

August 25, 2015

Andrew M. Slavitt  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Room 445–G  
Hubert H. Humphrey Building,  
200 Independence Avenue, SW  
Washington, DC 20201

**RE: CMS-1628-P Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program**

Dear Acting Administrator Slavitt:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the 2016 Proposed Rule for the Centers for Medicare and Medicaid Services (CMS) End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and the ESRD Quality Incentive Program (QIP). ASN is the world's leading organization of kidney health professionals, representing more than 15,000 physicians, scientists, nurses, and health professionals who strive to improve the lives of patients with kidney disease every day. ASN and the professionals it represents are committed to maintaining patient access to optimal patient-centered quality care, regardless of socioeconomic status, geographic location, or demographic characteristics.

The society appreciates CMS' ongoing efforts to improve the quality and efficiency of dialysis care in the Medicare ESRD Program. Reflecting the society's commitment to patient access, to the highest quality of dialysis therapy, and to preserve the ability of nephrologists and patients to provide and receive individualized care, ASN submits the following comments regarding the proposed modifications to the ESRD PPS and the QIP. In summary, ASN recommends CMS consider the following major tenets:

1. Continued transparency and collaboration in measure development and specifications. This includes minimizing use of non-NQF endorsed measures, focusing on those measures with transparent development and validation, consistency in measure specifications across measures, consistency in measure adjustments and exclusions across measures, and limited or no overlap among measures.
2. Parsimony in the QIP and other programs that comparatively assess quality of care performance. Measures incorporated in the programs should be limited to a concise set of discriminatory assessments that stakeholders identify as most meaningful for dialysis patient care.
3. Avoidance of incentives that may undermine the delivery of individualized patient care to obtain a more favorable QIP score.
  - a. Implementing measures with clear definitions and micro-specifications that consider potential biases, potential for gaming, and potential for misrepresentation of care that could compromise individualized patient care.

- b. Avoiding implementation of clinical measures that do not have established national benchmarks and performance standards, as these create potentially confusing moving targets for quality improvement. Such measures should initially be tested as reporting measures, enabling validation of data collection processes and accuracy.
  - c. Application of standardized measures (i.e. SRR, SIR, STrR) that avoids grading on a bell-shaped curve, stressing the basic tenet that facilities should not be penalized or misrepresented as providing poor care for results that are within the limits of the range of expected performance.
  - d. Avoiding use of facility level metrics that are vulnerable to results from a single individual.
4. Monitoring the effects of the PPS on access to care, including the ability of ESRD beneficiaries to promptly obtain prescribed oral medications covered under Medicare Part D.
  5. Recognizing promptly when a measure is topped out, either clinically or statistically, to avoid unintended consequences, including loss of the ability to individualize care, pressure to provide care that may not be in the best interest of an individual patient and/or diverting attention from other measures that may be better targets for quality improvement.

Overall, ASN echoes CMS' sentiment that the intent of the Quality Incentive Program and the Prospective Payment System are to provide accessible, economical, high quality patient care and stresses that this mission is shared among all members of the nephrology community. ASN reiterates that facilities should not be considered failures solely due to grading on a curve. ASN believes that this philosophy, as stated in the current proposed rule, is inherently flawed, not in the best interest of patients, and not mandated by MIPPA based on the use of the term 'appropriate distribution' in Section 1881(h)(3)(A)(ii) of the Act, as the term 'appropriate distribution' allows that clinical circumstances be accounted for. The purpose of evaluation is not to separate the outstanding from the excellent, but rather to identify subpar performers in order to facilitate improvement. In this regard, ASN highlights that the legislative purpose of the QIP is care improvement such that high quality care is provided to all beneficiaries, regardless of clinical characteristics that may make an individual beneficiary more risky for an individual facility to care for. The society provides more specific comments below.

### **Prospective Payment System (PPS)**

#### **Case-Mix Adjustment:**

ASN agrees that reassessing the methods used to develop the PPS case-mix adjustment is important. In particular, ASN favors the use of the most proximate available data to re-weight the current set of co-morbidities. ASN also agrees with the proposal to remove from case-mix adjustment acute and chronic comorbid conditions that cannot be reliably documented or that are particularly burdensome for dialysis facilities to verify.

Since implementation of the PPS, there have been significant changes in dialysis facility practices. Notably, clinical trials suggesting potential health risks from more aggressive use of erythropoiesis stimulating agents (ESAs), the Food and Drug Administration's issuance of a black box warning related to ESAs, and economic incentives resulting from the PPS have all contributed to decreased ESA use. In the setting of declining ESA use, the relative influence of different patient and dialysis facility characteristics on the cost of providing dialysis care by facilities has likely changed.

