

August 23, 2016

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-1651-P Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease 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 2017 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 nearly 16,000 physicians, scientists, nurses, and health professionals who strive to improve the lives of patients with kidney diseases 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 preserving 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:

1. Emphasize 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.
2. Recognize 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.

3. Ensure 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.
4. Finalize the proposal to pay for dialysis more than three times per week for patients diagnosed with acute kidney injury (AKI-D), as deemed appropriate by the nephrologist, and:
 - a. Do not include patients with AKI-D in quality reporting programs such as the QIP
 - b. Ensure appropriate data reporting to inform future research and better care for patients with AKI-D
 - c. Permit patients with AKI-D who do not recover native kidney function and go on to receive a diagnosis of ESRD have their first date of dialysis for AKI-D care used administratively for purposes of transplant wait-listing and the first of the 90 day Medicare eligibility waiting period based on ESRD status.
5. Prioritize the creation of a care delivery model encompassing the spectrum of advanced chronic kidney disease (CKD) for the duration of patient's life, including both individuals receiving and not receiving kidney replacement therapy and prioritizing transplantation (including pre-emptive transplantation) or comprehensive conservative care management as appropriate, aligning incentives to deliver the most high-quality, cost-effective, individualized care for patients with kidney diseases.

Prospective Payment System (PPS)

Payment for More than Three Hemodialysis Treatments per Week

CMS has expressed concern regarding payment for hemodialysis (HD) when more than three treatments are furnished per week. Since the composite rate system was implemented in the 1980s, CMS has reimbursed facilities for up to three HD treatments per week with additional HD treatments reimbursed if patient factors, such as heart failure, provided medical justification for more than three treatments per week.

CMS analyzed 2015 ESRD facility claims data and found discrepancies between HD treatments furnished and treatments billed. CMS has proposed the creation of an equivalency payment mechanism to address these discrepancies; this mechanism would serve three purposes: 1) provides a means to pay for more than three HD treatments per week in the absence of medical justification; 2) encourages facilities to report all treatments furnished; and 3) allocates the total amount of payment based on three HD sessions per week to match the actual number of treatments furnished.

ASN understands CMS' desire to obtain accurate data concerning the number of treatments provided to dialysis patients. However, ASN does not concur with the statement that facilities are currently unable to report extra dialysis sessions; facilities can identify sessions that do not meet the medical justification criteria as "non-covered" and can report sessions that do meet the medical justification criteria justified via a modifier. In order to achieve the goal of understanding the number of treatments provided, ASN encourages CMS to have all treatments documented using this existing mechanism, rather than establish a new payment equivalency system. The goal of CMS' proposal is to obtain a better understanding of the number of treatments furnished; specifically, the proposal by CMS does not significantly alter the payment amount beyond the three times per week levels for patients who do not meet the medical justification criteria.

Because a mechanism already exists to collect data on treatments provided that is less burdensome than the proposed new mechanism to create an equivalency payment—when no changes in payment would be made—the society believes CMS should stay the course with the existing mechanism and clarify the reporting expectations.

CMS also notes that it does not propose any changes to the existing medical justifications policy. While generally supportive of the current medical justifications approach, ASN observes that it can create administrative burdens and, in some cases, interfere with the patient-physician relationship. Due to the heterogeneity with which various Medicare Administrative Contractors (MACs) interpret what is medically justified, clinicians in some areas have less latitude to provide what they believe is medically justified care. For example, it may be appropriate for certain patients who have benefitted from a fourth dialysis session in one week to receive a fourth dialysis session in the following week as a prophylactic measure to prevent an adverse outcome from occurring again. ASN strongly believes CMS should urge all MACs to approach medical justification with a consistent, broad view and a respect for physicians' responsibility in determining—in consultation with their patients—what constitutes medically necessary additional dialysis sessions.

In summary, ASN supports CMS' efforts to obtain more data concerning the number of treatments provided to dialysis patients but encourages the Agency to do so in the least burdensome manner possible, not implementing a new equivalency system. Related, ASN encourages CMS to consider ways to ensure MACs honor physician latitude to prescribe appropriate dialysis more than three times per week in the context of the medical justifications policy.

Home Dialysis Training Payments

ASN is a strong proponent of home dialysis modalities as important options that should be available for patients and appreciates the Agency's continued attention to this issue. There are many factors influencing whether a patient and their family and care team determine whether home dialysis is the right option and, as ASN has observed in previous comment letters, the availability of resources to optimally train patients and their care providers through home dialysis training payment is likely an important factor.

ASN commends CMS for proposing an increase to the training payment add-on. The society is also supportive of efforts to obtain better data regarding home dialysis training and retraining costs. Some research has shown that individuals starting peritoneal dialysis commonly develop complications like peritonitis, hospitalization and transfer to catheter-based hemodialysis within the first 90 days of dialysis initiation. These data suggest that adapting to self-care dialysis is challenging and may indicate a need for improved initial training and a targeted increase in early re-training interventions.¹

While supporting the proposed payment increase, the society urges CMS not to require budget neutrality as a condition of its implementation. First, ASN does not agree that the statute requires CMS to make this a budget-neutral change. Additionally, the intent of the training add-on payment is to ensure that facilities are adequately reimbursed for the cost of training those patients who select home dialysis. It does not follow that the cost of care for patients who select to receive in-center dialysis decreases when other patients select home dialysis. These two

¹ "First-Year Outcomes of Incident Peritoneal Dialysis Patients in the United States", Joseph Pulliam, et al., *American Journal of Kidney Diseases*, [http://www.ajkd.org/article/S0272-6386\(14\)00821-X/references](http://www.ajkd.org/article/S0272-6386(14)00821-X/references)

costs are independent. Expecting budget neutrality could result in underfunding other dialysis modalities to cover increased costs of home training. ASN believes such a trade-off is quite simply not the intent of laws governing the PPS. Thus, applying budget-neutrality to fund increased home training expenses simply does not make sense.

ASN also observes that, were CMS to take a holistic view of the costs versus the savings associated with having more eligible patients select home dialysis, it may discover that additional home dialysis training costs are in fact more than recouped as a result of fewer hospitalizations, fewer ED visits, and lower medication use in the home dialysis patient population versus the in-center hemodialysis population. Taking the long view, any investments in appropriately reimbursing home dialysis training may recoup themselves over time².

While ASN recognizes that CMS does not typically make such comparisons across parts of Medicare, the society nonetheless believes this is further evidence that the approach to impose short-term budget neutrality is not logical.

The difference between training costs for HHD and PD is another nuanced issue ASN believes CMS should consider moving forward. While ASN recognizes that CMS does not currently have the data it desires to differentiate between these two home dialysis modalities and supports the Agency's proposals to obtain better data, the society observes that separately evaluating the adequacy of the payment for each unique modality may be warranted.

CMS also requested information regarding patient retraining for home dialysis; ASN appreciates the Agency's interest in obtaining more information about this activity and would be pleased to provide additional context beyond this letter. In short, there are numerous important reasons why patients and their caregivers need to access retraining for home dialysis. A recent informal survey of ASN members suggests that common reasons nephrologists determine retraining is warranted include:

1. After any episode of peritonitis, bacteremia, or infection in which root cause analyses suggests that it is because of a break in sterility of technique.
2. After prolonged period of hospitalization, including following or in anticipation of discharge from a skilled nursing facility, when the patient or caregiver may be out of practice.
3. After changes in HD access (catheter to fistula or graft, new fistula or graft, especially if on the opposite side, or difficulty with cannulation at a particular part of a fistula or graft).
4. Training for use of a heparin pump.
5. Change in dialysis machine or equipment.
6. When there is a change in who is going to perform or assist with home PD or HD; examples include if a patient has had a stroke and now their spouse will do PD or if one caregiver is replaced by another.

