

September 2, 2014

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-1614-P Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Dear Administrator Tavenner:

On behalf of the American Society of Nephrology (ASN), thank you for 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) 2015 and the ESRD Quality Incentive Program (QIP), including for payment year (PY) 2017 and beyond. ASN is the world's leading organization of kidney health professionals, representing nearly 15,000 physicians, scientists, nurses, and health professionals who improve the lives of patients with kidney disease every day. ASN and the professionals it represents are committed to maintaining patient access to optimal quality care, regardless of socioeconomic status, geographic location, or demographic characteristics.

The society appreciates CMS' ongoing efforts to improve the quality and efficiency of dialysis care in the Medicare ESRD Program. Reflecting the society's commitment to patient access to the highest quality of dialysis therapy and to 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 recommends:

1. Transparency and collaboration in measure development and specifications.
2. Parsimony in the QIP and other grading systems. Specifically, developing and implementing fewer measures that focus on the most meaningful items for patient care is a far better strategy than diluting both the QIP and the attention of dialysis providers with numerous measures of less substantial importance.
3. Diligence to avoid incentives that could compromise individualized patient care in order to obtain a more favorable QIP.
4. Monitor the effects of the PPS on access to care, including the ability of ESRD beneficiaries to obtain promptly prescribed oral medications covered under Medicare Part D.

5. Not implementing the SRR measure to the QIP until several serious concerns with the measure have been addressed.

Proposed Adjustment to the ESRD Prospective Payment System

ASN applauds CMS for codifying the Protecting Access to Medicare Act of 2014 (PAMA), as this implementation will greatly mitigate the bundled payments cuts that Congress had previously called for in the American Taxpayer Relief Act (ATRA). The PAMA provisions will help alleviate concerns ASN and other stakeholders in the kidney community had raised regarding the potential effects of a cut on patient access to high-quality care, particularly in rural and inner-city areas.

Reimbursement of Current Pharmaceuticals and Clarification of Third Party Medication Distribution for Medications Possibly Included in the Bundle

ASN remains concerned that current CMS guidance has resulted in Part D plan sponsors inappropriately refusing to cover certain oral medications that are not prescribed in relation to the provision of renal dialysis nor essential to the delivery of such services.

Congress defined the scope of the bundle as "renal dialysis services." The statute defines renal dialysis services to include ESAs, certain laboratory services, and "other drugs and biologicals that are furnished to individuals for the treatment of ESRD." This Congressional mandate is intended to prevent dialysis providers from shifting patients from intravenous to oral versions of drugs in order to be reimbursed outside of the bundle.

Through regulation, CMS has also indicated that "renal dialysis services do not include those services that are not essential for the delivery of maintenance dialysis." Therefore, only drugs or biologicals that are directly related to the provision of renal dialysis services, and are essential for the delivery of maintenance dialysis, should be paid for under the ESRD prospective payment system. However, some Part D plans have refused to cover or have required a prior authorization (which can take hours or days) before authorizing dispensing of medically necessary drugs not related to maintenance dialysis. This is particularly concerning for time sensitive medications like antibiotics, the oral versions of which are most often used to treat respiratory, urinary tract and other infections not related to dialysis. In some instances, patients have had to be hospitalized or sought treatment in emergency departments in order to receive medications unrelated to maintenance dialysis.

In the proposed rule, CMS included a table titled 'ESRD Drug Categories Included in the ESRD Base Rate but May be Used for Dialysis and Non-Dialysis Purposes' that is exceptionally broad and may include many medications used for multiple reasons, including many that are not associated with dialysis care. We request that CMS clarify this policy for two reasons: 1) When the PPS rate was calculated, oral medications given for these indications outside of the dialysis facility were not included in this calculation; and 2) The intent of this table and policy is that medications used in the dialysis facility should not be substituted with medications purchased elsewhere and brought into the facility.

ASN suggests that a reasonable criteria regarding which medications should be covered under the bundled payment (as opposed to a Part D plan payment) is whether the dialysis procedure could be altered or intensified in some way that it would make the medication unnecessary or if the medication is essential to perform dialysis. In this scenario, for instance, lidocaine cream for

access site pain with cannulation would be included in the bundle while an anti-pruritic agent taken twice daily for chronic pruritus that persists despite adequate dialysis would not be included in the bundle. Integral into this calculation is that the cost of these agents be included in the calculation of the bundled rate and the interpretation that these agents are equivalent to intravenous agents used in dialysis care, the latter of which is debatable.

