ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

1510 H Street NW • Suite 800 • Washington, DC 20005
p 202.640.4660 • f 202.637.9793 • www.asn-online.org

August 30, 2013

Marilyn Tavenner
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-1526-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Proposed Rule

Dear Administrator Tavenner:

The American Society of Nephrology (ASN), the world's leading organization of kidney health professionals, represents more than 14,000 professionals who improve the lives of patients with kidney disease every day. 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) 2014 and the ESRD Quality Incentive Program (QIP), including for payment year (PY) 2016 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, complexity of comorbid illness, 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 PPS and QIP. In summary, ASN suggests that CMS:

- Assess the significant negative effect on patient access to care, and on the quality of care, a cut of the proposed magnitude would likely generate.
- Provide the option to phase-in *any* PPS bundle rebase over a four-year period in equal parts.
- Implement and describe publicly a comprehensive monitoring program to identify any unintended consequences that could arise as a result of any PPS bundle rebase, including consolidation of the dialysis market.
- Eliminate the concept of a "holdback" for home dialysis training.

- Maintain a reporting-only hypercalcemia measure instead of transitioning it to a clinical measure.
- Collaborate with ASN and other stakeholders in the kidney care community to update the 2728 form and corresponding annual co-morbidity reporting list.

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.

Proposed Adjustment to the ESRD PPS Base Rate to Reflect Changes in Utilization of ESRD-Related Drugs and Biologics

ASN appreciates the opportunity to comment on recent the CMS proposal to update policies and payments related to the end-stage renal disease (ESRD) prospective payment system (PPS) for CY2014. In essence, the proposed changes include a tentatively projected 2.5% increase in the ESRD PPS base rate along with a wage index budget-neutrality adjustment factor of 1.000411. An additional proposed adjustment, called for in the American Taxpayer Relief Act of 2012 (ATRA), would reduce the ESRD PPS base rate to reflect changes in utilization of ESRD-related drugs and biologics. This adjustment is projected to reduce the ESRD base rate in CY2014 by $29.52, to $216.95. CMS projects that this will decrease total payments to ESRD dialysis facilities by 9.4%, with an 11.5% reduction in Puerto Rico and the US Virgin Islands, compared to CY2013.

ASN is concerned about the potential serious adverse effects on the quality of patient care and patient access to care that the proposed reduction in payment for ESRD services would have if implemented. The society strongly urges CMS to evaluate fully the implications of this proposed reduction and to reconsider accordingly. The Medicare Payment Advisory Commission's (MedPAC) March 2013 Report to Congress projects a Medicare margin of 3-4% for dialysis providers and specifically cautions that "it may be too early to determine how much rebasing is needed without 2011 dialysis facility cost reports, which would help to provide a more complete picture of facilities' response to the modernized payment method."

If MedPAC's projections are accurate, an immediate 9.4% reduction will result in substantial losses for the vast majority of dialysis facilities. According to MedPAC's 2012 report to Congress, which presented data reflecting the final year before CMS implemented the PPS—2010—the two largest dialysis providers saw Medicare margins of 3.4% on nearly 70% of spending, while, for all other providers, the margin was 0.1% for 31% of spending. Notably, rural facilities in 2010 operated on a -3.7% Medicare margin. This suggests that many dialysis facilities, particularly those that are not vertically integrated or possess adequate purchasing power to negotiate favorable pricing, will face substantial risk of closing—compromising patient access to care, likely for the most vulnerable populations.

The uncertainty implicit in this proposed change in dialysis reimbursement—which would be superimposed on substantial recent reimbursement cuts, including the 2011 98% budget neutrality reduction, the QIP, sequestration and other regulations and requirements that necessitate increased facility expenditures, factors that were not fully accounted for in rebasing—is significant.

If CMS has more current data regarding the likely effect of the proposed cut, these data should be shared with the renal community, both to assist facilities with planning for a cut of this

magnitude as well as to assure the community that most dialysis facilities will remain able to provide quality care following a cut of this magnitude. In the absence of these data, ASN views the current proposal with great trepidation, and the society urges CMS to more fully study the implications of a reimbursement reduction of this magnitude prior to considering implementation.

