ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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August 31, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G2
200 Independence Avenue, SW
Washington, D.C. 20201

RE: CMS-1352-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for All Medicare Providers; Proposed Rule

Dear Acting Administrator Tavenner:

On behalf of our nearly 14,000 physicians, scientists, and other health professionals, the American Society of Nephrology (ASN) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2013 and the ESRD Quality Incentive Program (QIP), including for payment year (PY) 2015 and beyond. ASN is a not-for-profit organization dedicated to promoting excellence in the care of patients with kidney disease. Foremost among ASN's concerns is the preservation of equitable patient access to optimal quality dialysis care and related services 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 preservation of reasonable latitude for patients and their nephrologists to individualize care, ASN submits the following comments regarding the proposed modifications to the ESRD QIP.

ASN appreciates CMS' decision to limit the scope of this rulemaking to payment for dialysis services furnished by ESRD facilities. The society believes it would be appropriate for CMS to address any proposed changes in payment for physicians' services—related to dialysis or otherwise—in a separate rulemaking process.

End-Stage Renal Disease Quality Incentive Program for Payment Year 2015

ASN continues to strongly support CMS' goal of monitoring the quality of care provided to patients with end-stage renal disease (ESRD). Evaluating the quality of care as well as patient access to dialysis services and medications continues to be of utmost importance within a bundled payment system. Nonetheless, given the limited scientific evidence currently available regarding what comprises optimal care for patients on dialysis, the society has reservations about some aspects of the proposed modifications to the QIP program. **Of greatest concern**

to ASN are the proposals to expand the existing mineral metabolism measure and add a clinical hypercalcemia measure, and to establish a high performance standard for the percent of patients with a fistula. Furthermore, ASN believes that the existing and proposed new measures for the QIP are not as relevant as others CMS might have chosen; these measures are overly focused on processes—such as monitoring and collecting data—rather than on outcomes that affect quality and value.

In addition, ASN is cognizant that the QIP program remains focused on the care of patients who dialyze in-center thrice weekly. While these individuals constitute the majority of patients treated with dialysis, the society encourages CMS recognize the recent growth of patients who dialyze via peritoneal dialysis (PD), home hemodialysis and other treatment strategies including in-center daily and nocturnal dialysis. ASN urges CMS to ensure, to the extent possible, that existing and future measures include patients treated with these modalities. Furthermore, at some point CMS should consider adding metrics to evaluate appropriate referral to transplantation, as well as appropriate choice of palliative care.

Removal or Replacement Criteria

Overall, ASN believes that the seven criteria CMS proposes to use to evaluate quality measures for replacement or removal are reasonable. ASN agrees with CMS that developing such criteria is an important component in ensuring that the QIP reflects the most currently available evidence and guarantees patient safety; however, the society has a request for clarification and offers several suggestions for improvement to this proposal.

ASN would appreciate specification regarding the specific outcomes—as referred to in criteria numbers two and five—that CMS will be examining. ASN encourages CMS to be broad in the outcomes that it assesses, including patient-centered outcomes such as health-related quality of life. Additionally, the society supports the concept of proposed criterion number seven, but requests that CMS clarify the criteria it proposes to use to identify whether a measure causes "negative unintended consequences." Further, ASN recommends that CMS consider not only negative unintended consequences to the patient but also to the Medicare ESRD system as a whole.

Furthermore, the society suggests that CMS consider adding an eighth criterion to the list for removal or replacement: if data for a measure cannot be collected reliably and accurately, or if collecting the data places an undue burden on dialysis facilities.

ASN concurs with CMS that the ability to take swift action to remove a measure that raises patient safety concerns is vitally important. However, it remains somewhat unclear how CMS envisions this process would unfold, and who within CMS and/or which other entities would be consulted in the decision-making process. It may be helpful for CMS to contextualize this proposal by providing some illustrative scenarios. In addition, ASN suggests that CMS consider convening an emergency Technical Expert Panel or other group of experts to consider the identified concerns and make a recommendation prior to taking action. The society understands and fully agrees with the need for rapid action when patient safety is potentially at risk but seeks to ensure that any decisions made regarding removal reflect the data and the most currently available science.

Finally, the society observes that some of the measures CMS proposes to add to the QIP for 2015 do not meet the criteria outlined. For example, the vast majority of facilities are already performing at or above a level compliant with the hypercalcemia measure standards. **ASN**

suggests that the Agency consider implementing only new measures that meet the proposed criteria. This will require CMS to promote and ensure that a greater number of quality metrics are available for selection in the future.