² "Intensive Hemodialysis and Mortality Risk in Australian and New Zealand Populations", Mark R. Marshall, et al., *American Journal of Kidney Diseases*, [http://www.ajkd.org/article/S0272-6386\(15\)01259-7/abstract](http://www.ajkd.org/article/S0272-6386(15)01259-7/abstract)

"Nephrologist Caseload and Hemodialysis Patient Survival in an Urban Cohort", Dr. Kamyar Kalantar-Zadeh, et al., *Journal of the American Society of Nephrology*, <http://jasn.asnjournals.org/content/early/2013/08/06/ASN.2013020123.abstract>

7. When home dialysis patients move and/or transfer to another program (whether permanently or temporarily), reflecting that protocols, equipment and care practices may differ among programs.

In summary, ASN thanks CMS for the proposal to increase the home dialysis training add-on but does not support the proposed budget-neutral approach. The society strongly urges the Agency to continue its tradition of supporting patient access to the choice of home dialysis by finalizing the increase *without* imposing budget neutrality cuts to the base rate. ASN also supports CMS' proposal to improve the data regarding home dialysis training and retraining, and stands ready to provide additional information or context as needed.

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. The society appreciated CMS' recent decision to cap the withholding for the outlier payment at 1%, reflecting the low percentage of facilities that have qualified for the current threshold. While this shift will help facilitate optimal patient care and to ensure access to care for higher risk dialysis patients, the society continues to believe the outlier payment amount should equal the withhold amount.

As CMS continues to assess the outlier policy in future years, ASN suggests one of two options: 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%. Again, the society appreciates that CMS has made adjustments in this area and hopes to see refinements continue in the future.

Quality Incentive Program (QIP)

Topped Out Measures

ASN remains committed to the concept of parsimony in its approach to measures in the QIP, and the society urges CMS to promptly recognize when a measure is topped out, either statistically or clinically, and remove it from the QIP. Eliminating topped out measures is crucial to avoid unintended consequences, including limiting clinicians' 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 areas of focus for quality improvement.

Hypercalcemia

As articulated in prior comment letters, ASN views hypercalcemia as a weak quality measure in the QIP. This point was also made by the NQF in the endorsement process. However, the society recognizes that CMS is strongly encouraged in the statute to include mineral metabolism measures. As such, ASN recommends that the hypercalcemia measure should be reclassified as a reporting measure, particularly until oral drugs become a part of the bundle. While oral drugs remain excluded from the bundle, strong financial incentives exist to replace active vitamin D use (and its analogues), which are included in the bundle, with oral calcimimetics, which can prevent hypercalcemia and are not included in the bundle. This further underscores the unnecessary nature of a clinical hypercalcemia measure.

NHSN Dialysis Event Reporting Measure

CMS proposes to create a new Safety Measure Domain that combines a reintroduced Expanded NHSN Dialysis Event Reporting Measure with the NHSN Bloodstream Infection (BSI) Measure from the Clinical Measure Domain. CMS also proposes to create a third “Safety Measure Domain” comprised of these two measures to join the existing Clinical and Reporting Measure Domains.

ASN applauds CMS’ focus on the importance of reducing infections for all ESRD patients. The reduction of dialysis-related infections is critical to the health, safety, and overall quality of life of these patients; this is a point that cannot be stressed enough. However, the society is concerned by the approach CMS proposes to accomplish this important goal and suggests that an alternate tactic would be more effective and valid. At this time, the society cannot support the clinical NHSN BSI measure or the new domain as proposed. ASN strongly recommends that, if CMS adds this measure or creates a Safety Measure Domain, it be only a reporting approach with no penalties associated with self-reported infection rates.

The NHSN Bloodstream Infection measures strive to both achieve full and transparent reporting of all dialysis events and to grade facilities on BSI rates in order to improve clinical practices and thereby reduce infection rates. The combination of these two goals, with the proposed creation of a clinical measure domain, unintentionally places these intentions at cross purposes. We appreciate that CMS recognizes this conundrum, discussing it at some length in the text of the proposed rule and offering the entire safety domain as a means to thread this needle between disincentivizing and incentivizing infection reporting; unfortunately, the proposed solution results in a domain that will lack validity. Multiple studies have demonstrated that the data submitted to the NHSN are not valid, in part due to infections that are diagnosed in hospitals. As the literature cited here indicates, hospitals cannot directly report to NHSN and lack a reliable mechanism to provide dialysis facilities with complete information.^{3,4}

Indeed, CMS states in the proposed rule that the PY 2015 NHSN Dialysis Event Reporting Measure results and results from PY 2014 NHSN data validation feasibility study suggest that dialysis events were underreported by as much as 60 to 80 percent. ASN understands CMS’ desire to both obtain complete reporting and to grade facilities on outcomes—and the society supports the full and transparent collection of meaningful data to advance the care of all ESRD patients. Yet since this measure has not been validated and has been shown in the past to be unreliable, the measure cannot meet its goals.

Even if the measure were to be fully validated, combining accurate reporting with a scoring formula that penalizes facilities’ reimbursement when infections are accurately reported as such appears likely to produce less than desirable results. ASN believes that the proposed approach will not foster a culture of infection prevention in the future, which is the true purpose of the QIP, thereby jeopardizing true quality improvement in this crucial aspect of care.

Other high-risk sectors of society have similarly dealt with this type of reporting dilemma, and ASN believes these examples offer worthwhile insight. For instance, the Federal Aviation Administration (FAA) instituted a “no-fault” incident reporting system in 2008. While

³ Duc B. Nguyen, et al. Completeness of Methicillin-Resistant *Staphylococcus aureus* Bloodstream Infection Reporting from Outpatient Hemodialysis Facilities to the National Healthcare Safety network, 2013. *Infection Control & Hospital Epidemiology*, http://journals.cambridge.org/abstract_S0899823X15002652.

⁴ Nicola D. Thompson, Matthew Wise, Ruth Belflower, Meredith Kanago, Marion A Kainer, Chris Lovell and Priti R. Patel. Evaluation of Manual and Automated Bloodstream Infection Surveillance in Outpatient Dialysis Centers. *Infection Control & Hospital Epidemiology*, Available on CJO 2016 doi: 10.1017/ice.2015.336.

counterintuitive at face value, this approach fostered an environment in which the focus was appropriately placed on identifying and addressing the root causes of errors rather than avoiding the detection of errors altogether. ASN recommends that CMS take a similar approach when dealing with the broader issue of reporting in this situation. Fostering a culture of safety that is focused on data gathering and observation over time is more likely to create an environment of true commitment to reducing infections.

In light of the concerns regarding the NHSN clinical measure's fundamental validity and the data supporting the efficacy of creating a blame-free culture to improve safety, the proposal to double down with the combination of these two measures in a new clinical domain – especially when one of those measures has proven to be weak historically – appears very likely to cause more harm than benefit and to inappropriately penalize facilities who invest time and effort in thorough event investigation and reporting.

ASN strongly recommends that this proposed measure set serve only as a non-punitive reporting measure, and, if the domain is created, the safety domain be reporting-only. With regard to the reporting measure, if this is emphasized, ASN recommends a graded approach such that there is not a dramatic decline between 11 and 12 months of reporting but rather a step-wise reduction in points based on the proportion of months adequately reported. Critically, ASN notes that risk for or impact of infections are indirectly captured in other metrics that are either in the QIP or being developed for the QIP, including the SRR, SHR, SMR and VAT metrics.

Another alternative CMS could consider is a year-over-year approach to assess a given facility's progress over time, although this would require adequate risk adjustment and/or exclusion of very high risk populations (i.e., active chemotherapy, post bone marrow transplant, AIDS, substantial immunosuppression). ASN believes either of these approaches would better achieve the crucial goal of reducing infections. However, if CMS proceeds with its proposed design of this Safety Measure Domain, ASN strongly urges enhanced risk adjustment and that the reporting mechanism be weighted greater, such as at 80 percent, and the clinical mechanism be weighted much less, such as at 20 percent.

