ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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Donald M. Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1577-P: Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014; Ambulance Fee Schedule; and Durable Medical Equipment

Dear Administrator Berwick:

On behalf of our more than 13,000 physicians and scientists, 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 Prospective Payment System for CY 2012 and the End-Stage Renal Disease Quality Incentive Program Proposed Rule for PY 2013 and 2014. 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' efforts to foster reform in the Medicare ESRD Program and promote high-quality, cost-efficient dialysis care. Reflecting our members' 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. These comments first address proposed changes to the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and then proposed changes to the ESRD Prospective Payment System (PPS).

In general, ASN appreciates CMS' decision to limit the scope of this rulemaking to payment for dialysis services furnished by ESRD facilities. The society believes it is appropriate that any changes in payment for physicians' services—related to renal dialysis or otherwise—be addressed separately. In the future, should CMS move toward rulemaking regarding physician services, ASN stands ready to work with the agency in this regard. Given the current national environment for dialysis care, we believe close collaboration on such regulations between the Agency and the practicing nephrology community will be of utmost importance.

As ASN has previously stated, the society is troubled that CMS proposes to retroactively apply performance measures and standards and to a performance period that occurred before the measures and standards were finalized. CMS proposes that payment year 2013 would have a performance period of 2011. It seems unreasonable to hold facilities accountable in 2013 for data collected in 2011, when the final rule establishing the standards is unlikely to be released until November 2011. The society is troubled that CMS continues to set a precedent of creating *ex post facto* regulations and strongly urges the agency to reconsider this proposal for future years of the QIP.

Quality Incentive Program Proposed Rule for PY 2013 and 2014

ASN strongly supports CMS' goal of monitoring the quality of care provided to patients with end-stage renal disease (ESRD). In the context of a bundled payment environment, evaluation of quality and unencumbered access to dialysis services and prescribed medications continues to be of utmost importance. As described in greater detail below, given the limited scientific evidence currently available, the society has reservations about some aspects of the proposed regulations. Fundamentally, the QIP remains an experiment. As such, ASN offers the following overarching suggestions regarding the QIP:

I. Proposed Quality Measure Changes for PY 2013

CMS proposes elimination of the minimum hemoglobin anemia management measure (<10g/dL) in 2013. **ASN is concerned that the absence of any minimal safeguards for low hemoglobin levels could be problematic for patients, potentially leading to compromised quality of life and functional status or even necessitating otherwise-avoidable blood transfusions.** The society recognizes CMS' intention to move away from a target hemoglobin level and generally agrees with the goal, primarily because there is concern that ESA hyporesponsive patients receive inordinately large and potentially dangerous doses of ESAs to bring them into the 10-12g/dL range. ASN does not necessarily object to eliminating the 10g/dL minimum per se, but is adamant that CMS recognize the pros and cons of this change and put some measures in place to ensure that patients' hemoglobin remains at a safe level.

In the absence of high quality data on the effects of ESA dosing strategies or target hemoglobin levels on patient outcomes, it is difficult to predict whether this policy change will have a positive or negative effect. As such, ASN believes that CMS should closely monitor ESA administration amongst patients who have hemoglobin levels <10g/dL to ensure that they continue to receive *some* ESA dose or iron when appropriate. In general, most patients who have a hemoglobin below 10g/dL should receive at least a small dose of ESAs; this approach is also supported by the new FDA label, which recommends initiation of ESA treatment when a patient's hemoglobin level is less than 10 g/dL.

ASN proposes that CMS monitor and publicly report not only on how many patients are below a certain hemoglobin level, but what percent of patients with hemoglobin < 10 are receiving *any* ESA dose or IV iron supplementation, in as close to real-time as possible. The denominator would be the number of patients in facilities with hemoglobin less than 10g/dL and numerator would be the number of patients with hemoglobin <10g/dL receiving any ESA dose. This number should be close to 100%. CMS could consider using previous years' data as a benchmark. These data should be made public in as close to real time as possible through the Dialysis Facility Compare website so that providers and the nephrology community are aware of the implications of the change in QIP policy.