Reporting Requirements and Patient Qualification for Measures

CMS proposes that facilities should report data (or attest to obtaining data) for patients who have been treated in that facility at least twice in a month, and that they should report for 98% of Medicare patients treated. CMS also proposes that this reporting would include obtaining data and lab values for patients who were treated in other care environments, such as the hospital or another dialysis unit. While understanding CMS' desire to collect information that is as comprehensive as possible, ASN suggests that this proposal is flawed for several reasons. **A more reasonable alternative would be to consider only patients who received seven or more dialysis sessions per month eligible for the QIP quality measure—a threshold that would parallel the current maximum number of hemodialysis sessions a dialysis unit can provide without having ascertained dialysis adequacy in a given month while retaining the ability to bill CMS for that month's dialysis care.**

A patient undergoing thrice-weekly in-center hemodialysis receives up to 13 dialysis treatments per month. Reporting data for patients who have received as few as 2 of the 13 treatments in a given facility does not provide meaningful reflection of that patient's health or quality of care. Assessing performance based on two interactions increases the risk that dialysis facilities will be penalized for treating patients with suboptimal lab values that are not related to dialysis-related care provided in the specific facility. Hospitalized patients' lab values may not meet the QIP standards as a result of the clinical conditions that necessitated their hospitalization—other than ESRD. It is not reasonable to penalize facilities responsible for ESRD care for lab values that are out of range for non-ESRD related conditions.

For instance, under CMS' proposal, a dialysis facility could be held accountable for the lab values of a patient who received just two treatments in the facility in a month after having been discharged from the hospital. The dialysis care team and nephrologist often do not have control over the care of hospitalized patients. It would be unfair to hold the dialysis unit accountable for lab values they cannot influence. The proposed criteria also appear to hold dialysis facilities responsible for the care of so-called 'transient' or visiting patients, who may receive only a few treatments in one facility but the remainder of their treatments at their primary facility. Considering patients qualified for QIP quality measures who were treated at least seven times during a month would provide an accurate depiction of the quality of care administered by the facility and treating nephrologist.

In addition, ASN requests clarification regarding how CMS plans to count the number of treatments for patients on home hemodialysis or peritoneal dialysis. Most patients who perform peritoneal dialysis dialyze daily, and home hemodialysis patients typically dialyze between three and seven times per week. ASN encourages CMS to ensure parity for home dialysis patients with the threshold set for thrice-weekly hemodialysis patients when determining eligibility for the QIP, recognizing that many of these patients dialyze more times per week than in-center patients.

Furthermore, actually obtaining the data from other care environments would place a considerable administrative burden on the dialysis unit. In some cases, it may not even be possible. ASN suggests that dialysis units should not be required to report data for patients from whom the facility is unable to draw a sample from. Finally, the society proposes that CMS

eliminate the stipulation that facilities should only have to report data for 98% of their patients. **Instead, CMS should rely exclusively on the criteria of whether patients who were treated at least seven times during a month at that facility to determine qualification for a QIP measure and require reporting on all such patients.**
Finally, ASN believes that patient care would be greatly enhanced if dialysis facilities focused on obtaining more complete information about patients being discharged from acute care hospitals and other settings, such as a summary of major events, hospital course, discharge medications and the most recent post-dialysis weight, rather than in-hospital lab values. The society suggests it would be a more valuable use of dialysis facilities' time and resources to procure 'big-picture' information rather than lab values, which are typically rechecked when a patient returns to the dialysis unit anyway—and have a more meaningful influence on patient care.

Mineral Metabolism Measures

CMS proposes to expand the existing mineral metabolism measure, such that, in addition to certifying that the facility measured calcium and phosphorus levels, dialysis facilities would report the actual values. CMS also proposes to adopt NQF #1454, a measure that assesses the number of patients with uncorrected serum calcium greater than 10.2 mg/dL for a 3-month rolling average for the PY2015 QIP. ASN has several concerns about these proposals and suggests that CMS not implement NQF #1454 or expand the mineral metabolism reporting measure. Despite the adoption by NQF, the ASN emphasizes that insufficient evidence exists to substantiate the 10.2 mg/dL calcium level threshold for the clinical measure. The only evidence that exists supporting this benchmark is observational data, which ASN does not believe is sufficiently rigorous and should not be used to determine what constitutes high-quality care.