When the case-mix formula was originally constructed, CMS (with the assistance of UM-KECC) evaluated the association between a broad range of comorbidities and costs for then separately billable elements of dialysis care. The majority of these co-morbidities were ultimately excluded from final case-mix adjustment mechanism due to their small effect on variability in dialysis facility costs, while the chronic conditions that were selected were primarily related to patients' ESA utilization, as it was differences in ESA utilization that largely drove differences in dialysis facility expenditures prior to the expanded bundle. In the more recent setting of decreased ESA use, the original set of conditions likely has less influence on overall dialysis facility expenses. Similarly, it is possible that certain "high-risk" patients, who previously made relatively minor contributions to overall costs, now have a larger cost impact. For example, patients with mental illness, lower socioeconomic status, and fewer resources available at home, may contribute in different ways to higher resource consumption and expenditures for delivery of dialysis care. Additionally, patients initiating dialysis in the hospital with multiple medical comorbidities and complex disease states also can require more resources in order to coordinate care. The complex interactions among multiple co-morbidities and social circumstances are not captured through current risk assessment tools.

Case-mix adjustment plays an important role in promoting access to care. Efforts to adjust facility payments according to patient costs reduce the financial impetus to deny care for more costly patients. However, the focus of current case-mix regression models on facility costs paid by CMS ignores several other important dialysis facility costs and could limit access to care, particularly when viewed in conjunction with the QIP. When patients (either due to non-adherence, mental illness, social stress, frequent hospitalization due to severity of their illness or other identifiable but unadjusted for causes) are either unable to or refuse to attend outpatient dialysis, facilities do not receive payment. The fixed costs borne by the facility for a patient missing dialysis treatment as well as the opportunity costs associated with the lost revenues that could have been collected by a facility if a different patient who would not have missed dialysis had instead been dialyzed are not currently captured in case-mix adjustment. This means that dialysis facilities will collect more revenue by choosing to provide care for patients who are less likely to miss treatments and collect less revenue when they choose to care for patients who frequently miss dialysis. The potential for lost revenue can limit access to care for high-risk patients who are more likely to miss dialysis. While ASN recognizes the need for continual attention to new strategies to improve dialysis attendance, we note that many diligent and good faith efforts by facilities often are of only limited success. To maximize access to care for high risk patients, ASN urges CMS to explore methods of case-mix adjustment that further refine characterizing patients with non-modifiable medical contributors as well as non-medical contributors to the complexity of their health status.

Dialysis facilities also risk incurring decreased reimbursement when they care for high risk patients, stemming from the greater potential that some high risk patients will result in lower overall facility level ESRD QIP-defined quality metric goals. Patients who are at a high risk for not attaining QIP defined standards and negative health outcomes, such as blood stream infections, blood transfusions, and re-hospitalization, and patients who are not candidates for AV grafts and fistulas, are associated with higher risk for the dialysis facility. This is particularly true for outcomes that either are not or are inadequately standardized or adjusted, such as vascular access targets. The costs associated with meeting more recent QIP goals in high-risk patients, as well as the cost of potential QIP penalties in patients for whom facilities are unable to improve QIP-related metrics despite appropriate efforts to do so, are currently not reflected in the case mix adjustments. ASN urges consideration of these costs in order to ensure access to care among high-risk patients.

In addition to improving methods of identifying high-risk patients and considering all aspects of their costs, ASN stresses that it is essential that CMS actively monitor whether dialysis facilities decline to care for higher risk patients.

#### **Outlier Payments:**

ASN appreciates the efforts of CMS to recognize that the needs of all patients are not universally equal, and that a minority of patients will require treatments that carry markedly higher cost than the average ESRD patient. ASN supports the concept of an Outlier Policy to sufficiently reimburse dialysis facilities for implementing necessary dialysis-related treatments to meet the needs of these patients and established therapeutic goals. However, ASN is concerned that the Outlier Policy, as currently designed, is flawed, as evidenced by the low percentage of facilities who have received these payments and the annual lack of full distribution of the withholdings used to fund the outlier payments to dialysis facilities. To facilitate optimal patient care and to ensure access to care for higher risk dialysis patients, while reflecting the low percentage of facilities that have qualified for the current threshold, ASN recommends CMS re-evaluate the threshold for outlier payments with the goal of increasing the percentage of facilities that will appropriately be reimbursed for providing necessary dialysis care. Specifically ASN suggests one of two options to ensure disbursement of this withholding: 1) Annual adjustment of the threshold for outlier payments to fully expend the withholding or 2) Annual adjustment of the withholding based on the running average of the expenditure from the prior three years, with the total withholding not to exceed 1%.