Some members in the nephrology community have also suggested that CMS retain the lower anemia management measure (percent of patients with a hemoglobin of <10g/dL) in the QIP as a reporting-only clinical measure, with no payment penalties associated. ASN believes that this proposal is also reasonable.

Elimination of the minimum hemoglobin anemia management measure will remove any incentives to administer large ESA doses, potentially fostering more individualized dosing/care. The PPS has eliminated any economic incentive to administer unduly large ESA doses. Public reporting, as described above, would greatly reduce the potential for facilities to economize on ESAs by dramatically reducing doses or inappropriately interrupting therapy.

CMS should also monitor and publicly report (via Dialysis Facility Compare or another mechanism) the percent of ESRD patients receiving transfusions to treat anemia in as close to real-time as possible. ASN recognizes that tracking transfusions in the dialysis patient population would require that CMS also collect hospital data with an ESRD identifier. Nonetheless, **ASN believes that transfusion rates are an important indicator of quality care and recommend that CMS track them as well as consider transfusion rates as a future quality improvement measure**. Transfusions can lead to exposure to foreign human antigens, causing immune sensitization. Immune sensitization reduces patients' likelihood of receiving a kidney transplant, and immunosensitized patients who do receive a transplant face higher chances of long-term dysfunction of their kidney. ESAs enable nephrologists to effectively manage anemia without exposing patients to the significant risks that transfusions pose.

Regarding the proposal to maintain the maximum hemoglobin anemia management measure (>12g/dL) in 2013, ASN believes that the measure is unnecessary given that all financial incentives to over-dose ESAs have been eliminated. The society feels strongly that only patients receiving ESAs should be included in these calculations, as some patients have hemoglobin levels that naturally exceed 12g/dL and request that CMS explicitly state this in the final rule.

Furthermore, as discussed later in our comments pertaining to scoring methodology later in this letter, certain units may, based on their patient populations, occasionally require some flexibility in hemoglobin levels in the vicinity of 12g/dL. ASN recognizes that CMS is statutorily mandated to have some measure of anemia management in the QIP but notes that the currently planned measure likely has much less to quality of care in an era of reduced ESA administration. ASN suggests that it may be more appropriate to utilize a transfusion measure to meet the statutory requirement than the currently proposed maximum hemoglobin target.

CMS proposes to allot full payment only to facilities that achieve a performance score of 30 points (an increase from the 26 to 30 point range for a full payment in PY 2012). This increase is overly punitive and exacting, leaving little room for variability based on patient population. Units with patients who are particularly difficult to treat or who are less adherent (especially smaller units) could face insurmountable difficulty in achieving a perfect 30 point score despite providing high-quality care.

Such stringent performance score standards also greatly increase perverse incentives for facilities to cherry-pick only patients who have lower disease burdens, optimal vascular access, and who are most adherent to therapy regimens. Lack of flexibility is a particular problem for smaller units, in which just one or two patients with such characteristics could affect the units score so that it is always below 30, even if appropriate care is being prescribed. Anecdotal evidence already suggests that patients sometimes face difficulty being accepted into an outpatient dialysis unit because they are catheter-dependent. **In order to protect equitable patient access, ASN suggests that CMS maintain the 26-30 point range, or, at the very least institute full payments at 28-30 points, reflecting the variation in patient populations and the need to individualize care.**

II. Proposed Quality Measure Changes and Additions for PY 2014

ASN believes that four of the five clinical measures proposed by CMS are, with some important modifications, generally appropriate measures of quality based on the currently available evidence. However, ASN maintains serious reservations about the standardized hospitalization admissions ratio (SHR) measure, described below. Additionally, ASN would like CMS to clarify that peritoneal dialysis (PD)-only units are exempted from the QIP at this time. The majority of the measures proposed—especially the vascular access measures and the hemodialysis-specific ICH CAHPS survey—are not appropriate for PD patients. CMS does not propose any alternative methodologies to determine a performance score based on a subset of the few proposed measures that could apply to a PD-only unit. **The society requests clarification that PD-only units are exempted and request that CMS state this point in the final rule.**

Although ASN does not believe the measures as currently proposed should be applied to PD patients, it is unfortunate that CMS gave little consideration to the needs or opportunities for improvement for PD patients in the proposed rule.