ASN recognizes that Congress mandated that CMS reduce the base rate in ATRA legislation, reflecting changes in injectable drug use. A cut of the magnitude proposed is likely to result in a significant number of dialysis facilities operating on a negative margin, and therefore at risk of closure. **Considering the vulnerability of the dialysis population, ASN requests that these reductions be reconsidered and, that if any substantial reductions to the base rate do occur, they be phased in over several years, as suggested by CMS in the proposed rule.** Specifically, ASN suggests that this phase-in be optional, just as the original bundled payment implementation allowed the option of accepting the full bundle or a four year phase-in. Building on that precedent, ASN also recommends an equal phase-in over four years (25% per year).

Should reductions in the base rate occur, such a transition period possibly could allow ESRD dialysis facilities opportunity to examine their clinical and operational practices for potential areas where efficiencies in care may be gained and to implement changes that will be necessary to continue to operate while minimizing risk to patients. A phase-in period would also allow CMS and others to monitor for adverse effects of payment reductions on dialysis patients' access to care and the quality of care before a more extreme payment reduction is implemented.

ASN also urges CMS to reassure the renal community that the proposed payment reductions do not reduce the final payment to a level that is below the cost of providing dialysis services or so close to the cost of providing services that many providers can no longer continue to provide dialysis care. The society is concerned that this payment reduction, particularly if fully implemented in CY2014, may adversely affect certain providers to an extent much greater than others, resulting in complete closure of some facilities. This has the potential to create a business environment in which there is limited marketplace competition and exclusion of certain providers from being able to provide ESRD services.

ASN is particularly concerned that the proposed reductions would have the most significant negative effect on small and medium-sized dialysis providers, those providing ESRD services in rural areas, and those providing ESRD services in certain urban areas with few, if any, patients covered by commercial insurers. The society believes this scenario is one that places certain socioeconomically disadvantaged groups at greatest risk, particularly if the payment reduction is fully implemented in a single year. Most notably, these changes in payment could threaten access to dialysis care for the poorest populations as well as racial/ethnic minorities, including African-Americans, Latinos, and American Indians.

ASN is also greatly concerned that, as an alternative to closure, some providers of dialysis services will cut essential services and reduce staffing, or providers will attempt to increase facility utilization by shifting the timing of dialysis slots in facilities, requiring patients to start and end their treatments at hours that would adversely affect their quality of life, ability to work or go to school, and live full lives as citizens and taxpayers. If the proposed cut is implemented and facilities are faced with substantial negative margins, ASN foresees three possibilities and has concerns with all three:

1) **These facilities will find sufficient cost-cutting measures to stay in business under the new payment system:** Necessary cost-cutting measures may adversely affect

patient care as they may result in lower nurse to patient ratios, more restrictive medication administration, shorter dialysis sessions elimination of patient-centered dialysis choices such as home modalities or frequent dialysis, and other measures that may significantly affect patient health and well-being.

2) **These facilities will be acquired by larger provider organizations:** Further increases in consolidation may stifle innovations in care and result in a limited number of providers that become "too big to fail."
3) **These facilities will close:** Closure of facilities will significantly compromise patient access to life-saving dialysis care and/or affect the ability of patients who struggle to find dialysis facilities to maintain employment and family obligations.

In order to avoid risk to patients on dialysis, ASN urges CMS to carefully monitor access to and the quality of care provided, regardless of whether there is implementation of the proposed PPS adjustment or if *any* substantial reduction is phased in over three or more years. Lack of a monitoring plan that is publicly stated puts patient well-being at unnecessary risk, especially if not known prior to a significant payment reduction. ASN recommends that CMS specifically outline in the final rule, or commit outlining prior to implementation of any rebased amount, details as to how it plans to ensure that access to and quality of care is not compromised by the rebase.