ICH CAHPS Measure

ICH CAHPS initially required 30 responses surveyed in a one year period to be deemed a valid result. In fact, facilities treating fewer than 30 eligible patients are excluded from the ICH CAHPS. In subsequent reporting years, that requirement has gone to a minimum of 30 responses but surveyed twice in a one year period – one in the spring and one in the fall. ASN has concerns about the intention of CMS in this approach and statistical validity. For example, if the supposition was that 30 individual responses per year were required for validity, having a total of 30 responses with twice a year administration is, by statistical necessity, not valid if the same patients are responding more than once; this reflects the fact that more than one response from the patient is not an 'independent sample'. Stated plainly, 30 patients responding once is far more meaningful for this type of survey design than 15 patients responding twice, as the lack of independence of samples decreases the effective sample size. To take it to the extreme in an example, if the same patient responds 30 times to a particular survey or test, that is not the same as 30 patients each with a single result on that survey or test as one individual has all of the influence. These are concerns that CMS needs to address.

Given this, ASN feels strongly that independence of samples should be accounted for in determining the number of responses needed for valid performance assessment on ICH CAHPS.

Measure Domains Weighting

ASN observes that within the Patient and Family Engagement/Care Coordination Subdomain, only 55% of facilities are estimated to be eligible for the ICH-CAHPS measure. Consequently, many facilities will be left with only the SRR measure in that subdomain. The society asks CMS to clarify what will happen to those facilities' scores, as it seems unfair that an entire domain should be dominated by this one measure.

Replacing the Mineral Metabolism Reporting Measure with a Serum Phosphorous Reporting Measure

CMS proposes to replace the current mineral metabolism measure with a serum phosphorus measure, a change ASN does not oppose. However, ASN has long stressed the need for parsimony in the QIP and other programs that comparatively assess quality of care performance. ASN believes that in this instance CMS is effectively replacing one topped out measure with another topped out measure that will not be seen as highly meaningful for dialysis patient care. However, the society recognizes that CMS is congressionally mandated to include a measure in this arena and believes the serum phosphorus measure is an unobjectionable way to meet that requirement.

Ultrafiltration Measure

ASN supports incorporation of an Ultrafiltration Rate (UF) reporting measure that is based on the NQF-endorsed # 2701 "Avoidance of Utilization of High Ultrafiltration Rate." ASN urges CMS to align the QIP reporting measure as closely as possible to the NQF endorsed measure, as important differences between the NQF endorsed measure and the measure in the proposed rule exist. In addition, ASN recommends waiting for more definitive evidence that higher UF rates cause worse outcomes prior to transitioning this reporting measure to a clinical measure.

Standardized Hospital Ratio (SHR) Measure

Hospitalizations are a crucially important aspect of quality of care both in terms of outcomes and in terms of patient experience of care. ASN supports the proposed concept of adding an SHR measure to the QIP, and applauds CMS for adding an aspect of risk-adjustment to the measure. This measure is improved over the current SHR. However, the society believes that the specific risk adjustment strategy used to develop the proposed measure is problematic and urges CMS and the contractor to revisit the predictive modeling approach before including the measure in the QIP. These concerns have been described in prior letters from ASN, and focus on the use of a 'kitchen-sink' approach to variable inclusion in the predictive model. This approach resulted in a metric that deems the constellation of prostate, thyroid, and kidney cancer together as having twice the **protective** effect against death that gangrene has for harm and resulted in diabetic retinopathy appearing protective. These associations more likely represent coding habits and access to care rather than true risk factor-outcome relationships and, as coding practices and clinical practices change, will result in an increasingly poor adjustment model. This issue is correctable but requires revisiting the predictive model building approaches with inclusion of clinical knowledge.

In summary, ASN conceptually supports a hospitalization measure in the QIP and urges CMS to implement this measure after optimizing the risk-adjustment strategy and related data concerns.

QIP Scoring

The principle with scoring the QIP is that if a facility performs at or better than the achievement threshold that facility receives at least 1 point, at or better than the performance standard that facility receives at least 6 points, and at or better than the benchmark that facility receives 10 points.

In the currently applied methodology, the decisions made on how to round the facility performance rates ASN concern, particularly on metrics where the achievement threshold and/or benchmark within a few integers of each other, such as with hypercalcemia and adequacy.

Additionally, rounding rules are applied inconsistently. For the Kt/V Dialysis Adequacy Measure Topic, Hypercalcemia and the VAT measures, rounding of the facility performance rate is to the nearest integer while for the NHSN measure, the facility performance rate is rounded to the same number of decimal places (three decimal places) as the achievement threshold and benchmark, and for the SRR the facility performance rate is rounded to two decimal places while the achievement threshold and benchmark are to three decimal places.

Typically, when one is rounding numbers, they round to the same number of decimal places as the comparison. Accordingly, if the achievement threshold for hypercalcemia is reported to 2 decimal places, there is no reason why the individual facility performance rate is not also rounded to 2 decimal places as conforms to standard practices in mathematics and statistics.

Using hypercalcemia as an example in PY 2017 data, the facility performance rate used in QIP calculations are limited to 6 integers: 0, 1, 2, 3, 4, or 5 or higher. This actually results in the inability to achieve odd numbered measure scores on that metric; a facility can get 0, 2, 4, 6, 8 or 10 but it is impossible, given the achievement threshold and benchmark for this metric, to get 1, 3, 5, 7, or 9 points. To give a second example, again using hypercalcemia and PY 2017 data, if a facility performance rate is 4.50, this is a lower rate than the achievement threshold and the facility should get 1 point. However, this rounds to 5, resulting in a number higher than the achievement threshold and 0 points. In a third example, again using the PY 2017 achievement threshold and benchmark, if a facility has a performance rate of 99.44 percent on the Kt/V Dialysis Adequacy Measure Topic for Adult Hemodialysis, this exceeds the benchmark of 99.35% and the facility should get 10 points on the achievement score based upon the principles stated in the proposed rule and in prior final rules. However, because of rounding, the facility only gets 9 points.

ASN encourages CMS to use facility rates rounded to the same number of decimal places as the achievement thresholds and benchmarks used elsewhere in the performance measure score calculation, regardless of the metric. In the absence of incorporation of variance into metrics (i.e., imprecision in individual facility estimates that can be quantified using standard deviations or standard errors), rounding to the same number of decimal places as the achievement threshold and benchmark results in a more robust and reliable QIP scoring system.

Future Measures

CMS outlines several areas for potential new QIP measures for future consideration, and ASN appreciates the Agency's efforts to solicit stakeholder input early in the process. ASN agrees that several of the aspects of care CMS is considering assessing have important value from clinical and patient perspectives, and offers comment below. However, as CMS considers inclusion of new measures in the ESRD QIP, ASN once again urges the Agency to implement a parsimonious approach to guide the addition of new QIP measures. Avoiding measure duplication and inclusion of less meaningful measures, as well as avoiding adding new measures without retiring other measures, a strategy that dilutes the focus on and influence of each measure in the program, is key in order for the program to meet its goals.

ED Measure

A measure assessing ESRD patients' level of ED services utilization is a potentially interesting concept to consider for the QIP. Depending on the design and validity of an ED measure, ASN would potentially support it in the future. However, a successfully-designed ED measure would likely assess similar aspects of care that would be assessed by the SHR and SRR measures. This suggests that implementing an ED measure may negate the need for maintaining or implementing these other similar measures. ASN would encourage CMS to prioritize selecting the single measure that best captures this aspect of care.

Furthermore, there are several logistical factors that may complicate development of a robust ED measure. For example, many EDs have multiple observation-type programs and categories in place that may make it difficult to precisely determine when patients truly access ED services. The possibility that an ED measure could create unintended consequences in terms of patient access must also be carefully assessed in measure design. Additionally, an ED measure would require adequate risk adjustment, incorporating social factors like homelessness that may result in disproportionate use of emergency departments that are beyond the influence of dialysis facilities.

Transplant Measure

CMS indicates that it is considering developing a quality measure to examine kidney transplantation in patients with ESRD. Aligned with the Society's position that kidney transplantation is the treatment of choice for most patients with advanced CKD and ESRD, ASN welcomes efforts by CMS to foster both patient access to kidney transplantation as well as increase live and deceased kidney donation.