Kt/V Measure
ASN supports replacement of the URR measure with a Kt/V measure, and believes that the proposed targets of 1.2 and 1.7 are appropriate for hemodialysis and peritoneal dialysis patients, respectively. ASN appreciates that CMS will limit this measure to patients who dialyze thrice-weekly.

Vascular Access Measures
ASN believes that both of the proposed vascular access measures are reasonable, and supports the goal of moving towards "fistula first and catheter last." Overall the measures are a crucial step towards improving fistula rates and bringing the US into alignment with other countries. However, these measures would benefit from some minor but important modifications. While ASN lauds CMS for encouraging pre-emptive fistula placement, the society is concerned that the fistula with two needles measure could make it more difficult for some new patients with a central venous catheter as vascular access to be admitted to a unit.

Fistulas often take considerably longer than 90 days to mature, so unless patients have been cared for by a nephrologist prior to initialing dialysis and had a fistula placed—which is often not the case—the units could be unfairly penalized. Just 28.4% of new patients have been cared for by a nephrologist for at least a year before initiating dialysis, and 44% of patients starting dialysis have had no prior nephrology care. Nephrologists who provide pre-dialysis care are not always associated with the unit in which their patients will ultimately dialyze.

Facilities should only be held accountable for practices for which they are responsible. The selection of hemodialysis unit for treatment is generally dictated by where patients reside. Thus, patients often initiate dialysis in a facility in which physicians and staff were not responsible for their care prior to the start of dialysis. **Given the high prevalence of delayed referral, problems of attribution, and how long it takes for a fistula to mature, ASN strongly believes that the denominator for the vascular access type measure should include only patients who have been dialyzed in the facility for at least six months.**

Establishing this six month "grace period" for the fistula measure beginning when the patient initiates dialysis would decrease avoidance of patients without established fistulas (i.e., cherry-picking) and reduce penalizing facilities for care beyond their control.

Vascular Access Infection Measures (Clinical and Reporting)
ASN supports the proposed clinical vascular access measure and offers no suggestions for improvement. However, the proposed reporting measure through the CDC NHSN Dialysis Event Reporting system seems redundant and unnecessarily burdensome. It is unclear what added value this measure brings to the QIP or patients on dialysis that the clinical measure does not.

Furthermore, the NHSN system is internet-based and requires considerable additional training and staff time to upload patient information—whereas the clinical vascular access measure could be reported through existing processes with minimal additional added burdens. **ASN recommends that CMS not finalize its proposal to implement the CDC NHSN Dialysis Event reporting measure.**

Standardized Hospitalization Ratio (SHR) – Admissions Measure

The proposed SHR - admissions ratio measure warrants considerable reconsideration. ASN has trepidation about a disincentive to appropriate hospitalization and is concerned that patients would be dissuaded from elective procedures that would improve their quality of life. Together with the need for CMS to monitor and publicly report on patient access to ESAs following elimination of the minimum hemoglobin measure in 2013, this proposed measure is ASN's most significant area of concern.

CMS states that (Arbor Research found that) 90% of hospitalizations for ESRD patients are directly related to dialysis therapy. Other publications show that this figure is not accurate, and the true number of hospitalizations related to ESRD are not as high as publicized. According to Ross et al, most ESRD patient hospital resource utilization is not a direct result of kidney failure. Substantial inpatient costs and hospitalizations were for nonrenal primary diagnoses, including malignancies, substance abuse, trauma, HIV, and psychiatric diseases: 37% of admissions, 36% of inpatient days, and 32% of charges (Ross, Alza, Jadeja. *Clin J Am Soc Nephrol* 1: 1234–1240, 2006). Personal experience also suggests that approximately 50% of admissions are directly related to ESRD. It is critical that CMS describe the derivation of the 90% number in more detail, recalling that nearly every dialysis patient who is admitted to a hospital will receive dialysis care and a nephrology consultation during their hospitalization.