Given the medication access challenges that beneficiaries currently face, ASN recommends that CMS provide additional clarity in the final rule, revise the language in the Benefits Policy Manual, and provide revised guidance to Part D plan sponsors.

Outlier Pool

ASN appreciates CMS efforts to update to the fixed dollar loss amounts that are added to the predicted MAP amounts per treatment to determine the outlier thresholds for CY 2015.

CMS indicates in the preamble that the “proposed update to the outlier MAP and fixed dollar loss amounts for CY 2015 will increase payments for ESRD beneficiaries requiring higher resource utilization and come closer to meeting our 1 percent outlier policy”. However, the outlier pool has never been paid out in its entirety. ASN is concerned that proposal may raise issues related to the fairness of reimbursements to facilities that treat higher-cost patients, given that while one percent is withheld from the base rate to fund the pool, only 0.5 percent of that amount was paid out to facilities in CY 2013 (which is the most paid out since the program started). As Congress did not mandate a specific amount for the outlier pool, ASN, along with others in the kidney community, believes that CMS could and should set the pool at less than one percent to address the fact that the one percent withhold is more than is needed to fund the outlier payments in any given year. One possible option would be to annually update the amount withheld in the outlier pool based on actual use in the two prior years.

Reconsider Definition of “Medical Necessity”

The society notes that in the proposed rules CMS states that modality choice does not constitute medical justification for paying for more frequent hemodialysis treatments. This comment stands in stark contrast to CMS and Congress’ stated goal to increase the utilization of home dialysis in the United States. ASN observes that despite such advocacy, only approximately 10% of patients in the United States receive dialysis at home and fewer than 2% of patients receive home hemodialysis. Patients select, and physicians recommend, home hemodialysis to their patients for a variety of reasons. Central to such choice and recommendation is the greater flexibility that home hemodialysis offers patients vis-à-vis the frequency and length of each of hemodialysis session.

In addition, frequent hemodialysis has demonstrable medical benefits as noted in the Frequent Hemodialysis Network clinical trial, including significantly lower blood pressure, fewer medications to decrease serum phosphorus, greater reduction in left ventricular hypertrophy, and an improved sense of physical functioning. Finally, a recently-concluded study followed individuals enrolled in the Frequent Hemodialysis Network daily trial after completion of their participation in the research study, reporting that patients who received short daily treatments had a significantly lower risk for death compared to patients dialyzed three times weekly for longer treatment periods. Many of the patients currently undergoing home hemodialysis are performing treatments more frequently now in response to health problems that occurred months or years ago (such as episodes of volume overload).

Accordingly, ASN believes that CMS should not preclude modality choice as a medical justification for more frequent hemodialysis treatments, as it is likely to have significant adverse impact on physical and emotional well-being of patients undergoing home hemodialysis currently. Moreover, it is likely to significantly limit Medicare beneficiaries' access to this dialysis modality. This, in turn, would be counter to the CMS and Congress' stated goal of promoting the use of home dialysis in lieu of continued growth of patients undergoing in-center hemodialysis.

Continue to Eliminate Barriers to Home Dialysis

As described above, ASN supports efforts to ensure patient choice and informed decision-making as patients seek treatment for kidney failure. One important decision is which dialysis modality patients select to use for their treatment. ASN supports efforts to ensure that patients have access to their preferred treatment modality and to remove barriers that might discourage patients from pursuing certain modalities, including home dialysis.

The society appreciates the increase in payment for home dialysis training that CMS finalized in the 2013 final rule, but believes that training rates are still low and should be more closely related to the actual cost of providing the service. However, ASN was disappointed that the increase in payment for home training came at the expense of dollars from the base rate. While removing barriers to home dialysis is important, it should not come at the expense of in-center patients. ASN encourages CMS to increase the payment amount for the training add-on by adding new money to the system, not removing funds from the current bundled payment amount.

Timing of Inclusion of Oral-Only Drugs in the Bundle

ASN concurs with CMS' interpretation of PAMA with regard to the timing of inclusion of oral-only drugs in the bundle. ASN recommends a collaborative process to determining when a product is no longer an oral-only drug, noting that MIPPA is unclear on this point for non-ESA medications.