#### **Body Surface Area (BSA) and Body Mass Index (BMI):**

ASN requests that CMS clearly define the methodology of calculating BMI and BSA. For example, for peritoneal dialysis patients, is weight defined by that with an empty peritoneal cavity or a full peritoneal cavity? This is particularly relevant for those patients who have high volume dwells at all times, as the full volume could theoretically be subtracted from the weight to derive a value that more closely approximates body weight. Similarly, for hemodialysis, ASN requests that CMS define when weight is assessed in regard to dialysis schedule.

#### **Low-Volume Payment Adjustment (LVPA):**

ASN appreciates CMS' efforts to take into consideration the Government Accountability Office (GAO) recommendations regarding low-volume payment adjustment. The GAO report recommended targeting low-volume, high-cost facilities that are essential to ensure access to care, reducing incentives to limit services in order to maintain the LVPA threshold and ensuring appropriate payment to true low-volume facilities. The increase in LVPA adjustment factor from 18.9 to 23.9, based on CMS regression analysis, seems to attempt to partly address the low-volume, high-cost factor. However, this measure was developed before CMS had any data on SRR and other recent measures that might change the validity of the measure. ASN wants to ensure that these modifications will not have a larger effect on small dialysis units and subsequently cause closures. Similarly, eliminating the grandfathering policy, and reducing the geographic proximity criterion to 5 miles seems to partly address the issue of correctly identifying essential low-volume facilities. However, the analysis used by CMS indicates that 30 facilities would lose the LVPA due to these new criteria; as a consequence, some of these facilities may be forced to close due to the downstream adverse effects on their financial performance and viability. Accordingly, ASN strongly recommends that CMS work closely with the parent networks to evaluate the impact of any closures on patient access to care and to consider providing, at a minimum, a period of transition for potentially affected facilities that could lose LVPA.

#### **Geographic Payment Adjustment for ESRD Facilities Located in Rural Areas:**

ASN supports CMS's efforts to account for the unique financial and resource challenges facilities in rural areas face. The fact that a facility would be eligible to receive both rural and

low-volume payment adjustments **is appropriate**. However, the proposed payment multiplier of 1.008 seems to be based on limited data; again we are concerned about the lack of accounting for SRR and other measures. In addition, CMS suggests conducting further analysis examining subsets of rural areas to potentially establish a larger payment adjustment. ASN recommends that CMS postpone this measure until additional data can be generated.

**Refinement of Pediatric Case—Mix Payment Adjustments:**

ASN, along with the American Society of Pediatric Nephrology (ASPN), agrees and is supportive of CMS' efforts to ensure adequate reimbursement for pediatric dialysis facilities. However, like ASPN, we are concerned that an eight percent increase in the pediatric case mix adjuster might still be inadequate to cover the actual costs of providing dialysis care to children and adolescents. ASN supports ASPN's goal to ensure that CMS receives uniformly accurate and comprehensive information from pediatric facilities that captures the full breadth of resources required to provide quality pediatric dialysis. ASN urges CMS to continue to reevaluate and regularly update the pediatric payment adjuster by utilizing the most recent data from Medicare cost reports and CROWNWeb. We agree with ASPN in requesting that CMS allow pediatric facilities to apply for an exception to the ESRD composite rate as it has in the past when a facility's cost reports showed that the actual cost per treatment was higher than the composite rate.

Historically, both CMS and Congress have recognized that the higher costs for pediatric dialysis warrant increased reimbursement rates for pediatric facilities than adult facilities. These higher costs stem not only from specialized nursing expertise to meet the unique requirements for care of small children on dialysis but also additional unreported expenses for the key support personnel responsible for addressing the unique challenges related to cognitive, physical, and developmental disabilities in pediatric ESRD. Again, while the proposed eight percent adjustment to the pediatric payment adjuster is certainly needed, we continue to believe that ongoing updates are warranted. Our mutual goal should be to ensure that reimbursement is appropriate to costs so that pediatric facilities, pediatric dialysis providers, and pediatric dialysis staff can continue to provide high quality services with good health outcomes to those children in need of pediatric ESRD care.

**Drug Designation Process and New Technology Payments:**

ASN appreciates the detailed discussion of the drug designation process to appropriately determine items pointedly related to dialysis care. The society also appreciates the close consideration of new technology payments, including placing the current status in the context of the recent changes in legislation regarding inclusion of MBD agents in the bundle. Critical to this process is maintaining patient access to medications, ensuring patients' access to future new drugs and technologies, and preserving physicians' ability to individualize medications prescribed to dialysis patients.

Patients with ESRD deserve the hope of new and innovative therapies, and ASN is committed to working with CMS to ensure appropriate reimbursement exists to drive innovation in the dialysis space. Ensuring a fair and predictable payment rate for new technologies will be crucial to incentivize innovation in a disease state that has seen too little advancement in recent years.