The proposed SHR measure poses a significant threat to equitable patient access. The sickest patients, who are the greatest risk of being hospitalized, could face difficulty being accepted to a dialysis unit. As proposed, the SHR – admissions measure could create perverse incentives to cherry-pick the healthiest patients. **The *only* fair, feasible way to institute an SHR – admissions measure would be to issue a list of ICD-9 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.**

ASN also has serious reservations about the methodology used to standardize facilities' rates, which employs an insufficient case-mix adjustment model based primarily on data provided at the time of dialysis initiation. Among other flaws, the case-mix adjustment model obtains comorbidity data from the 2728 form, which is not updated to reflect changes in patient co-morbidity status over time—changes which would have significant predictive power over likelihood of hospitalization.

To hold facilities accountable for all dialysis patient hospital admissions would be patently unfair, in direct contradiction to current evidence, and likely to create serious access issues for the sickest of patients. Limited access to dialysis units is already a problem for sicker patients and well recognized by academic nephrologists. Thus, penalties based on hospitalizations, particularly those unrelated to ESRD, would likely only exacerbate this trend.

Patient Survey Reporting Measure

ASN applauds CMS' recognition of the importance of patient input in the care process, and supports the reporting measure for the ICH CAPHS survey for in-center, hemodialysis patients. However, ASN reiterates that the survey was not designed to capture the experiences care of peritoneal dialysis patients. CMS should clarify that facilities are exempted from administering the survey to peritoneal dialysis patients.

ASN also supports CMS' decision to institute a reporting measure, rather than a measure that takes into account specific patient feedback. Capturing what patients report on the survey would require considerable additional labor for dialysis unit staff. The society encourages CMS to bear in mind the potential for creating additional bureaucratic demands when contemplating future measures, including those related to patient surveys.

Additionally, studies show that what is reported on patient surveys does not necessarily correlate with outcomes. A variety of factors—not all of which are related to the quality or timeliness of care—can influence what patients report on surveys. For instance, a patient may want to dialyze for less time than is medically necessary. If the nephrologist insists on a complete time on dialysis, the patient may indicate dissatisfaction with his or her care on a survey—even though the care provided was appropriate. Although patient perceptions should not in any way be devalued, they are not necessarily reflective of the quality and safety of care administered. **In the future, ASN suggests that CMS maintain the patient survey measures as a yes/no, reporting only, measure.**

Mineral Metabolism Reporting Measures

ASN commends CMS for establishing the mineral metabolism measures as reporting measures rather than as clinical measures. No controlled trials have identified an upper limit for phosphorus, and the upper limit of 10.2 mg/dL for serum calcium is based on observational data. 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 anemia management target hemoglobin levels in the past.

We now know that the higher hemoglobin targets accepted as “appropriate” and promulgated in clinical practice guidelines at that time—despite being based on observational data—may have caused adverse patient outcomes. Clinical trials have since demonstrated either no benefit or a higher risk of fatal and nonfatal cardiovascular events in individuals randomized to higher hemoglobin targets, and practice patterns have changed accordingly. The history of anemia management underscores the inherent danger in developing pay-for-performance measures without controlled trial data demonstrating benefit on hard clinical endpoints. **ASN strongly urges CMS not to establish any clinical measures—for calcium, phosphorus, or other patient data—for which no proven causal association exists between improving the values and improved patient outcomes in terms of morbidity and mortality. The society applauds CMS for its recognition that, given the lack of evidence regarding appropriate ranges for calcium and phosphorus values, establishing a clinical quality measure would not be appropriate.**

Assessment of Iron Stores

CMS requests comment on inclusion of three potential iron measures in the QIP, which were examined in the CMS Anemia Management/Iron Targets TEP report:

- Percentage of all adult (>= 18 years old) dialysis patients for whom serum ferritin and TSAT are measured simultaneously at least once during the three-month study period
- Percentage of all adult (>= 18 years old) dialysis patients with a serum ferritin < 100ng/mL and a TSAT < 50% or at least one simultaneous measurement who received IV iron in the following three months
- Percentage of all adult (>= 18 years old) dialysis patients with a serum ferritin >= 1200 ng/mL or a TSAT >= 50% on at least one simultaneous measurement during the three-month study period who did not receive IV iron in the following three months