ASN suggests that reasonable criteria for inclusion of previously oral-only agents in the bundle may be when a parenteral formulation has been adequately shown to be clinically superior in terms of efficacy and safety with acceptable cost and cost-effectiveness compared to already available oral medications. ASN also believes it would be appropriate to include new products into the bundle if they are intended to be used in practice as substitutes for already bundled products or if their primary use reflects management of conditions specifically related to ESRD and its complications as evidenced by current use of bundled medications or oral but not bundled medications. The society stipulates that the bundle payment be appropriately adjusted to account for actual costs of any new bundled medications if these products are proven to be clinically superior in efficacy and safety compared to existing products; determining these costs for novel agents that are not simply substituting for agents currently in use may require a pass-through payment for the initial years in order to determine the appropriate adjustment to the bundle.

Low Volume Adjuster

Preserving access for patients in rural areas and otherwise underserved areas is essential; ASN encourages CMS to consider implementation of GAO recommendations if feasible, and urges CMS to vigilantly monitor access to care for this vulnerable dialysis population. ASN suggests

that CMS revisit the low volume adjuster to ensure that facilities in areas where dialysis would otherwise be unavailable are appropriately able to access this adjuster.

Proposed Adjustments to the ESRD 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 necessary in a fixed, bundled payment system. ASN offers the three following overarching tenets regarding the QIP as well as specific comments on proposed new, revised, or eliminated measures.

1. CMS should work transparently and collaboratively with the kidney community in measure development and specifications.
2. CMS should strive for parsimony in the QIP and other grading systems. Specifically, CMS should focus on developing and implementing fewer measures that focus on the most meaningful items for patient care as a far better strategy than diluting both the QIP and the attention of dialysis providers with numerous measures of less substantial importance.
3. CMS should avoid establishing incentives to compromise individualized patient care in order to obtain a more favorable QIP. This requires establishing metric thresholds such that decisions that benefit an individual do not harm the facility's overall QIP score. Vascular access serves as an example, as all nephrologists acknowledge that not everyone should have fistulas and that there are roles for catheters and grafts based on individual factors. Accordingly, metric thresholds cannot be so high as to require unnecessary surgeries for access creation when a non-fistula access may be the more appropriate option for the individual. This tenet has further implications:
 - a. Facility metrics should not exist on a forced normal distribution curve.
 - b. Facility level metrics that are vulnerable to a single individual should not be included in the QIP or in other grading systems.

In regard to the third tenet above, ASN strongly disagrees with CMS' interpretation provided in the current proposed rule that continued escalation of metric thresholds is required because *"Section 1881(h)(3)(A)(ii) of (MIPPA) requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of payment reductions across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions."* In the current proposed rule, CMS interprets this to mean that increasingly more stringent performance requirements for metrics are continually required because, for example, *"facility performance on the Anemia Management, Mineral Metabolism, NHSN Dialysis Event, and ICH CAHPS reporting measures in the PY 2015 program is so high that the median score on each of the measures was 10 points."*

Rather than punishing the community for high performance on these items, ASN stresses that CMS should be congratulating facilities for what they deem as high performance. While MIPPA does state that *"providers and facilities achieving the lowest total performance scores receive the largest reduction in payment"*, this statement does not mandate a normal distribution of grading, a system that has been dismissed as not valid in most other professions in the current era. The society encourages CMS to work collaboratively with stakeholders and the dialysis community to determine appropriate targets rather than artificially distributing performance on an ever right-shifting curve in an attempt to assure spread among units.

ASN reminds CMS that the intent of the Quality Incentive Program is to encourage quality patient care and that the mission for both CMS and dialysis providers is to achieve universal high quality care. When this time arrives (and for some metrics it may have already), should certain facilities still be considered failures due to grading on a curve? ASN believes that this philosophy, as stated in the current proposed rule, is inherently flawed, not in the best interest of patients, and not mandated by MIPPA based on the use of the term 'appropriate distribution' in Section 1881(h)(3)(A)(ii) of the Act, as the term 'appropriate distribution' allows that clinical circumstances be accounted for. The purpose of evaluation is not to discriminate between the very outstanding and the most excellent, but rather to identify the lower performers in order to facilitate improvement. This is the difference between a punitive system and a system that is designed to constructively improve care. In this regard, ASN highlights that the legislative purpose of the QIP was care improvement such that high quality care is provided to all beneficiaries.