The society hopes that this process will be transparent and will extend beyond existing quality metrics to include careful monitoring for unintended consequences that adversely affect dialysis patients, including but not limited to:

- Acute care hospital admission/readmission rate trending by facility level association
- Availability to patients of dietician and social work services
- Changes in numbers of shifts per facility
- Changes in staffing ratios or staffing composition (i.e., fewer nurses)
- Consolidation/sales of dialysis facilities in markets with limited numbers of providers
- ESA and other drug utilization rates (compared to baseline)
- Facility closures
- Facility-level mortality rate trending
- Infection rate trending, either via NHSN or by claims data ICD-9/10 codes
- IV drug utilization rates (compared to baseline)
- Reduction in mean treatment time
- Transfusion rates

ASN further recommends that CMS post quarterly updates on monitored aspects of care that are feasible to report publicly, especially dialysis facility closures/openings, starting with data from the first quarter of 2014 data period.

ASN also urges CMS to publicize ways for ESRD patients, their families, and care providers to alert CMS to changes in care delivery that raise concern about negative effects on the quality of care provided as a result of the rebase. Such mechanisms could include, but are not limited to:

- Medicare 1-800 number system;
- ESRD Networks complaint and quality of care reporting system; and
- A dedicated CMS email box for bundled payment outcomes concerns submission

CMS should publicize all available channels of communicating concerns to stakeholders, engage the ESRD networks to assure such engagement occurs and to be part of the active monitoring process, and to post quarterly results of issues communicated and CMS response (along with other monitoring data).

Finally, ASN notes that this has been and continues to be a time of great and rapid change for the ESRD dialysis community: implementation of the PPS and the QIP—which, to date, can be deemed successful—along with CROWNWeb, and other regulatory requirements. **ASN urges CMS to fully consider the real costs of these requirements as well as the financial effects of sequestration and QIP penalties (which are not adjusted for in the current rebasing proposal), the 98% budget neutrality adjustment in the CY 2011 ESRD PPS final rule, and standardization, as well as changes in utilization of other elements of dialysis care, in determining the appropriate overall level of payment for ESRD dialysis services rather than focusing solely on rebasing values derived from medication utilization.**

Self-Dialysis and Home Dialysis Training Add-on Adjustment

ASN maintains serious concerns regarding the proposed holdback policy for home dialysis training. In essence, this proposal will penalize facilities for unsuccessful training, thereby discouraging attempts at home dialysis dissemination to more infirm individuals, who, if they are able to successfully perform home dialysis, may derive greater benefits. This proposal appears at odds with the mission of CMS, where the goal is to optimize care for the individual in the most efficient manner, as well as with CMS' stated goal of using the PPS as a mechanism to promote increased utilization of home dialysis.

Indeed, a holdback for any service predicated on its successful outcome may be unprecedented in the Medicare program, other than "never events". For instance, CMS does not holdback reimbursement for heart transplants predicated on the transplant patient's outcome.
The proposed holdback may discourage matching individual patients with their preferred dialysis modality or transplantation if they are less than perfect candidates.

Accordingly, the society recommends that CMS eliminate the concept of a 'holdback', as it may result in additional non-compensated effort despite reasonable attempts to best match individual patients with their optimal modality. Plainly stated, sometimes home dialysis is unsuccessful. ASN believes that there should be no specter of a penalty for good faith, clinically indicated efforts that are unsuccessful.

The proposed rule discusses self-training by modality at length. CMS should be aware that many peritoneal dialysis patients are treated with prescriptions that include the use of a cycler machine at night and one or more manual exchanges during the day, and that optimal teaching involves patients being competent at both techniques. ASN therefore encourages CMS to pay for up to 4 weeks of training for both PD and home HD and we encourage CMS to incorporate breaks into this training to account for patients who, for example, require catheter repositioning or omentectomy, or who require other surgical interventions to successfully perform peritoneal dialysis.