Similarly to the Mineral Metabolism reporting measures, no randomized clinical trials exist that demonstrate that giving or withholding iron improves mortality, morbidity, or patient quality of life. Furthermore, although assessment of iron stores would seem clinically reasonable from a common sense perspective, there is little room for meaningful improvement—again, similar to the mineral metabolism reporting measures. **ASN believes that establishing anything other than a monitoring of assessment of iron stores quality measure (as proposed in bullet one above) could potentially cause unintended patient harm.** However, ASN is concerned that establishment of even a monitoring/reporting measure for assessment of iron stores could create a pathway for CMS to convert it into a clinical quality measure in the future—despite the fact that insufficient evidence exists to support such a measure.

Performance Period
ASN encourages CMS to continue defining the performance period as a complete calendar year (with the exception of the SHR – Admissions measure, as described below). Collecting the maximum amount of data minimizes the month-to-month variability commonly seen in chronic disease populations, including patients on dialysis. ASN remains, however, opposed to *ex post facto* application of the QIP.

III. Proposed Changes to QIP Scoring Methodologies

Evidence base
While supportive of the goal to improve the quality of care for patients treated with dialysis receive, ASN notes that it has never been prospectively demonstrated that achieving clinical targets on many of the proposed measures leads to improved clinically important patient outcomes. The limitations of the scientific evidence upon which the QIP measures are based are considerable. CMS should acknowledge the scarcity of scientifically validated performance targets in the dialysis arena and create opportunities to modify and replace QIP measures in the future as new evidence becomes available. Furthermore, because the QIP will almost undoubtedly have an effect on practice patterns and the care that patients receive, **ASN believes that CMS should dedicate resources for clinical trials to study the relationship between the five proposed clinical quality measures and patient morbidity and mortality outcomes.**

Aside from fundamental concerns about the implications of incentivizing providers towards performance targets that are not scientifically validated, ASN is concerned that the proposed approach to scoring and weighting QIP measures is overly prescriptive, sets unattainable goals, and has the potential to seriously undermine individualized care. The society is particularly concerned that quality data from facilities with few patients may be skewed due to the small sample size, thereby negatively affecting their overall performance score. In these small units, just one patient falling outside of the target ranges could result in performance scores that do not necessarily correlate with the true quality of care provided.

Alignment with the Inpatient Value-Based Purchasing Program
CMS states its intention to make the ESRD QIP scoring methodology as similar to the Inpatient Value-Based Purchasing Program (IVBPP) as possible. ASN notes that the dialysis environment is very different from the inpatient environment: inpatient providers have considerably more control over the care patients receive than nephrology professionals have over the care dialysis patients receive, as dialysis patients often see multiple providers outside the unit, and, in the outpatient setting, individual patients are required to assume far greater individual responsibility for determining the success of their own health care. The IVBPP also applies to a much larger patient population than most dialysis units; some units—especially those in rural areas—care for fewer than 20 patients. Aligning the scoring methodology for quality incentive programs that apply to such distinct environments is not necessarily advisable.

Individualized Plans of Care

Providing high-quality care is an important goal, but what constitutes high-quality care can be markedly different for different patients. ASN believes that the proposed scoring methodology and benchmarks do not sufficiently recognize the importance of individualizing care, pushing providers towards a "one size fits all" approach. For instance, while arteriovenous fistula establishment is the most appropriate course of care for most ESRD patients, placing an arteriovenous fistula in a patient with stage IV lung cancer and a very limited life expectancy whose primary goal is to spend her remaining days with family would be inappropriate.

ASN is concerned that the proposed scoring methodology and benchmarks either would push facilities toward adopting a strategy of ensuring that all patients reach a 'lowest common denominator' quality of care rather than care that is appropriate for their unique circumstances or would increase perverse incentives to "cherry pick" patients that are most likely to contribute to a favorable performance score. ASN suggests that the thresholds discussed below are too stringent in order to allow individualized care to occur without a substantial risk of incurring a financial penalty.

