- The Forum supports CMS' ETC proposed changes clarifying the ability of the CMS administrator to review targeted review determinations and would support all efforts that provide the timely provision of information (or clarification) to the ETC participant for the purposes of creating a transparent and informative value-based payment model of ESRD care.