ASN is deeply concerned that incentivizing providers to achieve performance targets that have not been scientifically validated could lead to unintended consequences for patients, as was seen with hemoglobin targets in the past. Furthermore, implementing this measure would effectively cement a practice based on observational data, impeding further progress towards generating more evidence regarding an optimal calcium level. **Because the optimal serum calcium and phosphorus concentrations remain unconfirmed, the society does not support finalizing the clinical hypercalcemia measure—NQF #1454—in the QIP.**

Moreover, virtually every dialysis facility already collects serum calcium and phosphorus concentrations. Because compliance with this measure is already so widespread, expanded reporting to CMS that dialysis facilities collected the data is unlikely to lead to improved patient care or outcomes. Finally, ASN recognizes that CMS proposes to collect calcium and phosphorus level data to help develop a baseline for a measure for future years. However, CMS does not specify what evidence it would use to substantiate the criteria for that measure, as optimal calcium and phosphorus levels remain unknown even if a baseline is established. The society requests clarification regarding what data CMS would use to develop clinical measures for serum calcium and phosphorus in the future. **At this time, ASN suggests that CMS not expand the existing mineral metabolism measure or add the hypercalcemia.**

NHSN Reporting Measure

In general, ASN supports CMS' proposal to expand the existing National Health Safety Network (NHSN) reporting measure. Infection is the second leading cause of death among dialysis patients, and the society strongly supports the Department of Health and Human Services' dedication to track and facilitate action to reduce infections. Since CMS implemented this

measure in PY2013, the nephrology community has become familiar with the NHSN system and ASN now concurs with CMS that expanding the measure would be beneficial.

It is unfortunate, however, that the NHSN database is separate from Crown Web database, creating an additional reporting burden for facilities. The society requests clarification that facilities are required to report only bacteremia or other infections that occurred in the dialysis unit. Dialysis units should not be held accountable for infections that were caused or occurred as a result of care in other environments. Finally, CMS should strongly consider expanding infection reporting—whether as a part of the NHSN or through CrownWEB—for home dialysis patients, including those treated with peritoneal dialysis (via episodes of peritonitis) and home hemodialysis.

Replacement of URR with Kt/V

CMS proposes to replace the Urea Reduction Ratio (URR) with Kt/V as the measure of dialysis adequacy for PY 2015 and subsequent years of the program, using NQF-endorsed measures for adult hemodialysis patients, adult peritoneal dialysis patients, and pediatric hemodialysis patients. ASN does not have any objections to this proposal per se, but offers a few comments for CMS' consideration.

The society recognizes the advantage that Kt/V offers over URR in that it is applicable to home peritoneal dialysis patients and some pediatric patients. However, the Kt/V measure for hemodialysis would not be applicable to patients who dialyze more frequently than three times per week or overnight. ASN urges CMS to exclude patients who dialyze more than three times a week from the denominator for this measure at this time. In addition, most dialysis facilities already use Kt/V as a measurement of dialysis adequacy, so the shift from URR to Kt/V not likely to result in meaningful clinical benefit or practice changes.

Most importantly, ASN suggests that Kt/V does not actually provide a comprehensive measure of dialysis adequacy. While Kt/V has for years been described in the nephrology lexicon as a "measure of dialysis adequacy," the description is inaccurate, insinuating that Kt/V levels provide substantially more insight into the overall adequacy of a dialysis session than they actually can. **Kt/V is simply a calculation of the removal of urea during a dialysis session. While this information is important, it does not provide the all-inclusive picture the phrase "dialysis adequacy" suggests.**

ASN suggests that the nephrology community collectively reframe the language that it uses to describe Kt/V, using an alternate term such as "urea removal." This terminology shift would help the nephrology community focus on more comprehensive ways to monitor and improve the overall adequacy of dialysis therapy. Accordingly, the society suggests that CMS' changing the name of the measure in the QIP would be a significant step in that direction. ASN recognizes that CMS is mandated to include a measure of "dialysis adequacy," but hopes CMS' acknowledgement of this fact would encourage the community to identify additional measures of dialysis adequacy that are more meaningful than or complementary to Kt/V urea. Thus, the society encourages CMS to explore its legal and regulatory options to continue this measure under a different name.