The difficulties facing different patient subgroups in need of kidney transplantation have been well-documented and are numerous. First, all patients confront the challenge of scarcity of a life-extending kidney transplant, with a vast disparity between the demand and availability. While over 108,000 patients are currently on the kidney transplant wait list, only 17,000 kidney transplants will be performed in the U.S. in 2016. Second, beyond the overall shortage of available kidneys, numerous other barriers exist particularly among minority groups. For example, while the incidence of ESRD in African Americans is four times greater than in their White counterparts, African Americans remain less likely to be referred for, or undergo kidney transplantation. Third, patients who are very highly sensitized are often hard to match and tend to experience longer wait times.

Finally, the long waiting times associated with limited availability, frequently results in older patients and those with diabetes and other co-morbidities, losing their window of opportunity for a kidney transplant and greater longevity because of a further deterioration in their health status while on the list to the point that they are no longer acceptable transplant candidates. While recent changes in the kidney allocation system (KAS) represent a first pass at addressing some

of the disparities in the system, time accumulated on the waiting list is still the major determinant of when most patients will be transplanted. These preceding scenarios underscore that referral for transplant as soon as possible is critical in order to give patients their greatest chance of finding a suitable match while still in acceptable health.

The need for better access to transplantation is clear. However, as outlined below, the development of a quality measure(s) to support that crucially important goal is a challenging endeavor. As with any quality metric, it is important that the aspect of care assessed is within the control of the entity being evaluated. The society hopes these comments are useful, but also reiterates that, as CMS ponders the creation and potential addition of quality measures to the QIP, an emphasis on parsimony is vital. Were CMS to develop this or other measures in the future, ASN would urge the Agency to simultaneously retire other existing measures in the QIP.

Continuum of Care

ASN believes strongly in a continuum of care perspective in medicine and especially in nephrology. A patient's progression from CKD to kidney failure and possible dialysis to transplantation, potentially back to dialysis or to re-transplantation, and, ultimately, to end-of-life care is a difficult and defining process for many patients. Ideally, a patient with kidney disease will be followed throughout their journey by a nephrologist who can serve as a "captain" – but in the current health care delivery system, too often this is not the case. Moreover, the current delivery system tends to "silo" patients in a manner that is not ideal for transplantation. Ideally, an integrated care delivery system would unite care processes and care teams assuming responsibility for patients with CKD all the way through end-of-life care, thereby aligning incentives to best prepare patients for transplantation as early as possible. In lieu of such alignment, significant challenges exist to both promoting transplantation as an option and to evaluating the quality of and access to the transplantation process.

Many individuals and facilities involved along the path of care make it difficult to attribute transplantation access or outcomes to solely one individual or group. While the nephrologist endeavors to slow the progression of CKD, at some point, the patient with CKD may require kidney replacement therapy (ideally a pre-emptive transplant, or a transplant). A dialysis patient's care will continue to involve their nephrologist, their PCP, dialysis nurses, dialysis social workers and other dialysis facility staff. The dialysis patient's transition of care to a transplant program is a complex, multifaceted process involving not only the clinicians described above, but also the transplant nephrologist and transplant center team. During this process, ESRD patients are typically under the care of one nephrologist for dialysis and another nephrologist for waiting list management and preparation for transplant. The significant overlap makes it difficult to ascertain which aspects of transplant care are directly under the control of any one stakeholder. This dynamic renders development of quality metrics for any entity involved in this process, including dialysis facilities, difficult.

There are several steps in the transplant process—education, screening, referral, evaluation, and transplantation—that could be considered for a quality measure, but each have limitations, discussed below.

Education

Education is a crucial first step in enabling patients and their families to consider transplantation as an option. It is evident, however, that mechanisms to educate patients regarding transplantation vary significantly across dialysis facilities and too often are suboptimal, even cursory. The society is aware that the 2728 form includes a "checkbox" asking whether patients have been informed of their modality choices, including transplantation, but does not believe this

checkbox reflects optimal education—a belief several published studies confirm. However, creating any measure to assess transplantation education would be difficult at this time as no standard curriculum or validated instrument exists to assess kidney replacement modality knowledge (and if it did, dialysis patients already suffer survey fatigue). Furthermore, as with any treatment modality options, education can be influenced by a patient’s receptivity at the time of the session. If that receptivity is not optimal, a single session that may be enough to check off a box may not be sufficient for the patient to make an informed decision. ASN strongly believes that the quality of transplant education should be improved but does not perceive that this area is ripe for measure development at this time.

Screening and Referrals

Screening patients for referral to a transplant facility for transplant evaluation is a critical step and one ASN wholeheartedly supports. Under optimal conditions, there would be clearly identifiable markers and standards for screening that would be readily adapted and easily incorporated into the day-to-day operations of every dialysis facility. However, that is not the case. In the meantime, it is unclear what the appropriate balance might be between screening all patients and screening only a limited number of patients who appear highly likely to be good candidates. ASN also observes that the nephrologist plays a leadership role in screening patients for transplantation—so while this aspect of the transplant process is crucial, responsibility is also shared.

ASN agrees that, if early referral leads to earlier kidney transplant, there can be measurable and significant increases in the quality of life and life expectancy for patients with ESRD. Again, for many patients, pre-emptive transplantation would be optimal—but the current care delivery system is not optimized to promote this modality. Similar to screening, it is unclear what constitutes an appropriate level of referrals to a transplant facility. Furthermore, different transplant centers maintain very different standards regarding the types of patients they will even evaluate. This occurs for a variety of reasons, including the level of competition among transplant programs in the area, and how conservative or aggressive the transplant care team is. Consequently, referrals of patients that would have a reasonable chance at evaluation in some parts of the country would be nonstarters in other regions. ASN is not implying that this heterogeneity is necessarily an optimal situation, but it points to the difficulty of developing a quality measure assessing referral rates.

Evaluations

The evaluation of ESRD patients as early as possible is a goal supported by ASN and by OPTN/UNOS. However, the timing of referrals by the nephrologist can sometimes be delayed by the need to improve an individual patient’s health to ensure that patient’s maximum chances of being accepted for transplant. Additionally, in some areas with long wait list times, patients without potential living donors may choose to delay evaluation until they have accrued a certain amount of time on the wait list, since under the current allocation system they begin accruing time at the onset of ESRD regardless of whether they have been formally evaluated. These are key steps for successfully moving to transplantation. Ultimately, however, the patient must be evaluated by the *transplant team* and then receive the team’s subsequent approval. As such, designing a dialysis facility quality metric around transplant evaluation, when the patient is actually evaluated by a transplant center, seems incomplete.

UNOS requires transplant centers to report the results of transplant evaluations to patients and the referring nephrologists within 10 days of the transplant team’s determination of a patient’s acceptability for transplantation; this notification includes the reason they were denied if not approved. But, a developing any quality metric based on this information at this juncture

concerns ASN as unintended consequences could occur, prompting either referral of only the healthiest patients or referral of many patients who are not good candidates—which would overwhelm most currently available transplant evaluation systems, and slow the process for truly eligible patients.

Transplantation

ASN is committed to access to kidney transplantation for all patients healthy enough to benefit. Assessing rates of transplantation would appear to be one avenue to assess this ultimate goal. However, designing a dialysis center-based quality metric that assesses successful transplantation rates appears to the society to be challenging for two major reasons. First, it is unclear what the standard for success should be; specifically, where should the bar be set for achievement? If set too low, it would be ineffective in assessing access for all patients who are reasonable candidates. If set too high, it would create pressures to transplant people who are not good candidates or would punish facilities without a healthy patient population. Furthermore, as described above, there are numerous factors and processes that lead up to transplantation that are not in the control of the dialysis facility. Under these conditions, the development of a transplant rate quality metric under the QIP seems problematic. To create a quality measure that does not recognize the many different parts involved is unlikely to benefit patients or yield any meaningful change.

