NRAA National Renal Administrators Association

September 10, 2018

Administrator Verma
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, DC 20201

RE: CMS-1691-P

Dear Administrator Verma:

The National Renal Administrators Association (NRAA) is a voluntary organization representing dialysis providers throughout the United States. Our membership primarily includes small and independent for-profit and not-for-profit providers serving patients in urban, rural, and suburban areas in both free-standing and hospital-based facilities. We strongly support efforts by the Centers for Medicare and Medicaid Services (CMS) to improve patient quality of care and health outcomes for Medicare beneficiaries with Chronic Kidney Disease (CKD) of all stages. We appreciate the ongoing recognition by CMS of the unique challenges posed to small and medium facilities providing high quality care to these vulnerable pediatric and adult patient populations.

The NRAA welcomes the opportunity to comment on "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, 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" (CMS-1691-P). Our comments address:

I. the Calendar Year (CY) 2019 ESRD Prospective Payment System (PPS);
II. the CY 2019 Acute Kidney Injury (AKI) benefit; and
III. Payment Years (PYs) 2019, 2022, and 2024 of the ESRD Quality Incentive Program (QIP); and
IV. the Request for Information (RFI) on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers.

Our comments reflect our continued desire to effectively partner with CMS to improve patient quality of care and health outcomes for Medicare adult and pediatric beneficiaries with CKD Stage 5 and AKI.

# I. CY 2019 ESRD PPS

### *1. Reduced Provider Burden in Obtaining Comorbidity Payment Adjustments*

**Recommendation: NRAA strongly appreciates the agency's recognition of the provider burden in collecting documentation necessary to obtain comorbidity adjustments in the ESRD PPS and thus welcomes the proposal to eliminate dialysis facility collection of diagnostic testing results to receive**

**for comorbidity adjustments for eligible patients. We further suggest that CMS supplement ICD codes with claims data for determining eligibility for comorbidity adjustments to better ensure more accurate payment to providers for patient comorbidities.**

In the proposed rule, CMS describes concerns raised by stakeholders over the documentation burden associated with collecting the diagnostic tests necessary to obtain comorbidity adjustments in the ESRD PPS. Rather than collect results from diagnostic tests, CMS proposes to use guidelines from the Official ICD Guidelines for Coding and Reporting to identify comorbidities present and eligible for payment adjustment in the ESRD PPS.

NRAA strongly welcomes and applauds this proposal and very much appreciates the agency responding to concerns raised by stakeholders, including the NRAA and the Medicare Payment Advisory Commission (MedPAC), among others, on the burden experienced by patients and providers in collecting diagnostic testing data. We look forward to this meaningful change in the payment system and very much thank you for addressing the concerns we and others have raised.

Furthermore, we request that CMS use claims data in addition to the ICD Guidelines for Coding and Reporting to identify comorbidities present in patients that are eligible for payment adjustments. The supplementing of ICD coding information with claims data will ensure more accurate payment to providers, as well as further ease administrative burden. As part of this effort, we would welcome the opportunity to work with CMS to help educate dialysis providers on how to code patient comorbidities on their claims. In addition to resulting in more accurate provider payment, improved comorbidity information on claims data will better inform future policymaking on how to better address patient comorbidities in the ESRD PPS.

### *2. Ensuring Comorbid Payment Adjustments Align with Particularly High-Cost Patients*

**<u>Recommendation</u>: While we appreciate the proposed burden reduction from use of ICD coding rather than diagnostic tests in securing ESRD PPS comorbidity adjustments, NRAA continues to urge CMS to eliminate comorbidity adjustments from the payment system until the agency develops appropriate adjusters that accurately capture variance in costs of care for particularly high-cost, high-acuity patients.**

The NRAA and CMS share a mutual goal of ensuring that the ESRD PPS is accurate and sufficient to provide high-quality care to the vulnerable pediatric and adult ESRD patient populations. These payment tenets are especially important for small and independent facilities where even slight fluctuations in payment can have a large financial impact, in some cases determining whether a facility remains open or closes.

We furthermore agree with CMS that the cost of dialysis treatment varies depending on the volume of services provided at the facility, its location and the adult and pediatric patients it serves and thus appreciate appropriate adjustments in the payment system that account for these differences in cost of care. However, the existing comorbidity adjustments in the ESRD PPS do not correspond well with the significant variance in costs that facilities experience in treating patients with certain particularly complex and costly comorbidities and other acute illness or trauma events. **As a result, the current comorbidity adjustments inappropriately take away funding from the ESRD base rate that otherwise could support provision of high-quality care.**

For the 2016 ESRD PPS, CMS analyzed 2012 and 2013 claims data to make refinements to the comorbid adjusters, as required by the American Taxpayers Relief Act (ATRA) of 2012. As part of the refinement, the agency removed two of the six comorbidity adjusters (bacterial pneumonia and monoclonal gammopathy) from the payment system. NRAA supported and appreciates CMS' removal of these comorbid adjusters from the ESRD PPS in 2016**.**

NRAA agrees with MedPAC and others that CMS should remove the four remaining comorbid payment adjusters from the ESRD PPS as we remain concerned that the current comorbidity adjustments do not align with the particularly high-cost, high-complexity patients. The comorbidity adjustments also in certain cases can be burdensome to obtain even with the much welcomed and appreciated changes to the required documentation requirements for obtaining such adjustments, for example because specialists may need to add a level of coding specificity that is difficult to obtain in many cases . Misaligned payment adjusters can negatively impact a facility's ability to provide individualized high-quality care to pediatric and adult ESRD patients. This is very concerning, as it creates greater financial risk for dialysis facilities – particularly for small and independent facilities with limited resources – that are inappropriately bearing financially burdensome costs for very costly patients.

**Therefore, we urge CMS to follow the recommendation of MedPAC and others to eliminate the existing comorbidity adjustments in the ESRD PPS until appropriate comorbid adjusters that align with truly high-cost patients can be developed.** We would welcome the opportunity to work with the agency in this effort.[1] In place of the comorbidity payment adjusters, NRAA urges CMS to establish separate payment for home dialysis therapy to increase equity in access to this modality that generally offers an improved quality of life for those patients for whom it is medically appropriate (described in more detail below).

### *3. CY 2019 ESRD Base Rate*

**<u>Recommendation</u>: While NRAA appreciates the proposed increase to the ESRD PPS base rate for CY 2019, we wish to express concern that the proposed amount will not fully cover costs associated with providing high-quality care to patients – particularly by small and independent providers offering care oftentimes to patients in areas where access challenges may be present.**

CMS proposes a base rate of $235.82 for the CY 2019 ESRD PPS, which reflects a market basket increase of 1.5 percent and application of the wage index budget neutrality adjustment factor of 0.999833.

NRAA appreciates the proposed increase to the base rate for CY 2019. However, we want to underscore that the proposed payment increase will not sufficiently cover the annual growth in costs for dialysis facilities necessary to offer high-quality care to pediatric and adult ESRD patients. This slight increase in payment is especially concerning for small and independent providers that, in many cases, give life-sustaining dialysis treatment to patients in rural and underserved areas. In some instances, just small changes in reimbursement can have significant impact on whether a facility remains open. Therefore, appropriate increases in overall reimbursement so that dialysis facilities can continue to provide this highly vulnerable patient population with the life-sustaining treatment required.