Threshold Updates

ASN applauds CMS for proposing to judge facilities on either an achievement or an improvement scale. Allowing facilities to improve relative to their own baseline data could help bring each facility up to its highest level of function. However, it is unclear how the achievement and improvement thresholds will be updated in subsequent years. It would strike ASN as unfair if CMS is planning to update each facility's improvement thresholds annually, based on data from previous QIP years.

As a facility improved care over time, the standards it would have to achieve to prevent a payment withhold would continually rise, eventually becoming a *de facto* automatic penalty if the facility is both unable (for instance, due to a patient population with a high co-morbidity burden) to improve any further and unable to achieve the benchmark. Facilities would be penalized in subsequent years for improving in previous years. Accordingly, ASN believes it is essential to set a fixed and reasonable achievement threshold, as well as benchmarks that are achievable, while allowing latitude for patients to benefit from individualized care plans and goals. Setting fixed standards is particularly important for smaller providers. As discussed below, the currently stated plan for updating achievement thresholds as well as the current benchmark threshold levels result in an overly proscriptive set of metrics given the lack of clinical homogeneity among dialysis patients.

Standardized Hospitalization Ratio - Admissions

Besides ASN's concerns about the premise of the SHR measure—that "a clear majority, estimated at 90 percent or greater, of admitting diagnoses are related to ESRD"—the society also has concerns related to its proposed methodology.

Transplantation is the preferred treatment for many patients with ESRD. ASN is adamant that CMS develop a method to exclude patients who are hospitalized for the purpose of obtaining a kidney transplant from the denominator when calculating performance scores for the SHR measure if it is retained in the final rule.

ASN also notes that UM-KECC reports SHR (both for admissions and days) on a 4 year running average basis, as this period of data allows for more meaningful comparison with reduced risk of being skewed. ASN suggests that, if this measure is maintained, CMS should follow the UM-KECC precedent by utilizing a longer performance period to create a more stable metric that is more likely representative of actual performance through increased robustness to random adverse events. While recognizing that this will attenuate the ability to demonstrate immediate improvement in performance, ASN believes that the greater validity associated with a several year running average is important.

Furthermore, the expected hospitalization rates against which facilities will be judged are based on a normalized distribution of events using national data. If the QIP is 'successful', facilities nationwide would decrease the number of observed versus expected hospitalizations. Because this is a standardized ratio (akin to a fixed Bell curve), when CMS updates the achievement threshold and the benchmark rate, the SHR measure will become increasingly—and unnecessarily—difficult for providers to achieve full performance points. **Besides issuing a list of ICD-9 codes pointedly related to dialysis care as described above, ASN suggests that CMS also address these methodological concerns by either eliminating the SHR measure, decreasing the weight of the SHR measure, and/or (as described in greater detail below) decreasing the benchmark necessary for full points and excluding patients who have a less than one year life expectancy from this metric.**

Setting Benchmarks and Thresholds

CMS proposes to set the benchmarks used for both the improvement and the achievement scales as the mean of the top decile of the national performance rate (equivalent to the 95th percentile). For previously high achieving facilities, in order to obtain a full 10 points on a given measure, that facility's patients must have values as good as or better than 95% of patients nationwide. ASN believes that this initial proposed benchmark is unreasonably high. The society is unsure as to how or whether this value will change over time, or whether it will be fixed in future QIP proposals as reflecting 2010 and 2011 data. Accordingly, ASN is concerned there may ultimately be unintended consequences for patients who would benefit from individualized care that is not necessarily reflected in the quality measures.

ASN recognizes that CMS is estimating, at this time, a threshold of 60 performance points for payment reduction to occur, although it is unclear whether that this number is fixed at the PY2014 level or will be a changing target thereafter. Accordingly, the society suggests that the benchmarks be fixed (or, if this is the current intention, that this be clearly stated) rather than varying annually, and that the benchmarks be established at a lower level. For example, the Fistula First Breakthrough Initiative target is 66%, which is 7% lower than the benchmark presented in the PY 2014 ESRD QIP performance scoring model.