ASN commends CMS' commitment to access to kidney transplantation for patients with ESRD and wishes to work with the agency to support this commitment. In general, ASN encourages CMS to view patient care from CKD to transplantation as a multifaceted process with many involved parties. The society believes that dialysis facilities have an important role to play as one of the many stakeholders influencing access to transplantation. There are a number of improvements in the development, execution, and standardization of the transplant process that could be made in the context of the dialysis unit—but many of these aspects of care do not appear to be prime for quality measure development. Further research to determine optimal dialysis patient referral, evaluation, and transplant patterns is clearly needed, and such information could help guide better care and potentially inform a quality measure in the future. As discussed elsewhere in this letter, a care delivery model encompassing people with advanced CKD (and including transplant care) would promote greater attention to pre-emptive transplantation, and transplantation in general.

Again, ASN thanks CMS and reiterates the society's commitment to work with the agency to develop a greatly needed care delivery model that supports the patient from CKD to dialysis to transplantation to end of life care. However, the society would welcome the opportunity to discuss this and all other potential transplant-related quality metrics the Agency may be considering in the future.

Certified Health IT

CMS encourages stakeholders to utilize health information exchange and certified health IT to effectively and efficiently help providers improve internal care delivery practices, support management of care across the continuum, enable the reporting of electronically specified clinical quality measures, and improve efficiencies and reduce unnecessary costs. As adoption of certified health IT increases and interoperability standards continue to mature, CMS says HHS will seek to reinforce standards through relevant policies and programs.

ASN believes that significant opportunities exist for health IT to improve nephrology care, and hopes that their increased adoption will meaningfully improve patient outcomes in the future. However, in order for health IT, including EHRs, to achieve their potential in advancing care for

patients, physicians and other health professionals need solutions that permit disparate EHRs to interface and provide genuine interoperability. Until EHR technologies achieve better interoperability than currently available, any EHR adoption requirements will be relatively ineffective at driving improved patient outcomes. HHS should not develop programs that impose requirements that outpace the development of wholly interoperable systems – particularly in the ESRD space, where patient care is shaped by numerous facilities, systems and health care professionals.

Rates vs. Ratios

For future years of the QIP, CMS proposes expressing the ratios as rates, which may be easier to understand for some audiences. While recognizing CMS's desire to make this data more comprehensible, ASN has concerns about the proposed methodology for converting the standardized ratios into facility rates. For example, the proposed approach to simply multiplying the SMR by the national median death rates ignores the fundamental uncertainty inherent in the SMR models that allow for a range of expected death rates for a facility that does not significantly deviate from national averages. Instead, ASN suggests that CMS explore a methodology that tracks year over year case-mix adjusted, normalized death rates from facilities that are computed directly and independently from the SMR. These comments apply generally to conversions of standardized ratios to rates as proposed by CMS.

Acute Kidney Injury Care in ESRD Units

Implementation of Section 808

Overall, ASN commends CMS for its proposals regarding implementation of Section 808 of the Trade Preferences Extension Act of 2015 and generally supports the approach outlined in the proposed rule. Here, the society offers additional recommendations it believes will help ensure the optimal quality of care for patients with AKI-D in ESRD outpatient units. ASN also underscores that recommendations concerning optimal care for patients with AKI-D requiring dialysis (AKI-D) may evolve over time as new evidence becomes available and as community consensus emerges. The society encourages CMS to continue to seek broad stakeholder input from the kidney community as it refines the implementation of Section 808 in coming years.

As CMS recognizes, patients with AKI-D discharged from the hospital to outpatient ESRD facilities to continue dialysis treatments while awaiting recovery are distinct from the patients with ESRD, who have little or no chance of recovery. Patients with AKI-D have the potential to recover kidney function and come off dialysis, although recovery may be dependent on how closely they are followed and on the attention paid to hemodynamic factors. Nephrologists, dialysis facilities, and other care providers must recognize this distinction so that they can focus on promoting recovery, avoid any potential dialysis and non-dialysis interventions which could further harm the recovering kidneys, and hence minimize complications, hospital readmissions and costs. To promote these goals, the patient's nephrologist and the medical director of the dialysis unit have key roles in the education of dialysis staff, advanced practitioners and the patient. When managed appropriately, many AKI-D patients will recover; therefore, it is desirable that the care team implement a care delivery process that facilitates their rehabilitation and enhances patient and family experience.

Definition of AKI-D

ASN supports the proposed definition of an individual with AKI-D as "an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b) (14)." Based on available evidence, it is not yet possible to predict which patients will or will not recover kidney function and if so, when.

The new law permits outpatient ESRD facilities to provide dialysis to AKI-D patients who are Medicare beneficiaries and to receive payment for doing so. CMS proposes, appropriately, that patients diagnosed with AKI-D would be considered as having AKI-D until a nephrologist makes a determination regarding whether or not their patients are likely to recover or are unlikely to recover and therefore should be designated as having ESRD. The long-term kidney functional status of many patients with AKI-D can usually be determined within 90 days, but some patients may take longer than 90 days to recover. It will be important for CMS to clearly communicate that physicians have latitude to make what ultimately is a clinical assessment concerning recovery versus ESRD on a timeline appropriate for each individual patient. Given this patient-to-patient variability and current status of knowledge, ASN urges the agency to refrain from establishing policies identifying a specific time frame for switching a patient's status from AKI-D to ESRD.

ASN recognizes that many patients who received a kidney allograft are still considered to be part of the ESRD program. However, ASN urges CMS to explicitly include transplant recipients who develop AKI-D *after* having a functioning allograft, in the rules governing delivery of care, reporting, and conditions for coverage for other AKI-D patients. ASN believes that restoration of allograft function in transplant recipients with AKI-D is a critical outcome, which will require optimal care. ASN anticipates that the care of these patients would be closely coordinated with the transplant nephrologist and the transplant care team—and that high rates of native kidney function recovery would be expected in this patient population.

AKI-D Care: Reflection on differences in patient care needs

In keeping with the theme that patients with AKI-D are fundamentally different than patients with ESRD, ASN commends CMS for proposing to pay for dialysis more than three times per week if necessary, and urges the Agency to finalize this recommendation. This appropriate reimbursement policy should be clearly and unequivocally conveyed to all MACs. ASN also endorses the recommendation of not applying the ESRD case-mix adjusters to individuals with AKI-D. ASN also supports CMS' proposal to identify AKI-D patients via a specific code, which will facilitate the identification of patients with AKI-D for appropriate reimbursement and data analysis in the future.

ASN strongly supports the proposal to pay separately for costs of items and services provided to beneficiaries with AKI-D, as part of the AKI-D care in a dialysis facility which is not part of the ESRD PPS bundle. Facilities should be appropriately reimbursed for these items.

ASN also reiterates that nephrologists and other caregivers should implement active measures to promote and to monitor renal recovery. Besides the variation in frequency of dialysis compared to ESRD care, AKI-D treatment may also substantially differ from that of patients with ESRD in other ways. For some patients, this will include different rates of utilization of items, services, and resources as part of their AKI-D care in a dialysis facility that *are* part of the ESRD PPS base rate. In the future, CMS may determine that different payment rates or approaches are required to appropriately reflect the level of resources facilities use providing these items, services, and resources for this patient population.

Such differences might include, but are not limited to, dialysis duration and timing as well as increased frequency of laboratory tests and other ancillary studies. Monitoring of pre-dialysis serum creatinine and electrolytes, urine output, and 24-hr creatinine and urea clearance are particularly important, and, if done to monitor recovery in an AKI-D patient, should be separately billable. Active measures to promote kidney recovery include avoiding intradialytic hypotension,

optimizing the patient's volume status, avoiding the use of nephrotoxic agents, and adjustment of medications for changing (increasing or decreasing) renal drug clearance. Active measures to monitor recovery include, at a minimum, a weekly face-to-face evaluation of the patient by a physician and/or an appropriately trained advanced practitioner. More frequent evaluations may be necessary in early stages. When and if appropriate for each patient, the nephrology care team should begin pre-ESRD planning, including education about dialysis modality choices, permanent dialysis access options, and kidney transplantation.

The society notes that while some of the same tests are provided for patients with ESRD and for patients with AKI-D, it is important to recognize that the tests are used for fundamentally different purposes. The below list provides several examples.