[1] MedPAC July 29, 2016 comment letter: http://www.medpac.gov/documents/comment-letters/medpac-comment-on-cmss-proposed-rule-on-the-esrd-prospective-payment-system-and-the-dmepos-competitive-bidding-program.pdf?sfvrsn=0

### *3. Increase to the Wage Index Floor*

**Recommendation: NRAA supports the proposal to increase the wage index floor for CY 2019 to 0.5000.**

CMS proposes to increase the wage index from 0.400 in 2018 to 0.500 in 2019. The NRAA supports and appreciates this proposal, as it will assist dialysis clinics in providing access to high-quality care particularly in rural areas where access challenges may be present.

### *4. Transitional Drug Add-On Payment Adjustment Revisions*

**Recommendation: NRAA welcomes and appreciates CMS's proposal to expand the Transitional Drug Add-on Payment Adjustment (TDAPA) for new renal drugs and biologicals, which should help incentivize the development of innovative therapies for the treatment of ESRD. We agree with members of the renal community that the expanded TDAPA should not be eligible for generic drugs and biosimilars. We request to reimburse for the expanded TDAPA at the rate of Average Sales Price (ASP) plus 6 percent (rather than ASP plus 0 percent as proposed) and to extend the expanded TDAPA beyond two years. NRAA further recommends modifications to the existing TDAPA process to address the operational challenges that currently exist.**

CMS proposes to expand the current TDAPA to include all new renal drugs and biologicals approved on or after January 1, 2019 except for oral-only drugs, which would become eligible for the proposed TDADA expansion on January 1, 2025 when they become part of the ESRD PPS bundle. All products separately paid for under the expanded TDAPA would receive reimbursement of ASP plus zero percent for two years. After that period, products that fall into one of the existing ESRD PPS "functional categories" would be eligible for outlier payments; CMS would modify or a create a new "functional category" for products that do not fall into an existing category.

**The NRAA strongly agrees with CMS that the proposed expansion of TDAPA will incentivize the development of innovative therapies to treat ESRD patients – a particularly vulnerable patient population that could meaningfully benefit from new treatment options – and thus we very much appreciate the proposed expansion of TDAPA to all new renal drugs and biologics approved on or after January 1, 2019.** We agree with others in the renal community that the expanded TDAPA should not be eligible for generic drugs and biosimilars. We further appreciate proposed modifications to the process that would require a manufacturers to have submitted a HCPCS application in accordance with the official HCPCS level II coding process, but not have to have received such code in order for a product to be eligible to receive the TDAPA. These proposals should incentivize manufacturers to engage in the development of innovative therapies for a patient population that could meaningfully benefit from new treatment options.

**The NRAA is very concerned, however, that the proposed payment of ASP plus 0 percent for drugs and biologics eligible for the expanded TDAPA will not adequately cover product acquisition costs for many small and independent providers with limited resources.** Inadequate reimbursement potentially could result in patients receiving treatment from small and independent clinics being unable to have access to innovative treatments in the same manner as those being cared for in large dialysis organizations (LDOs); such an outcome could create inappropriate and concerning equitable access issues for patients. Therefore, NRAA urges CMS to adopt the current TDAPA reimbursement amount of ASP plus 6 percent for all drugs and biologics eligible to receive the expanded payment adjustment.

**Further, NRAA asks that CMS extend the expanded TDAPA beyond the two-year period proposed in the proposed rule.** Facilities face significant administrative challenges in actually obtaining the TDAPA, which can slow the rate of uptake of new products. For example, physicians, nurses and administrative staff must receive education and training from the drug manufacturer so that it can be safely and effectively administered. Eligible patients must receive education on the medication prior to prescription and administration. The facility staff must review all patient insurance plans to initiate the authorization process to start the new drug. And, facilities must negotiate with vendors for the supply and pricing of the item so it can be purchased and administered to patients. Moreover, the particular acuity and severity of the ESRD patient population generally results in facilities more gradually increasing use of novel therapies in these patients over time. NRAA members report, for example, that in many cases a new drug may take at least 6 months of longer before facilities feel comfortable effectively and appropriately using the new therapy. Given these issues, NRAA recommends that CMS extend the period for TDAPA eligibility beyond the proposed two years to be consistent with the current TDAPA period.

### *5. Expansion of Products Eligible for Outlier Payments*

**<u>Recommendation</u>: The NRAA supports the proposed expansion of the outlier policy to include drugs, biologicals, and supplies that currently fall into the ESRD PPS composite rate.**

CMS solicits comment on whether to expand the current ESRD PPS outlier policy to include drugs and supplies in the composite rate. An expansion of items eligible for outlier payments would align with the proposed expansion of TDAPA for all new drugs and biologics payable under the ESRD PPS.

The NRAA supports expanding the types of items and services eligible for outlier payments to include those drugs, biologicals, and supplies that currently are considered part of the ESRD PPS composite rate. We strongly agree with CMS that an expansion of the outlier policy would promote and incentivize the development of innovative new therapies and devices to treat the highly vulnerable ESRD adult and pediatric patient populations and therefore urge the agency to propose such an expansion in future rulemaking.

Furthermore, we suggest that CMS include a line in the claim for identification of supplies for outlier payment. Having this information on the claim both ease administrative burden and improve payment accuracy.

### *6. Improving Transplant Evaluation and Referral Services*

**<u>Recommendation</u>: NRAA agrees that the rates of transplantation have remained stagnant due to a variety of factors and supports improving rates of transplant evaluation and referral. We suggest the following to increase rates of transplant evaluation and referral:**

1. **Revise the 2007 Conditions of Participation (CoPs) for Transplant Programs risk models and definition of "graft failure."**
2. **Reimburse beneficiaries for travel expenses to transplant centers, particularly patients in rural areas with transportation barriers and for transplant centers that conduct remote clinic evaluations.**
3. **Lower the patient age to 70 from 75 in the transplant assessment exclusionary criteria.**
4. **Add cancer as an exclusionary criterion in transplant assessment.**

5. **Provide more patient cost-sharing assistance to pay for the significant costs associated with transplant and post-transplant services.**
6. **Continue patient access to immunosuppressive drugs longer than the current 3-year period post-transplant.**
7. **Strengthen CfC survey to emphasize the importance of transplant assessment and referral.**
8. **Ensure that surveyors analyze every patient medical record to determine that facilities routinely document discussions with the patient on transplant assessment and referral as part of the annual plan of care.**
9. **Require Medicare Advantage organizations (MAOs) to expand the number of transplant centers in-network.**

CMS solicits comment on ways to ensure that facilities are meeting Conditions of Coverage (CfCs) requirements with respect to transplant evaluation and referral and asks whether additional requirements should be considered.

As a threshold matter, the NRAA strongly supports efforts to improve transplant evaluation and referral services for patients for whom it is medically appropriate. We would like to work with CMS to revise and remove the current barriers that exist in referring medically appropriate patients for transplant, including:

1. **Revise the 2007 CoPs for Transplant Programs risk models and definition of "graft failure"**: The 2007 CoPs for Transplant Programs require a transplant program to meet or exceed the expected graft failure rate based on the Scientific Registry for Transplant Recipients (SRTR) risk model. If the program does not meet the risk adjusted expected graft failure rate, the program is at risk for de-certification. As a result of this, all referrals for transplant that carry a relatively high risk for compliance, mental health issues, and/or medical/surgical risks may be denied approval for transplant. As the number of observed to expected rates increase, the more risk adverse the program becomes to accepting transplant patients. This is especially concerning for small transplant programs that simply do not have the volume to spread the risk over a significant number of patients in the same manner as larger programs.