Anemia management

ASN concurs with CMS that it is important to monitor hemoglobin levels in patients to ensure proper anemia management, and appreciates that the Agency highlighted its recent findings that transfusion rates increased from 2010 to 2011 in the proposed rule. The society agrees that hemoglobin/hematocrit levels are an important element of care for CMS to monitor and assess. However, ASN offers several recommendations for CMS to consider that could optimize its ability to accurately assess of anemia management. **In particular, the society suggests that CMS assess hemoglobin/hematocrit levels on a rolling 3-month or 6-month basis rather than assessing the levels on a monthly basis.**

Examining patients' hemoglobin/hematocrit levels on a monthly basis provides a relatively limited 'snapshot' of the overall care the patients are receiving. Studies show that hemoglobin levels in individuals with kidney disease fluctuate frequently above or below the recommended target levels within short periods of time even though the calculated mean hemoglobin remains within a target range of 11 to 12 g/dl. (JASN March 2009 vol. 20 no. 3 479-487.) Therefore, assessing a single value per month has limited clinical utility and offers nominal insight into the quality of care that an individual patient receives in a dialysis facility. A 3 to 6 month assessment of hemoglobin among of patients who are receiving any ESA therapy would provide a more complete picture of patients' overall anemia management.

ASN also requests confirmation that patients who did not receive any ESA but have a hemoglobin of 12.0 g/dL or greater not qualify for the anemia management measure. This exemption would reflect the fact that some patients on dialysis maintain a naturally high hemoglobin level without any ESA therapy, and facilities should not be penalized for caring for those patients.

In addition, as previously mentioned, ASN urges CMS not to require dialysis facilities to report data that is collected in other patient care environments. The society specifically encourages CMS to exclude patient data collected on hemoglobin during hospitalizations from the QIP quality measure.

Transfusion measure

CMS alludes to its efforts to monitor transfusions, stating that it anticipates using data collected in the anemia management measure for "measure development in a clinical area of critical significance to patient safety—anemia and transfusion." ASN agrees that transfusions are a critically important issue for patients with ESRD, as they can lead to exposure to foreign human antigens, causing immune sensitization, reducing patients' likelihood of successful kidney transplantation. Immunosensitized patients who do receive a transplant tend to experience accelerated allograft loss.

The society would welcome the opportunity to assist CMS in developing a transfusion measure. However, the society does not fully understand CMS' access to transfusion data and requests clarification on this matter so that it can make more effective recommendations regarding assessment of this crucial aspect of care. ASN recognizes that dialysis facilities often do not have any influence over whether dialysis patients receive transfusions in other care environments, so it may be challenging for the units or for CMS to identify why a transfusion was performed. (For instance, it would be important to know if an ESRD patient received a transfusion to treat a gastrointestinal bleed, or whether it was simply because they had a low hemoglobin level). The society also understands that in some instances, when a patient

receives a transfusion in the hospital environment, the DRG code associated with the admission may not specify that a transfusion occurred, making it difficult for CMS to track transfusions.

ASN specifically requests clarification regarding:

- The level of access that CMS has to transfusion data for dialysis patients across care settings;
- The level of access that CMS has to information regarding the underlying condition that a transfusion was ordered to treat (including low hemoglobin level);
- The timeframe in which CMS can access and analyze this data.

In conclusion, ASN is supportive of CMS' intent to develop a measure assessing transfusions but requests further information to inform more substantive recommendations to CMS. Recognizing the logistical challenges that the Agency faces, ASN sincerely hopes to serve as a partner in crafting the most comprehensive, accurate, and representative transfusion measure possible.

Standardized Hospitalization Ratio / Standardized Mortality Ratio

ASN has several reservations regarding CMS' consideration of a standardized hospitalization ratio (NQF #1463) as a measure for future years of the QIP. First, ASN is deeply concerned that this measure would promote so-called 'cherry-picking', making it challenging for patients with multiple comorbid conditions or generally compromised health to gain admission to a dialysis unit. Limited access to dialysis units is already a challenge for less healthy patients and this measure could potentially exacerbate that trend. In addition, the measure could create a disincentive to appropriate hospitalization. The society urges CMS to test and describe its plan for ensuring that such a measure would not compromise patient access to care before considering widespread implementation.