Given the current structure of dialysis care, ASN recommends that, when a new product for dialysis care becomes available, new money should be allocated to pay for this product.

For products that are truly de novo (not substituting any existing product in the PPS), a transition period and ASP +6% approach—based on current law—appears appropriate until the utilization of the new product is sufficiently mature to be subsumed into the PPS with accurate cost and use data.

Similarly, for agents that directly compete with existing agents in the PPS but offer improvement in patient outcomes, ASN suggests that the same approach with a transition period and a cost and use evaluation is also appropriate.

For agents that are newly introduced, have a role either similar to or identical to existing agents and are not associated with better outcomes than existing agents, we concur that these agents should be included in the current PPS without any changes in the total sum allocated to the PPS.

ASN believes that intravenous treatments for mineral and bone disorders, which are given in the dialysis unit and are not vitamin D receptor agonists, should fall under the first pathway described above, and be subject to a transition period and ASP +6% approach until the utilization of the new product is sufficiently mature to be subsumed into the bundle with accurate cost and use data.

Finally, ASN recommends that all decisions related to adding a new drug or biological to the ESRD bundle, as well as items that compete with other agents already in the bundle, should be presented through notice-and-comment rulemaking, giving patients, health professionals, and other stakeholder the opportunity to present their viewpoints.

### **Quality Incentive Program (QIP)**

#### **Proposal to Use the Hypercalcemia Measure as a Measure Specific to the Conditions**

##### **Treated with Oral-Only Drugs:**

ASN proposes that CMS put forward the phosphorus reporting measure currently within the QIP as the primary measure specific to conditions treated with oral-only drugs. A substantially larger portion of Medicare ESRD beneficiaries are treated with oral phosphate-binder therapy for hyperphosphatemia than with calcimimetics for hypercalcemia. The society considers hypercalcemia as a far less clinically meaningful secondary measure to use as a proxy for monitoring conditions currently treated with oral-only drugs. Furthermore, ASN recommends that as early as PY2018, the hypercalcemia measure be reclassified as a reporting measure similar to the phosphorus measure, consistent with the basic tenet of parsimony, the lack of data supporting a beneficial effect of treatment of hypercalcemia on outcomes, and the lack of current endorsement by the NQF. Finally, similar to phosphorus, where either serum or plasma measures are permitted, ASN recommends that CMS remove the restriction of calcium levels to serum calcium because the calcium levels obtained from hospital labs (allowed by the current rules to be reported by dialysis facilities) may be measured in either serum or plasma samples, depending on the specimen source.

### **Proposed Revisions to the Requirements for the PY 2017 ESRD QIP**

#### **Proposal to Modify the Small Facility Adjustor (SFA):**

The society agrees in principle with the modifications made to the small facility adjustor but requests that the same methodology be used throughout both the PPS and QIP for counting patients and patient time. Specifically, the SRR uses the number of discharges rather than the number of patients in the denominator. As discussed elsewhere, ASN feels that this is an inappropriate way to measure quality when dealing with finite and relatively small populations, like those cared for by dialysis facilities. Additionally, this denominator specification may result in inappropriate application of the SFA for the SRR and any future similar metrics. This is suggested by the fact that, in the details describing the SFA proposal, 22% of dialysis facilities are labeled as small when evaluating the SRR. More than a flaw in the proposed SFA methodology, this suggests that the SRR should be structured differently.

**Proposal to Reinstate Qualifying Patient Attestations for the ICH CAHPS Clinical Measure:**

The society agrees with CMS and understands that this attestation will facilitate documentation and QIP scoring assessment, and will further distinguish low volume as the reason that an individual facility is unable to meet the 30 patient ICH-CAHPS response target.

**Proposed Requirements for the PY 2018 ESRD QIP**

**Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Finalized for the PY 2018 ESRD QIP:**

The estimated performance standards for PY2018 pose several challenges that are covered by the basic tenets promoted by ASN.