   Additionally, the current definition of "graft failure" is flawed. Today's definition of graft failure is patient death or loss of the graft within one year of transplant surgery. However, some of the deaths attributed to graft failure are not related to the kidney transplant or kidney failure. For example, a patient may expire as a result of an accident, myocardial infarction, or fall and the kidney is still fully functional. This death is defined as a graft failure in the first year and is attributed to their risk score. Given these concerns, NRAA recommends that CMS re-evaluate the definition of graft failure and the risk modeling for transplant programs in the 2007 CoPs for Transplant Programs so more patients are approved for the transplant surgery.

2. **Reduce patient travel distances for transplant assessment**: For many rural programs, significant travel barriers can exist that deter patients from receiving an evaluation for transplant. For example, one NRAA member reports the closest transplant assessment center is roughly a 3.5 hour drive from the dialysis facility. Many rural patients simply do not have access to transportation that would allow them to travel such distances. To remedy this access barrier, NRAA recommends that CMS: (1) establish separate reimbursement to pay for patient travel

costs for transplant evaluation, particularly for patients in rural areas; and (2) require transplant centers to conduct remote clinic evaluations.

3. **Lower the patient age exclusion criterion to 70**: Patients aged 75 years and older currently are excluded from transplant evaluation and referral. We believe that the severity of ESRD make it clinically challenging for many patients past the age of 70 to successfully receive a kidney transplant. Moreover, unfortunately, many patients do not live to age 70 due disease severity and complexity. Thus, NRAA recommends that CMS lower the patient exclusion criterion to 70 years of age in the CfCs for transplant evaluation and referral services.

4. **Add cancer as an exclusionary criterion for transplant assessment:** ESRD patients with an active diagnosis of cancer are particularly sick and unlikely to able to receive a kidney transplant. As such, NRAA recommends CMS exclude beneficiaries with an active cancer diagnosis from the transplant list for up to five years post cancer diagnosis.

5. **Provide patient cost-sharing assistance with transplant costs**: Patients face significant out-of-pocket costs when electing to receive a kidney transplant and all medically necessary treatment post-transplant. As such, the vast majority of patients that pursue a kidney transplant are those that have full insurance coverage from Medicare and a secondary payer. Thus, NRAA recommends that CMS provide additional cost-sharing assistance to patients without full insurance coverage and establish new CfC exclusionary criteria to exclude those patients without full insurance coverage from transplant evaluation and referral services CfCs.

6. **Extend patient access and Medicare coverage of immunosuppressive therapies beyond three years:** Medicare provides coverage for life-sustaining immunosuppressive therapies 3 years post-transplant. For many beneficiaries on limited incomes without secondary insurance, the cost of paying for immunosuppressive therapies after 3 years is prohibitively high, effectively deterring them from pursuing transplant. Therefore, NRAA recommends that Medicare coverage for immunosuppressive drugs post-transplant continue until the patient no longer requires access to them.

7. **Increase focus in the CfC survey on transplant evaluation and referral:** The current CfC survey focuses significantly on ensuring that facilities adhere to patient safety and environmental requirements. NRAA firmly agrees these issues are critical for high-quality patient care. However, we believe CMS could strengthen the survey language to place greater emphasis on the importance of the facility's work in ensuring that patients receive transplant evaluation and referral services when medically appropriate.

8. **Ensure surveyors evaluate all medical record documentation concerning transplant evaluation and referral discussion**: Surveyors currently assess whether facilities discuss with patients the option of transplant evaluation and referral. However, while this work occurs in current surveys, surveyors do not necessarily check every medical record to find documentation demonstrating CfC transplant evaluation and referral assessments. As such, surveyors should enhance scrutiny of the medical record for every patient in a facility to determine definitively

that the dialysis provider discusses the option of transplant evaluation and assessment routinely as part of the annual plan of care.

9. **Require MAOs to expand the number of in-network transplant centers:** Medicare Advantage organizations generally require patients to go to certain in-network transplant centers. In many cases particularly in rural areas, however, the in-network transplant centers are often significant distances from a patient's home. Hence, NRAA recommends that CMS require MAOs to expand the number of in-network transplant centers so that MA enrollees maintain adequate access to transplant evaluation and referral services.

## *7. Improving Access to Home Dialysis*

**<u>Recommendation</u>: NRAA strongly supports efforts to increase access to home dialysis for patients for whom it is medically appropriate and recommends that CMS consider the following to help achieve this goal:**

1. **Require facilities that do not offer home dialysis to provide patients with information on facilities within a reasonable distance of their homes that offer home dialysis.**
2. **Establish separate reimbursement for home hemodialysis to reflect the increasing costs to providers of offering home therapy due to higher costs of equipment and required maintenance; increased training costs not reflected in the ESRD PPS; and innovative, costly new patient-friendly technologies.**
3. **Remove barriers in the survey and certification process so that: (1) facilities do not have to restart the entire training process if they lose a patient prior to the surveyors being able to conduct the on-site visit; and (2) facilities can replace an on-site visit with remote training and demonstration of compliance with CoPs for in-center hemodialysis.**
4. **Prohibit MAOs from making modality-specific dialysis authorizations.**

CMS solicits comment on ways to ensure that dialysis clinics are meeting their obligation to inform beneficiaries of all treatment modalities, including home dialysis, and ensuring equal beneficiary access to information, assessment and preferences with respect to treatment modalities.

As a threshold matter, NRAA broadly supports expanding patient access to home dialysis when medically appropriate as this modality can improve patient functionality and quality of life. Thus, NRAA very much appreciates CMS considering way to make this treatment option more widely available to patients and recommends the following to increase patient access to home dialysis when medically appropriate:

1. **Require facilities not offering home dialysis to provide patients with information on facilities within a reasonable distance of their homes that offer the modality:** Certain dialysis clinics simply do not offer home hemodialysis as a treatment option for their patients. To ensure equitable access to all modalities, CMS should mandate that facilities that do not give home therapy as an option inform patients of all dialysis clinics within a reasonable distance of their homes that offer home therapy.

2. **Establish separate, higher reimbursement for home hemodialysis to reflect the increasing costs to providers of offering home therapy:** The costs to dialysis clinics of providing home

therapy have increased significantly in the past few years for reasons described below. As such, NRAA urges that CMS establish a separate payment to support providers in offering home therapy; increased home therapy costs in the ESRD PPS could be offset by eliminating comorbidity payment adjustments.

- **Growth in supply costs has exceeded reimbursement:** There are few choices in suppliers of home hemodialysis and peritoneal dialysis therapy. Minimal competition in supply has led to substantially higher equipment and required maintenance costs for providers offering home therapy – cost growth that has significantly exceeded Medicare reimbursement amounts.

- **Training costs are not adequately paid for in the ESRD PPS:** Currently, the ESRD PPS assumes providers spend approximately 2.66 hours training patients on home therapy and makes a separate training add-on payment to providers accordingly. This assumption significantly underestimates the time – and associated costs – that dialysis clinics allocate to training patients on home therapy. For example, a Technical Expert Panel (TEP) convened by Dobson DaVanzo on behalf of NRAA concluded that facilities spent between 7.5 and 8 hours training patients on home hemodialysis.