In addition, ASN appreciates CMS' request for input on the cost of providing home hemodialysis (HDD) services. As ASN has stated in the past, the society is concerned that the current training add-on for home dialysis may be insufficient and believes it is appropriate for CMS to revisit the adequacy of the training payments. It is important to emphasize that the amount of time it takes to train patients to dialyze independently at home varies greatly by individual

patient characteristics, and there is no one “average” number or duration of training sessions. Factors such as patient age, switching home dialysis modalities, and care partner status can all influence the length of training needed.

As an example, members of the ASN Dialysis Advisory Group report that within the past year, training patients for home HD has ranged from less than three weeks of training, to six weeks, to eight weeks, to nearly ten weeks. Training times for home PD are typically shorter, but within the past year members of the ASN Dialysis Advisory Group report that home PD training sessions has ranged from 4 to 14 days, with patients training most of the day and conducting repeated exchanges. In light of this variability as well as ASN’s concern that the current payment is insufficient to cover the real cost of training, the society strongly urges CMS to reassess this aspect of the ESRD PPS.

Application of the ICD-10 to the Comorbidity Payment Adjustment Codes

With regard to the comorbidity payment adjustment variables, ASN has no immediate issue with the crosswalks to ICD-10 codes. ASN’s members continue to be perplexed by the inclusion of monoclonal gammopathy but exclusion of more the severe stages of monoclonal gammopathy, specifically multiple myeloma and plasma cell leukemia, in this classification system. A parallel to this decision would be paying more for asymptomatic HIV infection than for full-blown AIDS, an approach that lacks face validity. The Society encourages CMS to determine methods for proper disease identification as myeloma is the most common malignancy leading to ESRD and improvement in myeloma patient survival, reflecting advances in management, has resulted in more patients with myeloma treated with maintenance dialysis in recent years.

Ultimately, these two organizations—ASN and CMS—share the common goal of optimizing ESRD care for Medicare beneficiaries receiving dialysis or undergoing kidney transplantation. The society urges CMS to cautiously implement any legislatively-mandated ESRD payment reductions to be assured that care provided to this vulnerable population is not compromised.

Quality Incentive Program (QIP)

ASN continues to strongly support CMS’ efforts to monitor the quality of care provided to patients with end-stage renal disease (ESRD) via the Quality Incentive Program. Evaluating the quality of care as well as patient access to dialysis services and medications is of utmost importance within a bundled payment system, and is especially necessary in light of proposed changes to the base rate. 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 is the proposal to add a clinical hypercalcemia measure and the proposal to penalize the bottom 50% of performers on several measures regardless of how well they performed.**

ASN also continues to perceive 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 reflect quality and value. Moreover, for several clinical measures there is ample evidence that the majority of providers are meeting or exceeding quality standards. For example, virtually 100% of facilities meet the standards for the Hemoglobin > 12g/dL measure. Indeed, the only measures that the Society believes are likely to meaningfully improve patient outcomes in the QIP at this time are the vascular access measure and the bloodstream infection measure.

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

Hypercalcemia measure

ASN's most significant concern with regard to the proposed changes to the QIP is CMS' proposal to implement a clinical hypercalcemia measure. There are several reasons that this proposed measure should not be finalized. Despite the NQF adoption of this measure, there is insufficient scientific evidence to substantiate the proposed serum calcium target of 10.2 mg/dL or below. While this threshold has been suggested by some experts based on observational data, no clinical trials have demonstrated that this is the optimal target.

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 the hypercalcemia measure would effectively cement a practice based on observational data, impeding further progress towards generating more evidence regarding an optimal calcium level. ASN believes that this measure may have unintended consequences; for example, secondary hyperparathyroidism might go under-treated, calcimimetic agents or reduced dialysate calcium concentrations could be initiated principally for calcium lowering, without other clear indication, and the use of calcium-based phosphate binders might be discouraged, despite absence of definitive evidence of safety or efficacy of any of these strategies and their lower cost to patients.