- Monthly measurement of serum urea nitrogen to calculate Kt/V for adequacy of dialysis in ESRD vs. Weekly/Biweekly measurement of serum urea nitrogen and serum creatinine to assess recovery ("native kidney function") in an AKI-D patient.
- More aggressive fluid removal to reach a "dry weight" in ESRD vs. a more permissive and individualized strategy in AKI-D to avoid excessive intradialytic hypotension and avoid further ischemic kidney injury.
- More frequent monitoring of drug levels (for example Vancomycin) to ensure appropriate dosing in the face of changing renal clearance.

In light of these significant differences in care needs, ASN urges CMS to closely track the utilization of items and services that patients with AKI-D receive that are in the bundle, because it is quite possible that their rates of utilization of some aspects of their care may be higher. In the future, CMS may need to revisit this data to ensure that facilities (and clinicians) are fairly compensated for the provision of appropriate and medically necessary AKI-D care. Otherwise, dialysis organizations may be unintentionally incentivized to limit monitoring of endogenous kidney function and other variables in order to keep expenses commensurate with the revenues provided by the ESRD PPS bundle.

Relatedly, ASN also commends CMS for its proposals to monitor outcomes and practice patterns and as always, encourages the Agency to do so in as close to real-time as possible. Given the uncertainty regarding optimal care for patients with ESRD, the new approach to payment for AKI-D care in ESRD units and, for some facilities, a novel experience caring for patients with AKI-D, ASN believes that monitoring will be a vitally important activity for the agency on a frequent basis. Please refer to ASN's comments concerning data collection and sharing below for related observations.

ESRD Quality Measurement/Pay-for Performance Programs

Patients with AKI-D should not be included in ESRD Quality Reporting Programs. Because of the unique health challenges faced by patients with AKI-D, there are important differences between measures of high-quality care among patients with ESRD and those with AKI-D. ASN believes that the ESRD QIP is not appropriate for assessing quality of care provided to AKI-D patients, and strongly urges CMS not to include patients with AKI-D in the QIP. Reflecting on the same premise, these patients should not be included in the quality measures reported via the Dialysis Facility Compare online tool or the ESRD Five-Star programs.

Data collection

While ASN believes AKI-D patients should not be included in the aforementioned quality measurement programs, the society also believes that data collection is needed to identify clinical practice patterns associated with improved outcomes. There is concerning lack of

evidence to guide the clinical care of AKI-D outpatients, and the data sources to study this vulnerable population are currently very limited. Systematic collection of data will permit characterization of practice patterns and outcomes as well as monitor trends over time. Similar to the United States Renal Data System (USRDS), which greatly informs dialysis practices in the ESRD population, ASN recommends adopting analogous data collection tools with a specific focus on AKI-related data elements:

1. An “intake” form (analogous to CMS Form 2728)
2. A treatment form (analogous to CROWNWeb reporting)
3. A recovery form to document outcomes in patients who recover renal function (analogous to ESRD decertification)

Similarly, the society urges CMS to make available to the research community de-identified claims-based reporting concerning the care of AKI-D patients (identified as such via the proposed code) in ESRD dialysis units. Given the current paucity of evidence concerning best management strategies to promote recovery in this patient population, data collection will be essential to inform future research and to improve processes of care. Again, the society emphasizes that data collected should not be used to measure performance or in payment adjustment programs such as the QIP. ASN would be pleased to follow up with CMS and discuss these data collection recommendations in more detail.

Data and documentation

The availability of data and documentation of patient progress are important to inform proper patient care and to enable recovery of kidney function. Dialysis facilities should ensure that the data nephrologists and other members of the care team require, such as AKI-D status and laboratory values, are available in an accessible, user-friendly format to facilitate timely, accurate, and standardized documentation and communication. Documentation should reflect the nephrology provider’s assessment of the patient’s overall prognosis and likelihood of kidney recovery, patient education, and close monitoring of clinical parameters and medication adjustments.

ASN believes that existing information systems should be modified to support these objectives. While this is not necessarily an aspect of AKI-D care that would need to be assessed as part of the Conditions for Coverage, ASN is aware that at present data/documentation systems would not necessarily have the tools necessary for documentation of AKI-D patient care.

Transitions of care

A highly coordinated transition of care from hospital to outpatient unit is necessary for appropriate care of the patient with AKI-D. This important fact has implications not only for the dialysis care environment but also for the discharging hospital environment. Particularly, given the heterogeneity of AKI-D patients, which is even greater than among ESRD patients, the transition from hospital to outpatient ESRD unit will require special attention from the care team in both environments.

Initiation of outpatient dialysis treatment of patients with AKI-D should be performed with the goal of ensuring a seamless transition of care from hospital to outpatient unit. Critical factors needed for such a seamless transition include access to relevant medical records (from the hospital), review of those records and the initial treatment prescription, and establishing an effective communication process between patient, nephrologist and dialysis unit personnel about goals of care and monitoring for return of endogenous kidney function. The current

Conditions for Coverage appropriately specify that a comprehensive, timely intake process occur; this aspect of care is particularly critical for AKI-D patients.

Specialized strategies to differentiate patients with AKI-D

ASN observes that one of the most significant challenges to starting to dialyze Medicare beneficiaries with AKI-D in outpatient ESRD units will be developing a mechanism to distinguish between patients with ESRD and patients with AKI-D. For example, if 1 patient with AKI-D is receiving care in a unit with 50 ESRD patients, it may be challenging for staff to identify that individual and provide the unique care required.

Facilities caring for AKI-D patients may establish a “specialized AKI-D care program” for AKI-D patients within an ESRD outpatient unit. Creating a unique program of care delivery for AKI-D patients could help distinguish patients with AKI-D from those with ESRD. This could reduce variability and uncertainty for providers in the dialysis unit, galvanizing staff and the care team to focus on the unique needs of patients with AKI-D. This approach also may be limited by low numbers in any given facility at any given time. While ASN is not recommending that this approaches be mandated by CMS, the society believes it is are worth consideration by dialysis facilities and care teams nationwide.

Telemedicine

The use of telemedicine to facilitate the interaction between the nephrologist or other specialists and the patient with AKI-D receiving dialysis treatment in the outpatient ESRD unit should be strongly considered as a mechanism to help ensure optimal oversight and recovery—together with face-to-face in-person care.

In-person, patient-nephrologist interactions are ideal for this vulnerable AKI-D patient population, and in a perfect world this would be the case for every visit for every AKI-D patient. However, because the new law permits AKI-D patients to receive dialysis in any ESRD unit, it is conceivable that some AKI-D patients will receive their care in rural areas, or in areas where it is not feasible for the nephrologist to visit them in-person as often as would be ideal for AKI-D recovery supervision. The upside for patients is more convenient, patient-centered care closer to home—but the potential downside is lack of proximity to a nephrologist. So particularly for patients with AKI-D who reside in rural areas, having some interactions via telemedicine could help these patients receive optimal care close to home—even if home is not located near the nephrologist’s practice. ASN urges CMS to consider the advantages that adding nephrologist care and evaluation of patients with AKI-D to the list of telehealth eligible services would provide from patient experience and patient quality of life perspectives—recognizing that in-person face-to-face contact still plays an important role and cannot be totally substituted by telehealth.

Facilitating transplantation and establishing the date of ESRD Status

As discussed previously, ASN emphasizes that the date at which a patient is declared as having ESRD (i.e. a patient unlikely to recover kidney function) must be up to the discretion of the treating nephrologist. Some AKI-D patients will transition to ESRD status. Application of ESRD policies on facility payment, QIP data collection and administrative rules should be initiated at the time the patient is determined to be ESRD. However, ASN encourages CMS to use the date when dialysis was initiated for AKI-D purposes of determining transplant wait-list priority status and Medicare eligibility for patients who transition from AKI-D to ESRD. (This approach would not be appropriate for AKI-D patients who recover, come off dialysis, and no longer require RRT—even if they ultimately decline and become ESRD at some later date in the future).