Second, the society does not believe that it is currently possible to accurately case-mix adjust for changes in patients' comorbid conditions unrelated to dialysis. The data on the 2728 form, which is completed at the time of dialysis initiation, are, for many patients, too outdated to reflect their health status at the time of a hospital admission that may occur years after the form is completed. CMS proposes that facilities would report up to 17 comorbidities on the UB-92 form, yet it remains unclear how often that form would be updated and how accurate the data on that form are. If updated on an annual basis, the information could be more reliable, although this data collection strategy requires validation, and the administrative burden of accurately completing the form would be immense, necessitating that dialysis facilities expend substantial additional resources.

Furthermore, examining all-cause hospitalization for dialysis patients in the QIP is not reasonable; dialysis facilities should only be held accountable for hospitalizations that are directly related to patients' nephrology care—yet defining this is a very difficult task. In previous comments regarding the proposed rule, ASN has stated that the only fair, feasible way to institute an SHR – admissions measure would be to issue a list of ICD-9/ICD-10 codes that are pointedly related to dialysis care. The list could include, for instance, conditions such as volume overload, hyperkalemia, access-related infectious and non-infectious complications. Facilities would be judged only against expected versus actual admissions ratios for conditions contained on the list. That said, ASN recognizes that it may be too difficult to extract only a handful of dialysis facility-modifiable causes.

In light of these concerns, ASN suggests that CMS not implement the measure at this time, and at a minimum, pilot this measure before applying it to the entire ESRD patient population in order to assess whether these serious issues can be addressed.

ASN's concerns about implementing a potential standardized mortality ratio (SMR), NQF #0369, are similar to its concerns about a standardized hospitalization ratio. The potential for this measure to compromise patient access to care is concerning to the society. Any unintended consequences in terms of patient access would, from ASN's perspective, likely outweigh any benefit to patients that an SMR measure could provide.

The society understands that CMS proposes to compare the number of deaths at the facility during the time period versus the number of deaths that would be expected among at the facility during the time period (based on the national average mortality rate and the patient mix at the facility). However, it is unclear to ASN whether the national average used would be the current national average or one based on past data.

In recent years the dialysis patient population has become considerably more complex with a higher burden of comorbid conditions. Patients on dialysis today typically have non-renal organ system failure and undergo complex non-renal therapeutics, such as implantable ventricular assist devices (VADs), liver, heart, lung and stem cell transplantation, and concurrent chemotherapy. ASN is concerned that it would be extremely difficult to accurately case-mix adjust this patient population and that comparing it to past national average data would be inaccurate. **Ideally, an SMR ratio would reflect an assessment of co-morbidities at the time of death. The society does not have a solution for this challenge, but urges CMS to recognize this dilemma and not implement an SMR measure at this time.**

Rehospitalization

ASN proposes that a rehospitalization measure would be a more meaningful metric—and likely have less potential for unintended consequences, such as cherry-picking—than a standardized hospitalization ratio, and appreciates that CMS has suggested considering this measure in the future. A measure examining 30-day readmission rates could promote increased care coordination and more accurately identify low-quality care.

ASN also suggests that CMS consider a "grace period" of 10 to 14 days for dialysis units following patients' discharge from the hospital, as this would prevent dialysis units for being penalized for low-quality care provided in the hospital environment. For instance, if a patient whose pneumonia was not fully treated is discharged from the hospital on a Monday, has his or her first dialysis session in a facility on a Tuesday, and is then rehospitalized for pneumonia on a Wednesday, it would not be reasonable to hold the dialysis unit accountable for the rehospitalization. A grace period would also prevent any perverse incentives for dialysis units to turn away patients who have recently been discharged from the hospital.

Currently, dialysis patients are excluded from the calculation of hospitals' 30-day readmission rates. ASN suggests that holding hospitals accountable to the 10-day or 14-day readmission time frame as dialysis units may encourage greater care coordination and improve transitions and patient safety. The society encourages CMS to conduct more research on the feasibility of a 30-day readmission rate measure, including what effect a 10 to 14 day "grace period" during which hospitals are responsible, would have on patient outcomes and care coordination and would welcome the opportunity to work with the Agency to do so. Such an analysis would also clarify issues of the length of time following hospital discharge that should be incorporated in

such a quality measure to allow for accurate attribution – whether the rehospitalization should be attributed to the hospital or dialysis facility or both.