- **Innovative technologies are not adequately paid for in the ESRD PPS**: Innovative, patient-friendly technology has been developed in recent years that can advance home dialysis, but its significant cost that is not reflected in the ESRD PPS effectively prohibits dialysis providers from purchasing and making the technology available to patients.

3. **Remove barriers in the survey and certification process so that: (1) facilities do not have to restart the entire training process if they lose a patient prior to the surveyors being able to conduct the on-site visit; and (2) facilities can replace an on-site visit with remote training and demonstration of compliance with CoPs for in-center hemodialysis:** Under current survey and certification requirements, surveyors must make an on-site visit to watch dialysis clinics train a patient on home therapy before the clinic can offer home therapy treatment. In certain cases, unfortunately, the dialysis clinic loses the patient before the surveyor arrives on-site and the certification process ends and the entire survey process must restart with a new patient. Such an outcome is challenging for many facilities, but particularly challenging for facilities in rural areas and those with low patient volumes and thus makes it especially difficult for these unique types of facilities to offer home therapy to patients. Rather than mandating an on-site visit, NRAA urges that CMS allow for home therapy certification for facilities that meet two requirements: (1) they receive remote, online training for home therapy; and (2) they demonstrate compliance with all CoPs for in-center hemodialysis.

4. **Prohibit MAOs from making modality-specific dialysis authorizations:** Medicare Advantage organizations often make modality-specific dialysis authorizations, which can limit and discourage a beneficiary from using or switching to home hemodialysis. NRAA recommends that CMS require MAOs to make dialysis authorizations without regard to modality so patients can elect the modality that best meets their individual treatment needs. We further recommend that CMS require MAOs to authorize Medicare-certified facilities outside of the

plan's network as in-network in cases where the patient's travel distance to an in-network facilities exceeds 15 miles as traveling long distances to receive life-sustaining dialysis treatment can be highly burdensome for ESRD patients.

# II. Acute Kidney Injury

### *8. CY 2019 AKI Payment Rate*

**Recommendation: NRAA urges CMS to increase payments for AKI treatments consistent with data showing that average costs for an AKI treatment are nearly $50 higher than average costs for in-center hemodialysis patients.**

CMS proposes an AKI payment rate of $235.82 per treatment in 2019.

**An analysis of preliminary 2017 renal cost report data on reported AKI treatment costs performed by Prima Health Analytics (PHA) on behalf of NRAA found that the average reported cost per treatment for AKI patients was nearly $50 per treatment (about 19 percent) higher than the average cost per treatment for in-center maintenance hemodialysis dialysis patients.** In the analysis, 1,524 of a total of 5,255 freestanding facilities reported AKI treatments. The nearly $50 higher per treatment costs for AKI versus in-center maintenance dialysis were driven by the higher direct patient care staffing needs for AKI patients (4.0 staff hours per treatment) compared to maintenance dialysis (2.5 staff hours per treatment). Additionally, lab costs ($4.93 vs. $3.91) and administrative and general services costs ($80.06 vs. $65.48) were higher for AKI treatments than for in-center maintenance hemodialysis treatments.

**When the 2017 report AKI costs were applied to the proposed 2019 AKI payment rate, PHA found that 2019 payments would be between 11 percent and 56 percent below average facility costs. For NRAA member organizations, which include many small and independent facilities, the 2019 AKI payment rate would be 32 percent below 2017 costs on average.** Given that facility costs vastly exceed payment rates for AKI treatments on average, NRAA urges CMS to increase the AKI payment rate and make appropriate payment adjustments for case-mix, comorbidities, and others (described below) to more accurately account for the costs that facilities bear when treating AKI patients. More accurate and adequate reimbursement likely will result in more dialysis facilities being able to extend dialysis treatment access to AKI patients in a generally lower cost setting than the outpatient hospital setting where many AKI patients currently receive treatment.

### *9. Other Adjustments to AKI Payment Rate*

**Recommendation: NRAA urges CMS to apply the low-volume and pediatric payment adjustments as a minimum to the AKI payment rate.**

CMS proposes no payment adjustments to the AKI payment rate beyond the ESRD PPS geographic wage index for 2019.

While NRAA understands that CMS has just begun to collect claims data on AKI patients, we urge CMS to adopt certain adjustments to the AKI payment rate that do not necessarily require claims data to demonstrate their need in ensuring that facilities have sufficient resources necessary to provide high-quality care to AKI patients, including the:

- **Low-volume adjustment**: Facilities with low treatment volumes face similar cost challenges in providing dialysis to AKI and ESRD patients. The relatively high fixed costs in operating a dialysis clinic are more difficult to offset in facilities with low treatment volume. Therefore, NRAA urges CMS to apply a low-volume adjustment to AKI treatments for patients in low-volume facilities.

- **Pediatric adjustment**: Similar to pediatric patients with ESRD, pediatric patients with AKI experience costly treatment challenges that are unique and distinct from the adult AKI patient population. As such, NRAA urges that CMS adopt a pediatric adjustment to the AKI payment rate for facilities treating pediatric AKI patients.

### *10. Geographic Adjustment to the AKI Payment Rate*

**Recommendation: NRAA urges CMS to apply to a rural adjustment factor, in addition to the ESRD PPS geographic wage index, to the AKI payment rate to account for the additional treatment costs rural facilities experience.**

CMS proposes to adjust AKI payments by the ESRD wage index to account for geographic cost differences.

As CMS recognizes in the ESRD PPS, dialysis facilities in rural areas experience higher-than-average treatment costs and appropriately provides them with a rural payment adjustment reflecting the increased costs necessary to provide high-quality care. Rural facilities face all – and perhaps more – of the same challenges in the providing dialysis treatment to AKI patients as they do to ESRD patients. As such, NRAA urges CMS to apply a rural payment adjustment for treating AKI patients in rural dialysis facilities. Furthermore, we ask that CMS review the Core-Based Statistical Area (CBSA) methodology used for purposes of the rural adjustment, which prevents units that reside within a county that is rural from receiving the adjustment if they CBSA in which they reside is deemed urban.

### *11. Data Collection on AKI Dialysis Patient Recovery Support*

**Recommendation: NRAA recommends that CMS collect data on patients recovering from AKI treatment in both dialysis clinics and outpatient hospitals.**

NRAA believes it would be helpful to better understand the types of care offered to patients recovering from AKI treatment both in dialysis clinics and outpatient hospitals. Without appropriate, high-quality recovery care, AKI patients unfortunately can develop ESRD. Hence, data on care practices and patient outcomes would be useful for CMS and stakeholders in the development of quality performance metrics and determination of the most appropriate care settings for treating AKI patients. Thus, NRAA recommends that CMS begin collect data on AKI patient recovery in dialysis clinics and outpatient hospitals as soon as possible. We would welcome the opportunity to work with the agency to determine the most appropriate data elements for collection and best methods for such collection. For example, we recommend collection of CKD-related labs, including testing levels of phosphorous, calcium, creatinine, albumin, carbon dioxide, and hemoglobins in the patient. We further suggest that CMS collect information on the education provided to patients on how to prevent the onset of ESRD in these AKI patients who are at risk for developing the disease.