This “backdating” would be a patient-centric mechanism to appropriately reflect the amount of time a patient was on dialysis—an important consideration in their wait-list priority status. From a patient’s personal perspective as well as from a health outcomes perspective, patients were on dialysis from the date they began receiving it for their AKI-D. It would be congruent with the reasons that patients who have been on dialysis longer—historically designated in the Medicare ESRD program as the date of the filing of the 2728—to receive that designation irrespective of whether they were on dialysis due to ESRD or AKI-D that preceded ESRD. Similarly, the society also encourages CMS to consider using this approach to establish patients’ initial eligibility for the Medicare ESRD program based on having an ESRD diagnosis. ASN believes that this approach is well within CMS’ authority and would be pleased to discuss this proposal in more detail with the agency at any time.

Comprehensive ESRD Model and Future CKD Care Delivery Models

ASN thanks CMS—and the Centers for Medical and Medicaid Innovation (CMMI)—for the opportunity to provide input regarding future changes to the CEC Initiative as well as to share thoughts concerning how future kidney care delivery models could improve the outcomes and quality of life for people with kidney diseases. The society commends the Agency for its interest in innovative approaches to care delivery and financing for beneficiaries with end-stage renal disease (ESRD) in future payment models and in relation to the second round of entry into the CEC Model to begin on January 1, 2017

ASN strongly believes that the best, most innovative approach to improve care for people with ESRD is to move “upstream” to address care for people with advanced CKD—as well as to move “downstream” to focus on access to transplantation as the gold standard of treatment for most people with kidney failure. This approach would overcome the silos that currently exist in caring for patients with advanced kidney disease.

Comprehensive CKD Care Delivery Model Concept

CMS asks how it can build on the CEC Model or develop alternative approaches for improving the quality of care and reducing costs for ESRD beneficiaries. The CEC Initiative is an important and innovative step for CMMI and the kidney community as a whole, and we should draw on its lessons and expand on its principles of integrated kidney care moving forward. ASN firmly believes the development of a “comprehensive CKD care delivery model,” that builds on the lessons and experiences from the ESCO program is the necessary next step to truly transform kidney care, implementing genuinely innovative strategies to improve the lives of people with kidney disease and tackling previously unexplored opportunities to reduce healthcare expenditures. ASN stands ready to work with CMS and CMMI to shape this concept—as a physician-focused payment model and/or an alternative payment model (APM) or advanced APM (AAPM)—and encourages the Agency and the Secretary to prioritize a “comprehensive CKD care delivery model” approach to achieving the goals outlined in question four and elsewhere in this section of the proposed rule.

A comprehensive CKD care delivery model would be broader than the ESCO—encompassing patients with advanced CKD and including kidney transplant recipients—coordinating their transitions across kidney disease stages, and managing and slowing progression of kidney diseases and other complex chronic conditions that are common in the kidney patient population. Reflecting the fact that transplantation is, for many patients, the optimal therapy for ESRD, this model would include transplant recipients for the duration of their lives. This approach would, appropriately, create inherent incentives to promote transplantation and pre-emptive transplantation for the greatest number of patients possible who are candidates.

Besides a focus on promoting access to transplantation, ASN envisions that a comprehensive CKD model would emphasize patient education regarding and access to home dialysis modalities and assisted dialysis options and palliative and/or conservative care options, as those become appropriate considerations.

A comprehensive CKD care delivery model would present a unique opportunity to provide better, more cost-effective, and more patient-centered care than is possible under the current delivery system or in the context of the ESCO program. Presently, silos divide ESRD care (dialysis) from pre-ESRD care and from non-dialysis care options for ESRD. Transplantation is often an afterthought in each of these silos—where it should be a central focus. Such a model would target a kidney patient population “upstream” prior to kidney failure and follow them through each subsequent step, including possible dialysis and transplantation (ideally) and also end-of-life care.

Nephrologists are specifically trained to manage patients with multiple co-morbid conditions, and, in a comprehensive CKD care delivery model, the nephrologist and nephrology practice would assume principle responsibility for patients with kidney disease across the spectrum of their condition. Importantly, this does not mean that primary care providers are not involved in this model, but rather that they are not the care team leader within this model. Effective management of co-morbid conditions is especially important for patients with advanced CKD, during which proper care coordination by a nephrologist can help slow the progression of kidney disease, reduce provision of unsafe medications to patients for whom many medications either require dose reduction or should be avoided, and help prevent the worsening of co-morbidities that are caused or exacerbated by kidney diseases, such as hypertension and heart disease.

Led by the nephrologist as the care leader for a population of patients from the time of their diagnosis of advanced CKD, this model would assume responsibility for their care—in coordination or partnership with other providers, including other physicians such as cardiologists, endocrinologists, and palliative care specialists—through the transition periods of dialysis initiation, transplantation, or end-of-life care. Special attention to the relationship and role of the primary care provider would be crucial, and additional partners in such a model would likely include dialysis organizations and health systems—including transplant centers and the transplant team.

Shared goals and aligned incentives across all sites of care included in the model would contribute to more patient-centered, cost-efficient care for those with the complexity of illness associated with advanced CKD than current care delivery systems. A comprehensive CKD care delivery model would emphasize individualized, patient-centered care while incentivizing care coordination that improves outcomes and reduce costs, including:

- Focusing on slowing kidney disease progression, including patient education and incorporation of various innovative methods of disease-monitoring to enhance self-care. Eliminating the fragmentation that often characterizes the transitions of care from CKD to dialysis to transplantation.
- Facilitating timely, optimal preparation and education for the preferred forms of kidney replacement therapy, including all aspects and options of kidney transplantation, exposure to home therapy modalities, and vascular access planning and procedures.
- Allowing for thorough discussions of goals of care with patients and their families and allowing transitions to comprehensive conservative care and/or palliative care for those individuals who do not desire kidney replacement therapy.

CMS also inquires how participants in alternative payment models (APMs) and alternative payment models advanced (AAPMs) could coordinate care for beneficiaries with chronic kidney disease and to improve their transition into dialysis; target key interventions for beneficiaries at different stages of chronic kidney disease; and better promote increased rates of renal transplantation. ASN believes these critically important goals for people with kidney disease can best be achieved when viewed together as objectives in the spectrum of kidney care—as opposed to siloed targets.

Aligning the incentives so that clinicians and care delivery systems are accountable for kidney patients' outcomes—as well as their overall healthcare costs—throughout the progression and duration of their kidney disease will prompt optimal attention in each of the areas CMS lists. A care delivery model starting at a stage of advanced kidney disease (such as an eGFR of 30, or 45 ml/min per 1.73m²) would have the greatest incentive to effectively and efficiently manage that kidney disease as well as any other comorbidities, keeping patients as healthy as possible for as long as possible. For patients whose advanced CKD progresses, despite the best efforts of the care team, participants in such a model would *first* work with patients, their families, and their loved ones to establish their life goals and match them with the optimal treatment strategy for the individual. In many cases, this will involve attempts to secure a kidney transplant via deceased donor or living donor. Consideration of nonmedical management as an option for patients will be discussed. Finally, incentives in the model would align to thoroughly prepare patients to “transition smoothly and land softly” into dialysis care as kidney failure progresses for those for whom dialysis represents part of their optimal treatment approach. Importantly, goals of care will need to be periodically reassessed with the patient and their caregivers as their life circumstances change and disease progresses.

Many actions required to achieve the goals CMS, and ASN, share in terms of improving transitions to dialysis, deploying interventions that protect and improve kidney patient health, and advancing access to transplantation are clear. Indeed, the primary barriers to these actions is a care delivery system that creates silos in the natural spectrum of kidney disease progression—thereby failing to align incentives to deliver the best, most cost-effective care over a kidney patient's lifespan. These actions would be best addressed in the context of a nephrology-specific care delivery model, focused on meeting the needs of these vulnerable patients and led by the experts in kidney care: the nephrologist and the nephrology care team.