- a. Performance standards for “standardized” measures (NHSN SIR, SRR and STrR) in Table 14 are all below 1.0, indicating that point estimates that are at or higher than expected but with observed rates that fall within the “expected” (or predicted) range will generate lower QIP scores. These potentially will misrepresent these facilities as providing substandard care in the three subdomains (although the methodology for the Adjusted Ranking Metric for the NHSN SIR remains opaque, making this difficult to interpret). We suggest, keeping with the tenets described above, that the performance standards for these measures be re-evaluated.
- b. The ICH CAHPS measure is used as a clinical measure despite the lack of understanding of how patient scoring and completion rates are distributed nationally and a lack of knowledge on how non-modifiable patient factors may influence patient scoring. The society assumes a strong position against implementation of clinical measures that do not have established national benchmarks and performance standards because it creates a potentially confusing moving target for quality improvement. In this case, since the results could be partly impacted by individual or potentially regional patient responses based on personal or population-based expectations, it is prudent for facilities to have better understanding and guidance regarding the appropriate ways to interpret each composite section/score and item on the survey. This will inform the appropriate ways to address issues and improve patient experience ratings. It is more appropriate for validation of completeness and accuracy of data collection be performed with ICH CAHPS kept as a reporting measure for PY2018.
- c. Given that the hypercalcemia measure was not endorsed by NQF, ASN requests that this measure be reclassified as a reporting measure similar to the phosphorus measure. This change would also be consistent with the ASN’s tenet of parsimony among measures in the QIP.
- d. ASN is a strong supporter of the concept of the SRR measure as an important indicator of patient care but continues to have reservations about this measure as currently constructed. These reservations, discussed in detail in a letter dated September 2, 2014 to the CMS Administrator, are similar to those raised by the NQF when they failed to endorse the SRR. ASN requests that CMS test this measure prior to implementation, including assessing the effects of not counting readmissions that occur prior to a facility’s opportunity to intervene to prevent readmission. Additionally, ASN continues to request that the CMS assess the performance of a SRR measure that uses the dialysis facility population as the denominator rather than discharges as the denominator as this would facilitate

parsimony in measures by consolidating the information captured by the SRR and SHR into a single stand-alone metric that is more robust to small numbers of discharges for any given facility.

**Proposed Modification to Scoring Facility Performance on the Pain Assessment and Follow-Up Reporting Measure:**

ASN supports this proposal that avoids penalizing facilities with eligible patients in only one of two performance periods during the year. It is consistent with the tenet that the QIP measure accurately represents the care provided by a facility.

**Proposed Payment Reductions for the PY 2018 ESRD QIP:**

ASN appreciates CMS' description of the logic behind calculating the TPS and establishing the levels upon which penalties are levied. It meets the basic tenet of transparency that is valued by the society and the kidney community. However, while ASN accepts that allowing for a score of zero in measures that do not have a numerical standard is appropriate for calculating TPS within the proposed rule, the society urges CMS to avoid implementation of clinical measures that do not have established national benchmarks and performance standards because it creates a potentially confusing moving target for quality improvement.

**Data Validation:**

ASN supports data validation efforts by CMS to ensure that QIP measures are compared across a level playing field. However, the society strongly believes that validation efforts should be performed when a measure is introduced as a "reporting" measure and validation should be completed before a measure becomes a "clinical" measure. There are potentially serious consequences for facilities associated with findings released by CMS, reflecting the faith that consumers have in CMS' processes. If these processes are flawed, the resulting publication of QIP performance (or 5-star performance) could have irreversible consequences for patient impressions, patient choice of facilities and, ultimately, facility viability (particularly given a sensationalist culture that currently exists when it comes to instant information). When validation is performed after a measure is already in place as a clinical measure, it resembles an "audit" mechanism. Furthermore, levying a deduction of 10 TPS QIP points for loosely defined "non-compliance by 60 days" is a severe penalty that has grave consequences, particularly for PY2018 where CMS proposes a 39-point threshold for no reimbursement deduction and a 10 point change represents a drop in deduction category. Therefore, if CMS pushes through with the current proposal, a clear and transparent definition of non-compliance with the 60-day record request by the CMS contractor should ensure that compliance is within the control of the dialysis facility staff. For example, if a blood culture result is requested for an emergency room or hospital admission within 24 hours of acute care for a patient and a good faith effort has been made by the facility to obtain these data within the allotted timeframe, there should be no penalties levied on the dialysis facility.

**Proposed Requirements for the PY 2019 ESRD QIP**

**Proposed Replacement of the Four Measures Currently in the Dialysis Adequacy Clinical Measure Topic Beginning with the PY 2019 Program Year:**

The society applauds CMS for simplifying the QIP dialysis adequacy domain and effectively keeping the same parameters but implementing them within a single measure. ASN expects micro-specifications and technical details to be available for this adequacy measure among other measures, particularly with regards to the blood draw process and formulas used for calculating spKt/V and weekly Kt/V. Of note, the PY2019 technical specifications no longer include exclusion criteria for minimum (0.5) and maximum (2.5) values, excluding 8.88 and 9.99, that allows for accepting results from patients with spKt/V legitimately over 2.5 (e.g. patients that perform long nocturnal hemodialysis). However, the trade-off is that facilities become

responsible for ensuring that dialysis adequacy data entered into CROWNWEB are accurate. ASN suggests that spKt/V values greater than 2.5 be accepted for treatment durations of 6 hours or longer, where they are more plausible.