# III. ESRD Quality Incentive Program

### *12. Reducing Provider Burden and Better Informing Patients on Care through Implementation of Consistent Requirements across ESRD Quality Improvement Programs*

While the NRAA remains strongly committed to the agency's very important goal of achieving high quality care, we are concerned that certain components of ESRD quality programs are inconsistent, overly burdensome, and challenging to implement, especially for small and independent dialysis facilities. In particular, multiple initiatives assess dialysis facility quality performance, including the QIP, Dialysis Facility Compare (DFC) Star Ratings, and CMS survey and certification conditions of coverage requirements. While we appreciate efforts by CMS to incorporate measures that are meaningful and not redundant into provider quality assessment through the Meaningful Measures Initiative (MMI), we remained concerned that the multiple ESRD quality programs continue to include inconsistencies in reporting requirements and measure specifications that cause them to not necessarily align in all cases. **The lack of consistency is burdensome for providers and can lead to beneficiary confusion and anxiety in instances where a facility, for example, may receive a high QIP rating but a low number of stars in the DFC Star Ratings.**

**Therefore, NRAA urges CMS to align the DFC Five-Star Ratings with the QIP and ensure that CfC requirements align with requirements in these ESRD quality assessment programs.** NRAA strongly opposes the existing "bell curve" methodology used to assign star ratings in DFC Five-Star Ratings, which often results in incongruity between the facility's score in the QIP and the number of stars it receives. Instead, NRAA urges that the number of stars assigned to a facility reflects the facility's performance in the QIP. Benefits of the NRAA's recommended approach include:

- **Giving greater certainty to and reducing burden on providers in quality measurement and performance:** The inconsistency between the QIP and DFC Five-Star Ratings creates unnecessary burden on providers and does not offer as much certainty to facilities as they develop and implement policies to improve internal quality performance. Assigning stars based on a facility's performance in the QIP would establish consistency across assessment of ESRD quality of care. It also would align ESRD quality performance and assessment with other value-based programs in Medicare that use star ratings to inform the patients, families and caregivers of provider quality performance.

- **Presenting beneficiaries, their families, and their caregivers with clear and accurate information on facility quality performance:** Most importantly, aligning the QIP with DFC Five-Star Ratings would give beneficiaries a clearer and more accurate understanding of a facility's actual quality performance based on underlying data – unlike the "bell curve" methodology, which may confuse and concern beneficiaries because it can mistakenly suggest that the facility they use offers poor quality care even though the facility performed well in the QIP. Such an outcome can cause unnecessary concern and burden on patients, their families, and their caregivers and does not advance CMS's important goal of developing more consumer-friendly information about actual facility quality performance.

- **Encouraging facility performance improvement:** Assigning star ratings according to QIP results will encourage facilities to improve performance over time because the higher the performance they achieve, the greater number of stars they will receive in DFC Five-Star Ratings. This contrasts with the existing "bell curve" methodology, which perversely may continue to assign facilities a low number of stars due to the forced distribution, even though they have demonstrated improvement in quality performance in the QIP.

### *13. Revisions to the QIP Domains and Measure Weights for PY 2021*

**Recommendation: NRAA supports removal of the Reporting Measure Domain beginning with the PY 2021 QIP. We recommend that CMS revise the QIP methodology for PY 2021 to: (1) place greater emphasis on reducing use of catheters by imposing a higher weight on the Vascular Access Type Measures and Vascular Access Type Measure Topic in the Clinical Care Domain; and (2) remove the Standardized Transfusion Ratio (STrR) Measure from a facility's QIP total performance score unless the facility can validate that the third-party data submitted for the measure are accurate and that patients with certain comorbidities are excluded from the measure's assessment; and (3) modify the proposed redistribution of weights for a facility that is not able to report all measures so that the STrR Measure does not disproportionately impact the facility's total performance score (TPS).**

CMS proposes to revise the QIP measure domains and individual measure weights for the PY 2021 QIP to align them with the Meaningful Measures Initiative (MMI).

- **Support for removal of the Reporting Domain**: Under the proposed revisions to the QIP methodology, CMS would remove the Reporting Measure Domain to better align the QIP with the MMI beginning PY 2021. NRAA supports removal of the Reporting Measure Domain because it aligns with NRAA's broad goals of focusing on metrics that improve clinical outcomes and reducing complexity in the QIP.

- **Recommendation to increase the weighting of the Vascular Access Type Measures and Vascular Access Type Measure Topic:** CMS proposes that the two Vascular Access Type Measures (Hemodialysis Vascular Access: Standardized Fistula Rate and Hemodialysis Vascular Access: Long-term Catheter Rate) comprising the Vascular Access Type Measure Topic together would represent 6 percent of a facility's QIP Total Performance Score (TPS) for PY 2021. NRAA strongly believes the reducing catheter use is the single most important method to improve ESRD patient outcomes, as patients who use catheters have a 15-fold increased risk of catheter-related BSIs and an all-cause mortality rate ranging from 12 percent to 25 percent. Patients with fistula, by contrast, tend to have lower rates of hospitalization, better anemia management, and reduced rates of infection (see issue no. 14 below for more detail).[2] Therefore, we urge CMS to readjust the proposed weighting for the PY 2021 QIP to place significantly more emphasis and weight on the Vascular Access Type Measures and Measure Topic to incentivize facilities to promote fistula use.

[2] Landry et al. "Reducing Catheter-Related Infections in Hemodialysis Patients." *Clinical Journal of American Society of Nephrology*. 2014 July 7; 9(7); 1156 – 1159.

- **Recommendation to remove the STrR Measure from a facility's QIP TPS score unless the facility can validate that third party data submitted for the facility's performance on the measure are accurate and that patients with certain comorbidities are excluded from measure assessment:** CMS proposes that the STrR Measure would fall in the Clinical Care Measure Domain and have a weight of 22 percent of a facility's TPS beginning PY 2021. As described in more detail below (issue no. 15), NRAA has significant concerns with use of the STrR Measure in the QIP; in a meaningful number of cases, facilities are penalized in the QIP for patient transfusions even though many of those transfusions may be unrelated to anemia due to CKD but are recorded as such by hospitals and other third parties or are necessary because of a patient's comorbidities unrelated to ESRD, for example because the patient has sickle cell anemia.

  Under current program requirements, a facility is not able to independently validate third party data used in the STrR Measure to ensure that non-dialysis-related infusions are excluded from the facility's STrR score. The dialysis facility has no ability to correct the hospital or outpatient facility for incorrect coding on dialysis patient transfusions. And instead the burden falls on the dialysis facility to try to obtain the transfusion documentation from the hospital or outpatient center and then research the reasons for the facility receiving a poor score on the STrR measure. For example, many patients require transfusions for "unknown blood loss" and even after multiple GI appointments, colonoscopies, and other testing, the GI specialist still does not have a definitive diagnosis. In many instances, unfortunately, hospitals and other outpatient facilities simply default to anemia due to CKD as the reason for the transfusion if they know the patient has ESRD or AKI even though the patient has received a transfusion for reasons other than CKD-related anemia. Additionally, the exclusion criteria for the measure do not cover a significant number of patient comorbidities that require transfusions but are unrelated to dialysis treatment.

  When either of these issues arise, facilities perform poorly on the STrR Measure and often receive payment reductions in the QIP given the significant weight the program places on the measure. This is particularly problematic for small and independent facilities with limited resources where even slight fluctuations in payment can have an outsized impact on whether a facility remains open to care for patients. Therefore, to ensure that facilities are not inappropriately penalized in the QIP, NRAA urges CMS to exclude a facility's STrR Measure from its QIP TPS if the facility is not able to independently validate third party data submitted to assess a facility's performance on the measure or if certain patients with specific comorbidities are not excluded from the assessment.