A model (APM, AAPM, or otherwise) that spans the spectrum of kidney disease, bringing together the clinicians and providers who deliver care throughout a kidney patient's lifespan from advanced CKD onward will align their incentives to provide the most individually appropriate, high-quality, cost-effective services.

Primary Care-Based Models

CMS inquires how primary care-based models can better integrate with APMs or AAPMs focused on kidney care to help prevent CKD or ESRD. ASN appreciates this consideration and has long been concerned about the plight of patients with kidney disease in a general-population ACO. The society believes that CMS and CMMI's commitment to creating specialty APMs (or similar demonstration projects and care delivery models) for people with advanced kidney disease is in and of itself an important step to meeting their care needs. The development of specialty APMs (such as the comprehensive CKD care delivery model described above) will prompt the creation of more clearly defined referral patterns, precise timing of handoffs to specialist care from primary care, and create greater attention in the medical community to the unique needs of these patients. For example, establishing a handoff

point from a primary care model to a specialist model such as at an eGFR of 30, or 45, would help ensure a smooth transition to more specialized care at the right time.

The detection of a person with kidney disease is also a crucial aspect of care to be improved upon at the primary care-based model level. An appropriate focus on care of at-risk populations (such as certain minority patients, those with a family history of kidney disease, or those who have diabetes, hypertension, and cardiovascular disease) would be helpful in preventing the development or progression of CKD—and in timing access to specialty care. PCPs who identify patients with advancing CKD can start the conversations about what their future kidney care options might entail. CMS may also consider assessing primary care-based ACOs on aspects of care such as timely referral to a nephrologist (there is a newly-endorsed quality measure in this area).

ASN also believes that instituting policies that make it easier for specialists participating in primary care APMs (such as certain ACO programs) to have patients attributed to them would place greater onus on nephrologists in those programs to take an appropriate leadership role in their patients' care.

Reducing Health Disparities

Reducing disparities in the rates of CKD and ESRD—as well as the rates of transplantation—among racial/ethnic minorities is a critical area of need. Unfortunately, there is no single “silver bullet” to address this vexing reality that every APM or AAPM can implement. However, ASN strongly believes that all care delivery models should be encouraged to focus on identifying and taking steps to reduce health disparities in their local communities, using interventions that are best suited to their needs.

Peer-reviewed literature describes a wealth of strategies that have been tested and proven effective in communities nationwide (both in general care and in kidney care), and APMs and AAPMs should consider drawing upon this research to design and implement strategies that address their unique population's needs. By simply identifying those populations that have difficulty accessing care or applying the care guidance they receive, developing ways to deliver equitable care concordant with their kidney disease risk factors, APMs and AAPMs can help reduce health disparities. Developing systems to evaluate patients' health literacy, help them navigate the healthcare system if needed, and providing culturally appropriate education programs are among the many strategies APMs and AAPMs can consider that the traditional healthcare delivery and payment system would not necessarily support or incentivize. While in general ASN does not recommend that CMS “prescribe” specific such tactics and rather let individual APMs and AAPMs devise their own approaches, the society does see an important role for CMS to emphasize attention to disparities in APMs and AAPM application/formation and ongoing oversight processes.

A related concern to ASN is the equitable geographic distribution of APMs and AAPMs in general. The society is concerned, especially in light of the stringent financial thresholds that have been proposed, that APMs and AAPMs will coalesce around more affluent or better insured patient populations and geographic regions—leaving disadvantaged communities that are perhaps in the greatest need of more coordinated care bereft of options for better-coordinated care. Equitable access to APMs and AAPMs, broadly agreed to be a superior approach to payment and care delivery, will be a crucial aspect of reducing existing health disparities and preventing the formation of new disparities in the future. The society strongly urges CMS to pay close attention to this issue. ASN also suggests that CMS develop a robust monitoring program assessing patient data in as close to real time as possible to compare

patient cohort demographics pre-and post-APM to ensure that cherry-picking and/or lemon-dropping practices are not occurring and exacerbating disparities.

Patient Quality of Life

CMS asks whether there are innovative ways that APMs and AAPMs can improve the quality of life for CKD and ESRD patients. ASN thanks CMS for posing this questions, and confirms that the answer is most certainly “yes.” In fact, ASN observes that the framing of the question concerning “innovative” ways to improve quality of life suggests that there are presently many ways in which existing care delivery systems routinely focus on this aspect of the patient experience. Rather, ASN would posit that focusing on patients’ quality of life and their goals for care is in and of itself innovative—and is absolutely an aspect of care that should be prioritized in the development of future care delivery models.

As with health disparities above, ASN is wary of mandating specific interventions or innovations related to improving patient quality of life to APMs and AAPMs, but believes the general concept should be a strongly encouraged area of emphasis on a model-to-model basis. Patient quality of life is a severely under-recognized concern and the society believes that every future care delivery model (including the comprehensive CKD care delivery model described above) should place this issue front-and-center. Patient-centric areas of focus to improve quality of life could include, but are certainly not limited to:

- Access to a full range of treatment choices, including home dialysis, nocturnal dialysis, assisted dialysis (at home and in-center), and transplantation
- Assistance or support to identify a living donor (e.g. living donation champion program)
- Education regarding the full range of treatment choices, tailored to a range of health literacy levels
- Emphasis on patient employment
- Engagement of patient and family in shared decision-making
- Mental health care
- Pain management emphasis and resources
- Patient experience of care assessments and management plans
- Patient functional status assessments and management plans
- Transportation assistance

Home Dialysis

CMS asks whether there are specific innovations that are most appropriate for evaluating patients for suitability for home dialysis and promoting its use. As described elsewhere in this letter, ASN strongly supports efforts to increase patient access to the full range of treatment modalities—including home dialysis options. This includes both increasing the availability of home dialysis programs as well as strengthening patient education concerning home dialysis. The society appreciates CMS’ interest in this aspect of care as it considers future care delivery models.

Similar to the comments regarding patient quality of life issues, ASN observes that because home dialysis is overall under-utilized at present, there are likely significant gains to be achieved in this area. There are many factors influencing patients’ decisions regarding home dialysis but also many opportunities to make home dialysis a consideration for more patients. Development of a formalized process to provide robust patient education regarding modality options and offering decision support to help them and their families to make an informed decision is one clear area for improvement. Additionally, broadening the experience of physicians and other

care providers, including frequently used care settings like skilled nursing facilities and nursing homes, with home dialysis is critical for promoting this underused modality. .

There is no shortage of innovations that future care delivery models could draw upon as they consider strategies to increase home dialysis use, when appropriate. Several institutions across the country have developed standout home dialysis programs (for example, Northwest Kidney Centers is a leader in the number of patients who dialyze at home; Northwestern University is dramatically reducing disparities in home dialysis use) and the peer-reviewed literature offers numerous successful interventions to increase home dialysis access. Assisted home dialysis and more flexible in-center self-care dialysis are two other opportunities that would merit greater consideration. But because an effective approach in one area is not necessarily going to be an effective approach in another area, ASN encourages CMS and CMMI to emphasize a focus on greater access to home dialysis for appropriate patients in every future care delivery model (including the comprehensive CKD care delivery model described above) without specifying precisely what innovation should be used.

Mandatory models

CMS inquires if there are any specific innovations that could be most effectively tested in a mandatory model. ASN is skeptical of the establishment of a mandatory model of any kind; the society would prefer to see CMS and CMMI support voluntary participation in thoughtfully designed and carefully evaluated models on a limited scale. The society thanks CMS and CMMI for its interest in refining and expanding such models in the kidney care space and would be pleased to collaborate to design and assess future innovative approaches—particularly the concept of a comprehensive CKD care delivery model, as described above.

Again, thank you for the opportunity to provide comment on this proposed rule. ASN would be pleased to discuss these comments with the CMS if it would be helpful. To discuss ASN's comments, please contact ASN Director of Policy and Government Affairs Rachel Meyer at (202) 640-4659 or at rmeyer@asn-online.org.

Sincerely,

A handwritten signature in black ink that reads "Raymond Harris". The signature is written in a cursive, flowing style.

Raymond C. Harris, MD, FASN
President