ASN recognizes that CMS' goal is for facilities to improve care over time, but believes that, as currently proposed, the program presents unattainable challenges on individual measures for most facilities, particularly if the total performance point threshold changes over time. Not all of the quality measures are appropriate for all dialysis patients. **ASN suggests two alternatives that would still incentivize improvement on these measures over time, but would give facilities—especially smaller ones—reasonable leeway to individualize care where appropriate.**

1. **Decrease the number of patients included in the denominator:** Using available demographic patient information, identify patients with life expectancy of one year or less. Exclude these patients from the SHR and vascular access type quality measures denominator, thereby enabling the most frail, sick patients with relatively limited life expectancies to work with their nephrology team to develop an appropriate plan of care for their individual situation. This would enable, for instance, a hospice dialysis patient to forgo establishing a fistula without causing the unit in which he or she dialyzes to be penalized. Octogenarians and nonagenarians are the fastest-growing patient populations among dialysis patients and there is uncertainty as to whether this population will uniformly benefit from attempts to create AV fistulas at dialysis initiation. Increased flexibility on the SHR and vascular access type measures would help protect this patient population's access to appropriate care. Again, all patients hospitalized for a kidney transplant should be excluded from the denominator for SHR.

2. **Set the benchmark at a more attainable level for all clinical quality measures:** The mean of the top decile of the national performance rate is, practically speaking, not possible for many units based on patient population; this is particularly true if the baseline period is not fixed in time but rather remains two to three years before the payment year. Achieving the benchmark would, for many units, almost certainly require provision of overly-uniform care. Reducing the benchmark such that facilities can achieve the full 10 points if its performance score is as good as or better than 80% of patients nationwide would strike the appropriate balance between incentivizing facilities to achieve the quality standards while providing appropriately individualized care.

Weighting the Anemia Management Measure
ASN recognizes that CMS is mandated by statute to have a measure of anemia management. However, in the interest of protecting patient and physicians' ability to individualize care, the society suggests several methodological alternatives to the current proposal. First, CMS could weigh the hemoglobin >12g/dL measure less than the other clinical quality measures. This would give more flexibility to units with younger patients who report a markedly higher quality of life with hemoglobin either near or even above 12g/dL. The ESRD bundled payment system already provides a substantial disincentive to overuse ESAs, meaning that the only people who would conceivably be maintained with a hemoglobin at or above this range are those for whom a higher hemoglobin offers a substantial lifestyle benefit.

ASN notes that no data exist to suggest that younger and healthier patients who are ESA responsive have any increased risk with a hemoglobin target of 12 g/dL or higher (recent major ESA trials all excluded younger, healthier patients) and that there are patients who, knowing the risks, would themselves elect for a higher hemoglobin target. Additionally, there are patients, albeit unusual, with higher hemoglobin levels in the absence of ESA therapy. Given a benchmark of 2% estimated for this metric, maintaining this metric in its current form only serves to further amplify the disincentive for individualized care. A second option, balancing the statutory mandate for an anemia measure against existing financial disincentives for providers to administer any ESA given the absence of a basement hemoglobin level within the QIP, is to set the quality measure at an even higher hemoglobin target, such as >12.5 g/dL or even 13 g/dL, while a third option is to eliminate this metric entirely, substituting a transfusion metric as described above.

CROWNWeb
As QIP implementation and future expansion approach, ASN believes it is necessary for CMS to establish nationwide CROWNWeb functionality as soon as possible, so that the data substantiating the QIP can be collected in a uniform manner with minimal burden to providers.

IV. Proposed Changes to the ESRD PPS

In general, ASN believes that most of CMS' proposals related to updates to the ESRD PPS were reasonable. However, the society identified a few aspects of the ESRD PPS portion of the proposed rule that warrant potential consideration by CMS, as described below.