- **Recommendation to reduce the weighting for the STrR Measure for facilities that do not report all QIP measures:** CMS proposes that the STrR Measure would fall in the Clinical Care Measure Domain and have a weight of 22 percent of a facility's TPS beginning PY 2021. NRAA is very concerned that certain transfusions inappropriately are counted toward a facility's performance on the STrR Measure because they are unrelated to dialysis treatment and beyond the facility's direct control of care (discussed in more detail in issue no. 15). Hence, we are particularly concerned that imposing such a high weight on the STrR Measure in the QIP could disproportionately negatively impact those facilities that do not perform well on the measure

due to events and patient comorbidities entirely outside of their control. The proposed weight of the STrR is especially problematic for those facilities that do not have enough data points to report on all measures included in the QIP, for example home dialysis clinics that do not report either metric in the Vascular Access Type Measure Topic. For these facilities, the weighting of the STrR Measure would intensify and have an even further disproportionately adverse impact on the facility's TPS and payments. The problem is particularly acute for small and independent facilities with limited resources. Thus, NRAA urges CMS to not redistribute the weights within the QIP even more toward the STrR Measure when a facility does not report on one or more measures in the QIP.

### *14. Increasing the Importance of Vascular Access Type Measures in the QIP*

**<u>Recommendation</u>: Because NRAA believes that reduction in use of catheters is the single most important means to improve patient health outcomes, we urge CMS to develop a single measure assessing rates of catheter use and place greater emphasis on that measure in the QIP.**

CMS proposes to include the two Vascular Access Type measures in the QIP – Hemodialysis Vascular Access: Standardized Fistula Rate and Hemodialysis Vascular Access: Long-term Catheter Rate – in the Vascular Access Measure Topic with an assigned weight of 6 percent in the QIP for the PY 2021 QIP and beyond.

**NRAA believes that reducing rates of catheter use is the most important and meaningful way to improve ESRD patient health outcomes.** Patients who use catheters have a 15-fold increased risk of catheter-related BSIs and an all-cause mortality rate ranging from 12 percent to 25 percent. Patients with fistula, by contrast, tend to have lower rates of hospitalization, better anemia management, and reduced rates of infection.[3]

**Rather than having two separate measures incorporated into a broader measure topic, NRAA believes it would be less burdensome and more informative for patients and providers if a single measure assessed catheter use and received a significantly higher weight in the QIP.** Such a change would align with CMS's Meaningful Measures Initiative by placing increased emphasis on measures that can drive meaningful improvements in care practices that lead to significant changes in patient health outcomes. NRAA would welcome the opportunity to work the agency on development of such a measure.

**When developing a single measure assessing catheter use, NRAA strongly recommends that CMS extend the reporting period from the current 90-day period to 150 days.** Certain patients have difficulty scheduling surgery for fistula access, particularly in rural areas whether are not many vascular surgeons. A longer time period would give facilities more time to schedule patients to receive fistulas.

**Additionally, NRAA recommends that CMS exclude from a future measure on catheter use those home patients who return to temporary in-center hemodialysis while their peritoneal cavity or exit site heals from infection.** We make this request because, in certain instances, a patient has a surgery or an infection that requires removal of the catheter for healing purposes. In-center dialysis facilities do not put in a fistula for the patients because they eventually will return to PD, but it may take a few

[3] Landry et al. "Reducing Catheter-Related Infections in Hemodialysis Patients." *Clinical Journal of American Society of Nephrology*. 2014 July 7; 9(7); 1156 – 1159.

months for full elimination of the infection, replacement of a new catheter, and adequate time for catheter healing.

### *15. Ensuring Facilities Are Not Inappropriately Penalized for Transfusions Unrelated to Dialysis in the STrR Measure*

**Recommendation: NRAA urges that CMS make modifications to the STrR Measure to collect data only on those transfusion events related to CKD Anemia or the dialysis treatment and not inappropriately penalize facilities in the QIP for transfusion events unrelated to dialysis care.**

CMS proposes to continue use of the STrR Measure in the PY 2021 QIP and beyond and maintain existing specifications for the measure.

**NRAA remains very concerned that the measure specifications continue to capture transfusion events unrelated to dialysis treatment and, consequently inappropriately penalize dialysis facilities for events entirely unrelated to the care they provide.** Therefore, NRAA urges CMS to revise the STrR measure to further restrict the inclusion criteria particularly related to certain patient comorbidities for events counted toward this measure; unless the patient has CKD-related anemia, the patient simply should be excluded from the assessment in the measure. Comorbidities that increase risk for transfusions may include such things as sickle cell anemia; non-ESRD use of anticoagulants resulting in bleeds; cancer treatment; surgical blood loss; acute infections; acute patient injuries resulting in blood loss; gastrointestinal bleeds verified by occult testing where a GI specialists is unable to provide a definitive diagnosis; and trauma such as a car accident. Under the current QIP methodology, facilities are penalized inappropriately for these patients receiving such a high number of transfusions even though the transfusions are necessary for their treatment. In other words, NRAA firmly believes that the dialysis clinic should be held accountable in the STrR measure only for those patients who receive CKD anemia-related transfusions and not for transfusions related to the many other non-CKD anemia-related acute and chronic conditions the patients also may have.

**Moreover, NRAA continues to be very concerned that the STrR measure cannot drive meaningful improvement in quality of care – particularly without facility access to hospital or other third party data.** The data for the STrR Measure derive from third parties (hospitals) to which dialysis clinics do not have access. Without access to the data, dialysis clinics cannot verify that the data are correct or implement care practices that can improve performance in this treatment area. Therefore, NRAA strongly urges CMS to give facilities access to the third party data used to develop the STrR performance rates, thereby enabling facilities to implement treatment modifications as appropriate to improve care performance.

### *16. Separating Dialysis and Non-Dialysis Events in the National Healthcare Safety Network (NHSN) Measures*

**Recommendation: NRAA urges CMS to work with the Centers for Disease Control and Prevention (CDC) to segregate the dialysis-related infections from the non-dialysis-related infections reported to the NHSN so that facilities are not inappropriately held accountable in the QIP for infections unrelated to their direct patient care.**

CMS proposes to continue use of the clinical and reporting NHSN measures in the PY 2021 QIP and beyond.

**While the NRAA very much agrees with the policy goal of reducing patient bloodstream infections (BSIs), we are very concerned that the current NHSN measures inappropriately penalize facilities in the QIP for patient care beyond their control.** NRAA firmly believes that the QIP only should assess facilities on the quality of care they provide related to dialysis and should not penalize facilities for patient infections unrelated to dialysis. However, the current NHSN reporting system does not allow for facilities to separately report dialysis-related and non-dialysis-related BSIs. The inability to separately report these two types of infections in particular can disproportionately adversely impact facilities with low patient volumes where just one patient infection – that is totally unrelated to dialysis – can significantly negatively impact the facility's QIP total performance score. Such an outcome is especially problematic for those small and independent facilities with limited resources seeking to provide high-quality care to patients often in rural, underserved areas. While we agree with CDC that it is very important to identify, treat, and report all infections and their origins, we do not believe that dialysis facilities should be penalized in the QIP for BSIs unrelated to dialysis treatment. Thus, NRAA urges CMS to work with CDC to develop separate reporting of BSIs for dialysis-related and non-dialysis-related care. We would welcome the opportunity to work with you on conducting this work.