**Proposed PY 2018 Measures Being Continued in PY 2019:**

- a. **Vascular Access:** ASN supports the continued inclusion of the vascular access domain as one of the most important aspects of hemodialysis patient care. However, the existing measures do not consider the utility of arteriovenous grafts in some patients who may not be amenable to a native arteriovenous fistula but will benefit from not being exposed to a central venous catheter. It is hoped that the CMS TEP convened in 2015 will be able to recommend useful changes in measures that will allow for consideration of the population of patients in whom a fistula may not be the best option and in whom grafts are preferable to catheter use or who may truly be catheter dependent. Until this occurs, ASN hopes that CMS reviews performance data to ensure that the measure does not become too 'topped out', such that patients are inappropriately referred for fistula creation. This consideration could include setting an achievement threshold at a sufficiently high level of AV fistulas (for example, 75-80%), that would not be impacted annually by the performance of other facilities and would always result in maximal points.
- b. **Standardized Infection Rates:** In principle, ASN continues to support the National Health Safety Network (NHSN) Bloodstream Infection Measure. However, ASN supports use of an overall denominator rather than three stratified denominators (consistent with the original NQF reviewed specifications) and does not support use of the Adjusted Ranking Metric (ARM). From the limited methodology description available, the ARM incorporates a random-effects model to account for facility while, for the SHR, the ARM equivalent is a fixed effects model for facility. These inconsistencies in methodology result in far less confidence in the adjustment strategies used in these metrics. Based on a presentation by Mr. Jonathan Edwards of the CDC (the measure steward), the impetus for the ARM is a perceived need to differentiate among very low standardized infection rates, based on exposure characteristics. This has the effect of normalizing the distribution of otherwise left-skewed standardized infection rates. In contrast, ASN supports efforts to reduce the vulnerability of facilities to penalties for one or two events in the setting of low denominators. Additionally, we continue to stress that the need to rank-order dialysis facilities is not legislatively mandated and encourage CMS to work with the community to set fixed thresholds for high performance that will not change annually. Accordingly, ASN does not support the use of the ARM in developing the Standardized Infection Ratio as currently proposed to be continued (from the methods described from PY2018).
- c. **Hypercalcemia:** ASN recommends that, because it is not clinically meaningful on a population level assessment, the hypercalcemia measure be reclassified as a reporting measure similar to the phosphorus measure, consistent with the basic tenet of parsimony.
- d. **Standardized Readmission Ratio:** ASN has previously supported the concept of the SRR but recommended against incorporating the SRR measure in the QIP as currently constructed. In addition to the previous letter dated September 2, 2014 to the CMS Administrator, two additional issues have come to light recently that the society would like to share with CMS:

- I. A comparison of CMS Form 2728 data to claims data for comorbidity ascertainment 6-months before and 3-months after initiation of renal replacement therapy for ESRD highlights that the SRR relied on comorbidity data from claims rather than from the 2728 form (Krishnan et al, AJKD 2015). However, this is not true for the other standardized measures (e.g. STrR).
  - II. A 2013 ASN annual meeting presentation (Lacson et al, TH-OR118 JASN, 2013) indicated that 35% of 30-day readmissions from Fresenius hemodialysis facilities in 2011 involved patients being readmitted within 7 days post-discharge and 2/3 of them were readmitted either without having been treated at the facility (35.2%) or after only 1 hemodialysis treatment (32.7%) during this period. The characteristics of readmissions within 7 days relative to the subsequent period up to 30 days was recently studied (Graham et al., Annals of Internal Medicine, 2015); these authors posit that illness acuity and acute care issues within the hospital played a greater role early relative to chronic illness related factors. Further study is needed to determine the appropriate assignment of responsibility for early (e.g. first 7-days to the hospital) vs. late (e.g. 8-30 days, to the facility) as CMS evolves the rules around 30-day readmissions in the ESRD QIP program vis-a-vis the hospital-based quality program.
- e. **Standardized Transfusion Rates:** While appreciating the STrR as a potentially useful measure, ASN notes that transfusions represent only a small fraction of hospitalizations and urges CMS to consider inclusion of other critical adjustment factors that are more closely linked to anemia and transfusion events, either in the general population or in the dialysis population, including more proximate factors to the transfusion event. Documentation and analyses of the events leading to the decision to transfuse patients will be very informative (Lacson & Maddux, AJKD, 2013). As noted above, adjustments for comorbidity may be better sourced from claims rather than from the 2728 form (Krishnan et al, AJKD 2015). ASN believes that a fundamental scientific interpretation and use of standardized measures like STrR should avoid grading on a bell-shaped curve and should not lead to facilities being penalized or misrepresented as providing poor care for results that are within the limits of the range of expected performance. Finally, while ASN appreciates that transplant related hospitalization and transfusions will now be excluded, clinical experience dictates that conditions that require repeated admissions with a high risk of transfusions, such as angiodysplasia, may provide sufficient repeated events to penalize a facility despite limited actionability. It may be prudent to determine if patients with sufficiently high doses of ESA (e.g. >40,000 units/week) could be excluded from this measure and/or if repeated transfusions for a single patient should only be counted against a facility for a maximum of 3-4 times during the reporting period.
- f. **Patient Experience:** ASN remains concerned that the required administration of ICH CAHPS twice per year will not allow for sufficient time for facilities to review their results and make meaningful interventions to improve performance. Additionally, twice yearly administration may lead to survey fatigue that could impact completion of the ICH CAHPS or even responses on the ICH CAHPS. Finally, as noted above, the ICH CAHPS measure is used as a clinical measure despite the lack of understanding of how patient scoring, completion rates and associations of responses with important patient and facility outcomes are distributed nationally. In principle, the society opposes implementation of clinical measures that do not have established national benchmarks and performance