CMS published an interim final rule updating the amount of the transition budget neutrality adjustment from 3.1% to 0%, reflecting the actual number of facilities that opted to receive all payments under PPS. As ASN has previously commented, the society believes finalizing a 0% transition adjustment is a reasonable update to the 2011 ESRD PPS Final Rule and ASN is in full support of the proposal.

CMS proposes to allow dialysis facilities to receive separate payment for Vancomycin when administered for non-ESRD related conditions. ASN agrees that this is a logical change that would allow dialysis facilities to provide, and receive appropriate reimbursement for, medically necessary care.

ASN believes that CMS' proposal to eliminate issuance of a list of former separately payable Part B drugs and biologicals that would be eligible for outlier payments is a sensible proposal. The considerations CMS cites—lag in claims data, changing practice patterns—are understandable. However, in lieu of publicly issuing a list, ASN is concerned that CMS take measures to ensure it updates an internal list of products eligible for outlier payments based on ESRD claims in a timely, comprehensive manner.

ASN supports the proposal to recognize antibiotics furnished in the home for catheter infections or peritonitis as ESRD outlier services. This change would bring home and in-center dialysis antibiotic payment policies in line with one another. Equitable payment polices for home and in-center dialysis facilitate providers' ability to offer, and patients' choice in, dialysis environment.

CMS correctly notes that intravenous heparin is used for dialysis access management, and proposes to recalculate average outlier service amounts to exclude heparin and other thrombolytic drugs used for dialysis access management. The society supports CMS' proposal to recalculate the average outlier service amounts as described. However, ASN would encourage CMS to examine the relationship between heparin-induced thrombocytopenia (HIT) Type II and costs, specifically considering HIT Type II as a comorbidity resulting in payment adjustment as individuals with HIT (a heparin allergy) can be exceedingly difficult and costly to manage. The costs to the medical system associated with this condition are minimal as it is relatively rare but can be quite substantial for an individual dialysis unit. ASN is concerned that patients with HIT Type II would have diminished access to outpatient dialysis care, particularly if they required regular tPA (alteplase) administration or other anticoagulant administration to facilitate dialysis.

Overall, the society would favor revisiting the six pre-specified comorbid conditions that result in payment adjustment. These were included in the bundle due to their effects on the quantity of ESA required (and therefore total cost). Given the de-emphasis on ESA use in the intervening two years, ASN suspects that other comorbid conditions may be increasingly relevant.

CMS proposes to recalculate outlier service MAP amounts to include testosterone and anabolic steroids, citing their potential use in anemia management. ASN is concerned that this change could potentially increase the use of these medications for anemia management in place of ESAs, to the detriment of patients. Testosterone and anabolic steroid therapy for anemia management has been a dated treatment approach since the advent of ESAs, and a return to their use for this purpose would constitute a major backslide in care quality. ESAs are a cornerstone of care for anemia management in patients with kidney disease and have been proven effective for that purpose. ASN urges CMS to closely monitor testosterone and anabolic steroid use to ensure that these medications are not administered in place of ESAs. The society additionally hopes that these agents will not be included in the list of oral (or transdermal) agents that will be included in the PPS in the future as anemia management in kidney failure is not a common indication for these products in the modern era of dialysis.

ASN supports CMS' decision to monitor provision of renal dialysis services administered in emergency departments. Such monitoring is a reasonable safeguard that would prevent dialysis units from sending marginally sick patients to the emergency department for treatment in order to protect their quality data.

V. Conclusions

On behalf of ASN, thank you for your willingness to consider these comments for the ESRD and QIP Proposed Rule. The society's members are committed to providing the best possible care for dialysis patients and believe that a robust system monitoring the accessibility and quality of dialysis services is a vital necessity. ASN believes that many challenges remain in developing an evidence-based system that accurately reflects the level of care offered in dialysis facilities nationwide. Nonetheless, ASN offers several recommendations for CMS to consider in this letter and stands ready to discuss any of these suggestions with CMS. The society 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 Executive Director Tod Ibrahim at tibrahim@asn-online.org or at (202) 640-4676.

Sincerely,

Joseph V. Bonventre, MD, PhD, FASN
President