Second, no hypercalcemia performance gap currently exists; management of calcium levels is already widespread as the standard of care. Setting aside the fact that no rigorous scientific evidence exists to validate the target 10.2 mg/dL calcium level CMS' own estimates suggest that 98% of patients already achieve that target serum calcium level when corrected for serum albumin. Because CMS proposes a measure of *uncorrected* serum calcium— which invariably is either the same or often lower than serum calcium corrected for serum albumin levels— achievement of the target is likely to be even closer to 100%.

The society also observes that because the vast majority of facilities are already performing at or above a level compliant with the hypercalcemia measure standards, this proposed measure meets the criteria for "removal or replacement" that CMS finalized in the 2012 rulemaking cycle. Specifically, CMS determined that measures should be removed or replaced if "measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made." Introducing a new measure that immediately meets the established criteria for removal or replacement would suggest that the measure is of limited value.

In sum, ASN believes the proposed hypercalcemia measure would attempt to solve a nonexistent problem, creating a reporting burden for facilities without adding benefit for patients, and the society strongly recommends that CMS not finalize this measure.

Patient informed consent

CMS proposes to implement a measure requiring facilities to attest to obtaining an informed patient consent for ESA use on an annual basis. ASN agrees with CMS that patients should have a trusted conversation with their physician regarding the risks and benefits of ESA use prior to their administration. While ASN does not oppose this proposed measure the Society believes that it is not likely to be a particularly meaningful measure from a patient perspective, and offers several considerations for CMS. The Society notes that CMS does not require patient consent for other, arguably more hazardous medications, such as heparin, that are routinely administered to patients. In addition, the proposed measure appears redundant next to the existing U.S. Food and Drug Administration Risk Evaluation and Mitigation Strategy (REMS)—a program designed to support informed decisions between patients and their healthcare professionals who are considering treatment with an ESA by educating them on the risks of ESAs—that mandates that physicians must provide a *Medication Guide* explaining the risks and benefits of ESAs to all patients being treated with these drugs. The society encourages CMS to consider whether implementing a very similar QIP measure will deliver a patient benefit that is commensurate with the additional reporting burden.

ASN requests that should CMS move forward with implementing this measure, the agency should only require that a single consent be obtained at the first initiation of ESAs. It is not necessary to mandate an annual conversation about this medication, and it is reasonable to expect that any changes in, or concerns about, medications will be discussed within the context of the patient-physician relationship. The society also recommends that CMS clarify how this proposed measure would be fulfilled for patients who are not capable of making their own medical decisions, such as obtaining consent from the next of kin or an individual with power of attorney.

ASN recognizes that CMS is required by statute to maintain a measure of anemia management in the QIP. Since implementation of the QIP, compliance with the Hemoglobin > 12g/dL measure improved significantly, shifting from 22% of facilities not meeting the standard to 0% of facilities not meeting the standard. ASN commends CMS for the success of this QIP measure, and suggests the agency consider retiring the Hemoglobin > 12g/dL measure if it finalizes the patient informed consent measure for ESA therapy. ASN believes the patient informed consent measure may meet the statutory requirement that the QIP include “measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management.”

Finally, ASN observes that CMS already requires dialysis facilities to have a conversation with patients regarding their transplant options in the Conditions for Coverage and suggests that the agency could also implement the requirement for a conversation regarding ESA use via the Conditions for Coverage. To summarize, ASN does not oppose the proposed patient informed consent measure but encourages CMS to consider the above observations and, should it move forward with implementing the measure, require only a one-time consent rather than an annual consent.

Bloodstream infection measure (NHSN)

ASN is supportive of the proposed clinical measure for blood-borne infections, and believes that this measure has a strong likelihood of improving patient safety and quality of life. The society commends CMS for proposing this clinical measure, and offers several opportunities for improvement to the original proposal.

As explained in the proposed rule, CMS does not have baseline performance data on this measure and therefore proposes that the performance standard be the 50th percentile of the national performance rate in 2014. ASN believes that it is unreasonable to rate facilities on what is essentially a bell curve, which by default penalizes the bottom 50% of performers regardless of the quality of their performance on the measure. Depending on the spectrum of performance on this measure—which is unknown—facilities with reasonably low rates of blood-borne infections could be penalized simply because they have relatively less perfect rates of blood-borne infections than other facilities. Dialysis providers should not be at risk for a penalty simply because CMS lacks baseline performance data.