standards because it creates a potentially confusing moving target for quality improvement.

- g. **Mineral Metabolism:** ASN supports the change to allow for phosphorus results measured in both serum and plasma samples for mineral metabolism reporting and requests that the same change be implemented for calcium.
- h. **Anemia Management:** ASN has no additional comments regarding the anemia management reporting measure.
- i. **Pain Assessment/Follow-up:** ASN supports the concept of a pain assessment reporting measure; however, more information is needed to determine the system-level approach for patients with a positive screen and to optimize screening tests and management approaches. Recognizing that pain correlates with shortened treatments, ED visits and hospitalization (Weisbrod et al., CJASN 2014) and also may impact patient experience and quality of life, ASN strongly supports maintaining pain assessment as a reporting measure until more information is available.
- j. **Depression Screening/Follow-up:** There is no standard depression screening tool as the consensus choice for use in ESRD patients. While ASN appreciates the concept of a depression screening reporting measure, more information is needed to determine the appropriate management recommendations for depression as well as depressive symptoms (in the absence of major depression) in the ESRD patient. Therapy outcomes for depression are currently the subject of a PCORI trial (Mehrotra et al; ASCEND Study - <https://clinicaltrials.gov/ct2/show/NCT02358343>). Accordingly, ASN strongly recommends that it is maintained as a reporting measure until more information is available.
- k. **NHSN Healthcare Personnel Influenza Vaccination Reporting Measure:** ASN agrees that monitoring influenza vaccination among healthcare personnel at dialysis facilities is an important goal. However, there is continued concern about the definition of qualifying healthcare personnel who may be in the facility for only one day and recommends that this be changed to 30 days. It may pose logistical problems for visitors or create a lack of actionability for urgent needs such as to fill in with a temporary nurse or locum tenens physician coverage. ASN encourages CMS to ensure date flexibility based on vaccine availability.

### **Proposed New Reporting Measures Beginning with the PY 2019 ESRD QIP:**

#### **Ultrafiltration Rate:**

ASN has concerns with the Ultrafiltration reporting measure as currently proposed. Most hemodialysis patients are routinely dialyzed for a pre-specified treatment time that is consistent across all weekly treatments. However, because of the longer interdialytic interval during the weekend, there is often greater fluid gain that needs to be removed during the first weekly treatment (either Monday for MWF or Tuesday for TThS scheduled patients) relative to the other treatments later in the week. Since there is no specified treatment for which the metric is to be reported, there is a high potential for gaming by picking the single treatment with the least weight gain and for which the patient completed the prescribed treatment time.

ASN views the KCQA proposed and NQF endorsed ultrafiltration measure as preferable to the measure proposed by CMS as this measure reports values for at least all treatments performed

in a single week and allows for good faith efforts to reduce the UFR by increasing dialysis duration to at least 4 hours. ASN notes that the CMS measure is more susceptible to gaming because it is always possible to alter the single treatment by either removing less fluid allowable by the UFR (potentially detrimental to patients) or increasing treatment time for the single treatment (that may impact the next patient by having them wait longer and/or may end up with a shortened treatment if transportation time is not flexible). If measured over an entire week, these 'gaming' strategies are less tenable. Therefore, ASN recommends harmonization with the KCQA measure at NQF prior to implementing the UFR reporting measure. For both of these measures, ASN encourages CMS to evaluate the effects of normalizing for body surface area rather than for weight.