Efficiency

CMS requests comments regarding a measure of efficiency in the dialysis patient population. ASN does not have any recommendations at this time, but suggests that CMS bear in mind potential unintended consequences related to standardizing or decreasing the amount of time a patient's encounter in the dialysis unit would take. Individualization of care, including allowing dialysis unit staff and nephrologist time to communicate thoroughly with each patient, are critically important elements of care and the society recommends that CMS ensure any measures of efficiency do not impinge on them. In addition, ASN suggests that a measure or measures examining patient safety might provide more meaningful patient benefit than a measure of efficiency. The society would be pleased to collaborate with CMS to explore the possibility of patient safety measures.

Proposed Scoring, Performance Period, and Performance Standards for the PY 2015 ESRD QIP

ASN believes that the overall approach CMS proposes to develop scores, set performance standards, and implement payment reductions is reasonable. In particular, the society commends CMS for providing stakeholders the opportunity to give feedback regarding the measures prospectively, before the performance period has begun. ASN has previously expressed concern about retroactively applying performance measures and standards to a performance period that occurred before the measures and standards were finalized, and sincerely appreciates that the Agency has addressed the issue for PY 2015 in this rulemaking cycle.

ASN also agrees with CMS that it is preferable to assess facilities based on a full 12 months of data, as this will provide a more accurate picture than a lesser amount of time. However, the society offers suggestions for consideration regarding several elements of this portion of the rule; most importantly, ASN is concerned that the proposed standards for the percent of patients with a fistula are too stringent and could potentially result in unintended consequences.

In addition, the society remains concerned about the two-year time lag between performance period and pay period. ASN recognizes that CMS needs time to process the data and calculate facilities' scores; however, once CrownWeb is fully functional, ASN suggests that CMS investigate the possibility of reducing that gap from 24 months to 18 months as more immediate feedback is critical in quality improvement efforts.

Proposed Clinical Measure Performance Standards

ASN feels CMS' proposals to calculate the performance standards for the three proposed Kt/V measures using CY 2011 claims data are reasonable. ASN does not object to the CMS' methodology for calculating performance standards for the hypercalcemia measure per se, but as previously mentioned, suggests that it would not be appropriate for CMS to finalize the measure at this time. The society also recommends that CMS move forward with replacing the URR measure with the Kt/V measure. Nonetheless, ASN again urges CMS to recognize that a measure of Kt/V is not a complete measure of overall dialysis adequacy.

Estimated Performance Standards

CMS provides estimates of performance standards for the clinical measures using the most recently available data. While these estimates generally appear reasonable, ASN is concerned about the projected benchmark of 74% for patients with a fistula. The society recognizes and appreciates CMS' dedication to ensuring that patients have access to the most appropriate access type, but the society does not think that a standard in the range of 59% is a realistic or appropriate goal for many facilities. Furthermore, setting the benchmark at the 90th percentile may be appropriate for catheter rates but is not appropriate for fistula rates. For instance, patients above the age of 70 years comprise the fastest-growing segment of the incident dialysis patient population, and it is unclear whether there is benefit to creating an AV fistula, as opposed to an AV graft, in this demographic. Some facilities care for a significant number of patients who are not elderly but are physiologically aged such that the likelihood of creating a fistula that can ultimately be used for hemodialysis is extremely low.

Furthermore, the measure does not account for the possibility of grafts, which may be an acceptable and even preferable access for individual patients. Overall, CMS should ensure sufficient leeway between the maximum number of catheters and the minimum number of fistulas so as to not penalize facilities with patients who are appropriate candidates for grafts.

ASN suggests that CMS may wish to consider allowing certain patients to be excluded from the vascular access denominator. Permitting nephrologists to identify patients who are not appropriate candidates for a fistula—such as due to age, comorbid conditions, or limited life expectancy—to be excluded from the fistula vascular access denominator would help protect patient access to the most appropriate type of vascular access for their individual circumstances and mitigate 'cherry picking' concerns.

The society recognizes that CMS may have concerns that this system could be "gamed." However, ASN points to the United Kingdom's experiences with an exclusion option in its quality measurement program: A *New England Journal of Medicine* article found nominal "gaming" in that system. The society suggests that it is more feasible for CMS to permit physicians to make the determination to exclude patients on a case by case basis rather than developing a list or panel of reasons that patients could be excluded, as every patient is different and it would be impossible to generate a list that could apply to the vast majority of people.