Moreover, the bell curve approach could have unintended consequences, such as increased challenges for patients who start dialysis with a catheter—and are at greater risk for infections—finding a unit. Similar access challenges could arise for people who have been on dialysis for an extended period of time and can no longer support an AV fistula. ASN also notes that it would be more difficult for smaller units to hit the high end of the bell curve, placing them at an inherent disadvantage relative to larger units.

As an alternative to the bell curve approach, ASN suggests that CMS consider setting a maximally acceptable rate of *hemodialysis*-associated bloodstream infections in lieu of the entire spectrum of blood-borne infections, and recommends that 3 episodes per 1,000 patient days would be a reasonable standard. The society notes that that ratio corresponds to the number of acceptable rates of infection in patients with central venous catheters as determined by the vascular access TEP. The society encourages CMS to use data it collects on this measure to develop a reasonable baseline performance in the future.

ASN also requests that CMS clarify whether the proposed measure would apply to the peritoneal dialysis and home hemodialysis population. With the modifications described above such as with the substitution with hemodialysis-associated blood stream infection, ASN suggests that it would be reasonable for this measure to apply to the home hemodialysis population but not to the peritoneal dialysis population.

Finally, while ASN agrees with CMS that reducing Hospital Acquired Infections (HAIs) is a critically important goal, the society believes dialysis units should only be held accountable for bloodstream infections related to dialysis care—not HAIs or infections unrelated to dialysis—and that there should be a mechanism for facilities to differentiate the two. This mechanism exists in current NHSN reporting. The dialysis care team and nephrologist rarely have control over the care of hospitalized patients and it would be unfair to hold the dialysis unit accountable for care the patient receives in the hospital that they cannot influence.

Comorbidity reporting

ASN concurs with CMS regarding the importance of accurately assessing patients' comorbidities and tracking changes over time. The society appreciates that CMS has proposed this measure to attempt to address previous comments from ASN and others that certain proposed or existing measures do not take into account patients' current comorbidities, which can have a significant effect on the extent to which they can achieve the target benchmark.

With the recognition that the data collected could make other, more meaningful quality measures feasible to implement in the future, ASN supports a comorbidity reporting measure and offers recommendations to improve the proposed approach. That said, the society wishes to highlight the fact that that this is an unfunded mandate with a substantial reporting burden.

If CMS moves forward with asking facilities to provide an annual update regarding patients' comorbidities, ASN suggests that the agency develop a more meaningful, more specific list of comorbidities to make this the most valuable exercise possible. ASN recognizes that CMS has proposed to annually update the comorbidities that are currently listed on the 2728 form, which was last revised in 2005. The 24 conditions listed on that form are broad and could encompass a wide variety of comorbidities with various implications for patients' health status. Moreover, advances in medicine since the form was last updated mean that patients on dialysis are now living longer than in previous years, with development of additional comorbidities associated with aging and/or increasingly complex, invasive medical care.

For instance, in addition to continuing to treat patients with congestive heart failure, the nephrology care team now also treats patients with increasing degrees of complexity, including individuals with artificial circulatory support (e.g., ventricular assist devices). The society suggests that CMS assess whether the comorbidities currently listed on the 2728 are still appropriate and comprehensive before finalizing the measure with the current, relatively dated list. ASN also recommends that the agency may want to identify some comorbidities that need to be reported only once (such as history of hypertension or toxic nephropathy) versus comorbidities that should be updated on an annual basis (such as congestive heart failure). The society would be pleased to provide input and assist CMS in updating the 2728 form, ensuring that this proposed measure offers the utmost possible utility to the agency and the patients on dialysis who will ultimately benefit from a stronger QIP.