#### **Full-Season Influenza Vaccination Reporting Measure:**

ASN supports the influenza vaccination reporting measure for ESRD patients. Protection from influenza is a particular concern for patients receiving dialysis due to their frequent exposure to healthcare workers/other patients/family members and their susceptibility to developing severe illness from viral infections such as influenza. While CMS appropriately excluded patients who are on dialysis for less than 30 days as of the end of the performance period, it is also possible that a patient may be admitted for more than 30 days to an outpatient dialysis facility during the performance period but spend most of that time in the hospital or sub-acute care location.

Therefore, the society recommends that in-center hemodialysis patients who do not have at least 7 hemodialysis treatments or home patients that only have one clinic visit during the entire performance period (October to March flu season) be excluded from the denominator as well. Additionally ASN stresses that the assessment of vaccination be synchronized with availability of seasonal influenza vaccines, recognizing that this may be highly variable from year to year.

#### **Proposed Performance Period for the PY 2019 ESRD QIP**

The society concurs with the proposed performance period of CY2017 with the exception of the influenza vaccination reporting measures (October 1, 2016 to March 31, 2017) for PY2019.

#### **Proposed Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2019 ESRD QIP:**

ASN supports the proposal to use performance standards, achievement thresholds, and benchmarks from CY2015 for PY 2019 with the caveat that scientific interpretation and use of standardized measures (i.e. SRR, SIR, STTrR) are implemented in order to avoid grading on a bell-shaped curve; this reflects the basic tenet that facilities should not be penalized or misrepresented as providing poor care for results that are within the range of expected performance. For example, as noted above in our comments for PY2018, the confidence limits that define the range of expected values should be respected, because facilities that have observed outcomes within the range of expected values are by definition providing measurably equivalent performance, even if the standardized ratios being compared are on the opposite sides of 1.0.

#### **Proposal for Scoring the PY 2019 ESRD QIP:**

Vascular access remains one of the most actionable components of care quality; accordingly its weight should be increased relative to the other measures. ASN posits that, although patient experience is very important, the ICH-CAHPS measure is over-emphasized given the fact that no studies have shown an association between scores on the ICH-CAHPS and meaningful domains of quality. Thus, the society would favor lower weighting of ICH-CAHPS. With validation of the NHSN data underway, it is prudent to also decrease the weighting of the NHSN measure. Additionally, removing hypercalcemia from the clinical measures will further help to readjust weighting among the remaining domains.

**Future Achievement Threshold Policy Under Consideration:**

ASN strongly opposes an increase in the achievement threshold from 15<sup>th</sup> to 25<sup>th</sup> percentile while there are multiple ongoing changes to the measure, measure scoring, and unaddressed issues relating to appropriate rating using standardized measures.

**Summary of Key Recommendations:**

On behalf of ASN, thank you for your consideration of these comments regarding the ESRD QIP and PPS Proposed Rule. In summary, ASN's key recommends that CMS:

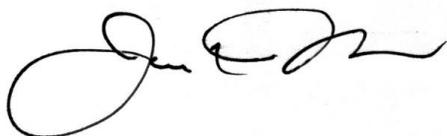
- Continued transparency and collaboration in measure development and specifications.
- Parsimony in the QIP and other programs that comparatively assess quality of care performance. Measures incorporated in the programs should be limited to those most meaningful for dialysis patient care.
- Avoidance of incentives that may undermine the delivery of individualized patient care to obtain a more favorable QIP score by:
  - Implementing measures with clear definitions and micro-specifications in order to maximize patient quality care.
  - Avoiding implementation of clinical measures that do not have established national benchmarks and performance standards.
  - Application of standardized measures (i.e. SRR, SIR, STrR) that avoids grading on a bell-shaped curve, stressing the basic tenet that facilities should not be penalized or misrepresented as providing poor care for results that are within the limits of the range of expected performance.
  - Avoiding use of facility level metrics that are vulnerable to results from a single individual.
- Monitoring the effects of the PPS on access to care, including the ability of ESRD beneficiaries to promptly obtain prescribed oral medications covered under Medicare Part D.
- Recognizing promptly when a measure is topped out, either clinically or statistically, to avoid unintended consequences, including loss of the ability to individualize care.

The society's members are dedicated to providing the highest quality care for patients treated with dialysis and are concerned that gains made in terms of access to care and quality of care are not undermined as an unintended consequence of rebasing efforts. ASN continues to believe that a robust system assessing the accessibility and quality of dialysis services is critically important.

The society hopes that the recommendations it offers in this letter are helpful and stands ready to discuss these comments. ASN welcomes the opportunity to continue to collaborate with CMS to refine the PPS and QIP in future years.

Again, thank you for your time and consideration. To discuss ASN's comments, please contact ASN Manager of Policy and Government Affairs at [rmeyer@asn-online.org](mailto:rmeyer@asn-online.org) or at (202) 640-4659.

Sincerely,



Jonathan Himmelfarb, MD, FASN  
President