**We further recommend that CMS should work with CDC to simplify reporting of the NHSN measure, which likely will result in more accurate data collection**. The current system assumes that facilities are closed – not open. The opposite should be true; the default in the system should assume that facilities are open. Additionally, CMS should work with CDC to grant facilities more time to report to NHSN. Currently, many small and independent facilities are doing this work after hours post patient care. Having additional time to report this information to NHSN would help ease the burden on facilities trying to report accurately on this measure.

### *17. Reducing Patient and Provider Burden for ICH-CAHPS Reporting*

CMS proposes to continue use of the In-Center Hemodialysis Survey Consumer Assessment of Healthcare Providers and System (ICH-CAHPS) survey for the PY 2021 QIP and beyond.

NRAA agrees with CMS that understanding patients' experience with the care they receive is a critical tool in improving quality of care and patient health outcomes. However, the requirement for two surveys annually leads to patient fatigue and poor response rates, particularly for facilities that perform their own patient satisfaction surveys; without meaningful responses, it is difficult for facilities to meaningfully improve the care patients receive. Moreover, dialysis facilities bear considerable expense paying for survey administration, which particularly can impact SDOs and MDOs.

Consequently, the NRAA urges CMS: (1) to return to the requirement of one ICH-CAHPS survey administration per year; (2) to return survey results within a short period of time, such as 30 days, so that facilities can initiate an action plan to address patient-identified areas that need improvement; and (3) to simplify the survey for patients to limit the number of questions, for example to less than 10, that focus on patient feelings and the care they are receiving from physicians, nurses and other direct patient care staff. Each of these changes will reduce patient and provider burden while also likely leading to higher response rates with meaningful information that can drive improvements in the quality of care patient receive. **Furthermore, NRAA would welcome the opportunity to work with CMS on the development of an alternative statistically valid and meaningful patient satisfaction assessment tool that could capture particularly germane aspects of an ESRD patient's satisfaction with the quality of care received.**

### *18. Proposed Measures for Removal from the PY 2021 QIP*

**<u>Recommendation</u>: NRAA recommends against removing the Healthcare Personnel Influenza Vaccination measure because it could have the unfortunate consequence of eliminating many facility mandates that their personnel receive the influenza vaccination. NRAA supports removal of the Pain Assessment and Follow-Up Measure and recommends that CMS modify ESRD Network Statement of Work (SOW) to reflect the measure's removal. We support removal of the Anemia Management and Serum Phosphorous Measures.**

CMS proposes to remove four measures from the ESRD QIP beginning PY 2021: (1) Healthcare Personnel Influenza Vaccination Measure; (2) Pain Assessment and Follow-Up Measure; (3) Anemia Management Measure; and (4) Serum Phosphorous Measure.

1. **Healthcare Personnel Influenza Vaccination Measure:** NRAA recommends against removing this measure because its removal could have the consequence of resulting lower vaccination rates of healthcare personnel in dialysis facilities. Currently, the measure essentially functions as a mandate for facilities to vaccinate all healthcare personnel given that non-vaccinations can result in lower QIP scores with associated payment reductions. With its proposed removal, CMS effectively eliminates that mandate. As a result, there is the potential that in certain cases, facilities that otherwise would ensure that their healthcare personnel receive the influenza vaccination may no longer do so.

2. **Pain Assessment and Follow-Up Measure:** NRAA supports removal of this measure from the QIP. However, NRAA strongly recommends that CMS make appropriate modifications to the ESRD Network SOW to ensure that the SOW reflects the removal of this measure so that the goals of measure removal align throughout all parts of CMS's ESRD quality programs.

3. **Anemia Management Measure**: NRAA supports removal of the Anemia Management Measure. However, as discussed in more detail above, we disagree that the STrR Measure represents an adequate substitute for ensuring that patients maintain appropriate anemia levels and do not receive inappropriately low levels of ESAs.

4. **Serum Phosphorous Measure**: NRAA supports removal of this measure. We agree with CMS that the Hypercalcemia Measure more appropriately measures bone mineral metabolism than the Serum Phosphorous Measure because the Hypercalcemia Measure centers on clinical factors more under the facility's direct control. We also strongly support inclusion in the QIP of only those measures that have received endorsement from the National Quality Forum (NQF) like the Hypercalcemia Measure.

### *19. QIP Methodology and Measure Adjustments for Small and Low-Volume Facilities*

**<u>Recommendation</u>: NRAA would welcome the opportunity to improve adjustments to individual measures and the overall methodology of the QIP for facilities with low patient volume to better account for the fact that currently just one adverse patient outcome can have a disproportionate impact on a low-volume facility's QIP total performance score.**

While CMS makes no specific proposals with respect to adjustments in the QIP for facilities with small patient populations, we urge the agency to make further modifications to both the QIP methodology and individual measures to better account for the challenges that facilities with low patient volume face.

We appreciate that CMS understands that adjustments in the QIP are necessary to account for small facility size, as reflected by the small facility adjustment (SFA) included currently in the QIP as well as the case minimums for most measures. However, NRAA believes that the current SFA is insufficient and additional modifications to both the overall QIP methodology and specific measures in the QIP should be made to better account for low patient volume. For small and independent facilities, poor performance on just one measure due to just one patient can have an outsized impact on the facility's overall QIP total performance score. This is inappropriate and unfair especially with respect to facility assessment on measures that are out of the facility's direct control of care such as the STrR and NHSN measures (described in detail above in issue nos. 15 and 15). For small and independent facilities, even slight variations in payment can have substantial impacts on their abilities to provide access to high-quality care. Thus, NRAA would welcome the opportunity to work with CMS in developing additional changes to the QIP methodology and individual QIP measures to better account for the low patient volume that many small and independent facilities have.

### *20. NHSN Data Validation Study*

**<u>Recommendation</u>: NRAA urges that CMS work with CDC to modify NSHN data collection so that facilities can separately report dialysis- and non-dialysis-related infections. NRAA firmly believes that the QIP should penalize for infections unrelated to dialysis treatment. Facilities should have the ability to comment on results of individual data validation studies to demonstrate any discrepancies from between facility and audit results to ensure that NHSN data are accurate. Any future changes to NHSN reporting should be equitable across all facilities.**

CMS proposes to expand the NHSN data validation study in the PY 2019 and PY 2020 QIP. Additionally, CMS solicits comment on future policy proposal to improve the accuracy of reporting to the NHSN.

**NRAA strongly agrees with the policy goal of reducing rates of blood stream-related infections (BSIs) as lower rates of infections result in improved patient outcomes.** However, we remain very concerned the NHSN currently cannot distinguish between BSIs related to dialysis and those unrelated to dialysis. Without such distinctions, facilities inappropriately are penalized in the QIP for non-dialysis related infections. This is particularly problematic for small and independent facilities where even slight reductions in payment can substantially impact a facility's resources and ability to offer access to high-quality patient care. **Therefore, NRAA urges CMS to work with CDC to improve NHSN data collection and separate reporting for dialysis- and non-dialysis-related infections in the NHSN.**

NRAA further urges that CMS work with CDC to allow facilities to validate third party data submitted to NHSN on BSIs. Currently, dialysis facilities have no way to verify the third party data is correct and accurate. For example, a hospital could attribute a BSI to an ESRD patient that may be entirely unrelated to dialysis care. Hence, a dialysis facility should have the ability to verify and validate all third party data used for the QIP before CMS calculates its final QIP performance score.