Mineral Metabolism

CMS notes in the proposed rule that it inadvertently excluded home peritoneal dialysis patients from the mineral metabolism reporting measure, and proposes to include them in future years. ASN believes this is a reasonable update, and appreciates CMS' attention to inclusion of home dialysis patients in the QIP.

CMS also proposes to eliminate the requirement that facilities report serum calcium levels as part of the current mineral metabolism reporting measure, if the Agency finalizes the proposed clinical hypercalcemia measure. As discussed above, ASN is strongly opposed to the proposed clinical hypercalcemia measure given the lack of supporting scientific evidence and the fact that there is not a performance gap that needs addressing with regard to serum calcium management. While ASN does not perceive any clinical or patient benefit to reporting serum calcium levels, given that statute mandates that the QIP program include some measure of bone and mineral metabolism, the society suggests that CMS maintain the reporting-only mineral metabolism measure.

In-Center Hemodialysis Consumer Assessment of Healthcare Providers Reporting Measure

ASN concurs with CMS that providing a patient-centered dialysis experience is a key factor in the overall quality of care, and that it is important to obtain patient input about how they perceive the care they receive. CMS proposes converting from the current reporting-only In-Center Hemodialysis Consumer Assessment of Healthcare Providers (ICH CAHPS) to a clinical

measure, wherein CMS would obtain actual patient responses and then asses facilities' performance based on those responses, in future years. ASN believes that the reporting measure is appropriate to include in the QIP, but offers several observations and improvements for CMS to consider.

One major challenge that dialysis units already face is getting a reasonable number of patients to complete the annual survey. Despite the best efforts of the care team to encourage every patient to complete the survey, a very select group of patients who are not necessarily reflective of the "average" patient in the unit typically do so. Indeed, a recent survey showed that just 53% of patients on dialysis are even capable of completing forms for patient-reported outcomes. This demonstrates the limitation of generalizing the responses received from a selected sub-group of patients to the experience of all patients receiving care in the dialysis facility. ASN appreciates CMS' observation that the survey results are more reliable if more than 30 surveys per facility are submitted and supports the proposal to exclude facilities that treat fewer than 30 qualifying cases from the measure.

In order to facilitate improved response rates, ASN recommends that CMS make the form available in more languages than English and Spanish, so that it is accessible to the diverse population of patients on dialysis. Although ASN recognizes that the survey is a validated tool, the sheer length of the form is a deterrent for some patients, and any steps that could be taken to shorten it would likely be beneficial.

The society also observes that the requirement to hire a CMS-approved vendor to administer the survey twice a year instead of annually will create a significant new cost for facilities—a cost that is not reflected in the bundled payment—and constitutes another unfunded mandate.

Finally, ASN wishes to highlight that studies suggest 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 who wants to dialyze for less time than is medically necessary may indicate dissatisfaction with his or her care on the survey—even though the care provided was appropriate. Although patient input is important and should not in any way be devalued, survey results are not necessarily reflective of the quality and safety of care administered.

Anemia management reporting measure

CMS clarifies in the proposed rule previous that rulemaking efforts inadvertently excluded home peritoneal dialysis patients from the anemia management measure. CMS also proposes that facilities that treat fewer than 11 qualifying patients during the performance period must report on this measure for all but one case. ASN believes both of these modifications are reasonable and does not present any objections to the proposals to clarify which patients qualify for this measure.

Summary of key recommendations

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

- Assess the significant negative effect on patient access to care, and on the quality of care, a cut of the proposed magnitude would likely generate.

- Provide the option to phase-in *any* PPS bundle rebase over a four-year period in equal parts.
- Implement and describe publicly a comprehensive monitoring program to identify any unintended consequences that could arise as a result of any PPS bundle rebase, including consolidation of the dialysis market.
- Eliminate the concept of a "holdback" for home dialysis training.
- Maintain a reporting-only hypercalcemia measure instead of transitioning it to a clinical measure.
- Collaborate with ASN and other stakeholders in the kidney care community to update the 2728 form and corresponding annual co-morbidity reporting list.

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

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,

Bruce A. Molitoris, MD, FASN
President