Proposed Scoring for the PY 2015 ESRD QIP Proposed Measures

ASN thanks CMS for proposing to continue to judge facilities on either an achievement or an improvement scale. Allowing facilities to improve relative to their own baseline data may help bring each facility up to its highest level of function. The society does not have any objections to the proposed periods of time CMS proposes to use in calculating thresholds for these scales.

CMS proposes to require facilities to report at least six and up to 12 consecutive months of data to receive points on the Anemia Management, Mineral Metabolism, and NHSN Dialysis Event reporting measures. ASN understands the Agency's motivation to hold facilities responsible for providing continuous quality care, but has some reservations regarding this proposal.

ASN is concerned that it would be difficult for facilities to report six consecutive months of data for patients who are traveling or are hospitalized, as it would require obtaining lab values and other information—a challenge described previously. Also, facilities who accept new patients who are very ill may be penalized for infections or abnormal lab values that they did not have

any control over. The society suggests that CMS consider instituting a 'grace period' of two to three months when patients begin dialyzing at a facility in order to give the facility time to adjust for any abnormalities or conditions a patient arrives with. From that point forward, facilities would be required to report on every consecutive month that they are responsible for the patient's care (i.e. the patient receives at least seven dialysis treatments). This approach would eliminate the concerns related to transient or hospitalized patients and provide a more complete reflection of the quality of care provided.

Proposals for Weighting the PY 2015 ESRD QIP Measures and Calculation of the PY 2015 ESRD QIP Total Performance Score

ASN appreciates CMS' proposal to ensure that a facility is not included in the program unless it meets a minimum case requirement of 11 patients for at least one clinical measure/measure topic. The society also finds it reasonable to require a facility to qualify for a score on at least one reporting and one clinical measure in order to receive a Total Performance Score. ASN agrees that this is the minimum amount of data with which CMS could calculate a Total Performance Score.

CMS proposes to equally weight the clinical measures for which a facility receives a score, with the clinical measures accounting for 80 percent of the Total Performance Score. CMS also proposes to equally weight the reporting measures, with the reporting measures accounting for 20 percent of the Total Performance Score. ASN does not object to allocating the clinical measures and reporting measures weights as 80 and 20 percent of the Total Performance Score; however, the society is deeply concerned that CMS states that it intends to use reporting measure data "for purposes of developing and creating clinical measures in the future."

As previously stated, insufficient evidence exists to substantiate clinical measures for the current reporting measures. ASN strongly urges CMS not to establish any clinical measures—for calcium, phosphorus, or other elements of care—for which no proven high-level causal evidence exists between improving the values and improved patient outcomes in terms of morbidity and mortality. Collecting data regarding national performance on these measures is not a sufficient substitute for a rigorous clinical trial to determine the optimal target levels for patients treated with dialysis, and it would be inappropriate to develop a clinical measure with such limited information.

Proposed Minimum Data Requirements for Reporting Measures by New Facilities

ASN believes that CMS' proposals related to data reporting and participation in the QIP for new facilities are reasonable and offer no further suggestions for improvement.

Proposed Payment Reductions for the PY 2015 ESRD QIP

CMS proposes to employ a very similar payment reduction calculation in PY 2015, including the structure wherein facilities do not have to meet or exceed the performance standards for every clinical measure to avoid receiving a payment reduction under the ESRD QIP. Based on the most currently available data, CMS estimates that facilities would receive no payment reduction if they achieve 52 of 100 possible points. ASN believes CMS' proposals regarding the proposed payment reduction scale are generally reasonable and would allow appropriate flexibility for facilities to individualize care without experiencing unreasonable payment reductions.

Nonetheless, the society reiterates its conviction that providing high-quality care is an important goal, but what constitutes high-quality care can be markedly different for different patients. While the proposed payment reduction scale allows leeway, ASN encourages CMS to seriously consider the society's other comments regarding performance standards—in particular, for the fistula vascular access measure. The importance of flexibility to individualize care and deter "cherry-picking" practices cannot be overstated.

Conclusions

On behalf of ASN, thank you for your consideration of these comments regarding the ESRD QIP Proposed Rule. The society's members are dedicated to providing the highest quality care for patients treated with dialysis and believe that a robust system assessing the accessibility and quality of dialysis services is critically important. Many challenges remain in developing an evidence-based system that accurately reflects the level of care offered in dialysis facilities nationwide.

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 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 rshaffer@asn-online.org or at (202) 640-4659.

Sincerely,

Ronald J. Falk, MD, FASN
President