Additionally, as stated above, we recommend that CMS should work with CDC to simplify the overall reporting process to NSHN. The current system assumes that facilities are closed – not open. Rather, the opposite should be true; the default in the system should assume that facilities are open.

Additionally, CMS should work with CDC to grant facilities more time to report to NHSN. Currently, many small and independent facilities are doing this work after hours post patient care. Having additional time to report this information to NHSN would help ease the burden on facilities trying to report accurately on this measure and should improve reporting accuracy.

Finally, we support the policy goal of ensuring "accurate, comprehensive" reporting to NHSN. Accurate data will help drive improvements in provider care of patients. However, NRAA urges that any changes to NHSN must be equitable across all facility types and not advantage or disadvantage one type of facility over another.

### *21. Percentage of Prevalent Patients Waitlisted (PPPW) Clinical Measure Proposed for PY 2022 and Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patient (SWR) Measure Proposed for PY 2024*

**Recommendation: NRAA opposes adoption of the Percentage of Prevalent Patients Waitlisted (PPPW) Measure for the PY 2022 QIP and the Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patient (SWR) Measure for the PY 2024 QIP because the transplant center – not the dialysis clinic – has control over the transplant waitlist. Therefore, the dialysis clinic is unable to meaningfully impact its performance on both of these measures and, accordingly, should not be penalized in the QIP on measures over which it has no control.**

CMS proposes to include the PPPW Clinical Measure beginning with the PY 2022 QIP and the SWR beginning with the PY 2024, explaining that the measures align with the MMI by emphasizing the shared accountability between dialysis facilities and transplant centers in transplant efforts.

**NRAA opposes adoption of the PPPW and SWR measures for the QIP because the transplant center – not the dialysis clinic – has control over the transplant waitlist. The** QIP should not penalize a dialysis clinic on measures over which it has no direct control. Moreover, there are a number of reasons that otherwise eligible patients may be uninterested in joining the transplant waitlist or dialysis clinics may have difficulty increasing the number eligible patients on a transplant waitlist. These include:

- **Patient cost-sharing for transplant-associated costs**: Patients face significant out-of-pocket costs when electing to receive a kidney transplant and all medically necessary treatment post-transplant. As such, the vast majority of patients that pursue a kidney transplant are those that have full insurance coverage from Medicare and a secondary payer. Thus, many otherwise eligible patients may not pursue joining the transplant waitlist because they simply do not have the financial resources to pay for the transplant and post-transplant costs.

- **Patient access to immunosuppressive therapies for only three years:** In line with the concerns about patient cost-sharing outlined above, for many beneficiaries on limited incomes without secondary insurance, the cost of paying for immunosuppressive therapies after three years is prohibitively high, effectively deterring them from pursuing transplant. Hence, these otherwise eligible patients may not pursue joining the transplant waitlist.

- **Travel distance to the transplant center from the patient's home:** For many rural programs, significant travel barriers can exist that deter patients from receiving an evaluation for transplant. For example, one NRAA member reports the closest transplant assessment center is

roughly a 3.5 hour drive from her facility. Many rural patients simply do not have access to transportation that would allow them to travel such distances to determine if they could be eligible to join the transplant waitlist.

### *22. Medication Reconciliation for Patients Receiving Care at Dialysis Facilities Reporting Measure Proposed for PY 2022*

**<u>Recommendation</u>: NRAA supports adding the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities Reporting Measure to the QIP in PY 2022.**

NRAA supports adoption of the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities Reporting Measure in the PY 2022 QIP. The proposed measure improves patient care and patient safety.

# IV. RFI on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

**The NRAA supports promoting increased interoperability and exchange of electronic healthcare information between hospitals and providers, including dialysis facilities.** Electronic exchange of healthcare information enables more coordinated patient care, which leads to improved quality of care and better patient health outcomes. As CMS considers revising the existing CoPs/CfCs/RfPs for hospitals and other providers to promote increased interoperability, we recommend the following:

- **Hold hospitals accountable for ensuring effective communications with community providers:** Current CoPs/CfCs/RfPs do not hold hospitals accountable for effectively communicating with community providers. As such, some dialysis providers, for example, do not receive all information necessary from hospitals post-discharge for optimal patient care. Therefore, NRAA recommends that CMS hold hospitals accountable in CoPs/CfCs/RfPs as appropriate for ensuring good communications with community providers and informing dialysis providers certain minimum information on the patient's inpatient care. The NRAA would welcome the opportunity to work with CMS to identify the specific data points on the inpatient admission that hospitals could be required to communicate to dialysis clinics to better ensure more coordinated, high-quality patient care.

- **Require the adoption of disease-specific Health Information Exchange (HIE):** NRAA urges that CMS require the development and adoption of disease-specific HIEs, such an ESRD HIE. An ESRD-specific HIE would assist hospitals in communicating effectively to dialysis facilities all minimum information necessary to support optimal patient care post-discharge and improve overall discharge coordination.

- **Establish exceptions for small and independent facilities:** CMS asks in the RFI the types of exceptions it should consider for providers in meeting the new or revised interoperability CoPs/CfCs/RfPs. NRAA urges that CMS establish exceptions for small and independent dialysis facilities in meeting these requirements, similar to the exceptions it established for small physician practices in the Quality Payment Program.

  Unlike most other provider groups, dialysis clinics were not eligible to receive a portion of the $20 billion in funding allocated for the development and adoption of HIT in the American Recovery and Reinvestment Act (ARRA) of 2009. As such, many small and independent dialysis providers with limited resources in particular have faced significant financial challenges in adopting HIT compared to other healthcare provider types. Even faced with such challenges, the NRAA has self-funded the development its own HIE to serve our membership. However, our members likely would require additional funding to meet the interoperability requirements under consideration by CMS. Thus, NRAA urges that CMS either extend exceptions to small and independent providers to meet any revised CoPs/CfCs/RfPs or provide grant funding to help small and independent dialysis providers meet such requirements particularly since ARRA funding was not available to these dialysis clinics unlike so many other provider types.

- **Allow small and independent facilities to access electronic medical records (EMRs) held by the hospital through secure login:** As stated above, dialysis clinics were not eligible to receive any portion of the ARRA funding for the development and adoption of HIT. Particularly for small and independent dialysis facilities with limited resources, this lack of funding has hindered the adoption of interoperable HIT. Until such time when small and independent facilities are able to widely adopt interoperable HIT, NRAA urges CMS to make appropriate changes to existing requirements to permit dialysis clinics certified to treat Medicare beneficiaries to access a patient's EMR held by the hospital through secure login. This information will better enable the dialysis clinic to provide high-quality care to the patient even though it may not have sufficient resources to fully adopt a comprehensive HIT and EMR system.

# V. Conclusion

In conclusion, NRAA again wishes to thank you for the opportunity to comment on CMS's proposed rule covering the 2019 ESRD PPS, QIP, AKI benefit, and RFI on promoting interoperability and electronic health information exchange. We look forward to continuing our valuable partnership with CMS to improve the quality and cost of care for these highly vulnerable pediatric and adult patients. If you have any questions concerning our comments, please do not hesitate to call Marc Chow at 215-564-3484.

Sincerely,

William Poirier

NRAA President