NHSN Bloodstream Infection Measure and Date Validation

In principle, ASN continues to support the National Health Safety Network (NHSN) Bloodstream Infection Measure. This measure targets a clinically meaningful event that in many cases may be preventable. Unlike the proposed SRR measure (see later comments), the NHSN measure accounts for the entire population in the denominator, making it less vulnerable to the effect of a single patient. ASN shares CMS and the community's concerns with the inherent subjectivity in determining whether a positive blood culture is truly an infection as well as the subjectivity of the designation of an infection as 'access related' as is done on NHSN forms. In particular, ASN is concerned that facilities that are more diligent in reporting may receive financial penalties due to this diligence. Additionally, the society offers the following comments based on elements within the measure specification that require clarification before we can fully support this measure:

- 1) The specifics for how the numerator is adjusted for access type are not readily available in the measure specification or in the NQF Measure Evaluation Form and are not apparent in the links provided. As with all metrics, ASN encourages complete and clear reporting of methodology in documents that are readily available to the public and to stakeholders.
- 2) The addition of 'stratified by the access type' to the denominator statement is new for this proposed rule as compared with the measure specification available for the 2014 calendar year and is not specified in the NQF 1460 summary document. Does this mean that three separate scores are being calculated for the three major access types and somehow being summed, or is this simply specifying more detailed reporting to enable better quality improvement efforts by the facility? Further, ASN has difficulty understanding how the numerator can be adjusted for access type and the denominator stratified for access type, as is suggested by the current measure specification form. ASN supports use of an overall denominator rather than three stratified denominators, and requests clarification of this statement.
- 3) CMS requests comments on the Adjusted Ranking Metric (ARM). From the limited methodology description available, the ARM incorporates a random-effects model to account for facility while, for the SHR, the ARM equivalent is a fixed effects model for facility. These inconsistencies in methodology result in far less confidence in the adjustment strategies used in these metrics. Based on a presentation by Mr. Jonathan Edwards of the CDC (the measure steward), the impetus for the ARM is a perceived need to differentiate among very low standardized infection rates, based on exposure characteristics. This has

the effect of normalizing the distribution of otherwise left skewed standardized infection rates. ASN supports efforts to reduce the vulnerability of facilities to penalties for one or two events in the setting of low denominators but continues to stress that the need to rank order dialysis facilities is not legislatively mandated and encourages CMS to work with the community to set fixed thresholds for high performance that will not change annually. Accordingly, ASN does not support the use of the ARM as currently proposed.

NHSN Data Validation

ASN believes that the cost estimate CMS cited in the proposed rule is too low for the effort required for NHSN data validation. Specifically, the individual with NHSN privileges would logically be the individual who would extract the desired data. This individual tends to be the nurse manager, the nurse educator or the 'charge nurse,' depending on the facility. These individuals are among the highest paid nursing professionals in dialysis facilities. CMS proposes a hard 60 day turn-around time for data requested, proposing a substantial QIP penalty for failure to adhere to this time frame. While ASN encourages a mechanism be created for flexibility with this time frame in the setting of unforeseen circumstances, ASN also questions whether CMS has the authority under MIPPA to include a penalty specifically within the QIP for failure to submit audit documents to validate data collection mechanisms within a specified period of time.

In the proposed rule, CMS states that "a CMS contractor will then develop a methodology for determining when a positive blood culture qualifies as a "candidate dialysis event," and is therefore appropriate for further validation." ASN strongly urges transparency with this process and encourages that practicing nephrologists and dialysis professionals be included in a meaningful methodology development project. This comment echoes ASN's overarching call for transparency and collaboration in measure development and specifications.

Balance Between Reporting and Clinical Measures in the Total Performance Score (TPS)

In concept, ASN supports many of the new reporting measures CMS proposes for inclusion in the QIP in 2017 and beyond. For example, monitoring depression screening, influenza vaccination status, and pain assessment may ultimately lead to meaningful clinical measures that promote the delivery of high quality care to patients receiving dialysis. The society agrees that that it may be necessary to apportion a larger share of the QIP score weight to reporting measures in order to encourage dialysis facilities to undertake these new efforts.

To the extent that the new reporting measures are not already a part of routine care, dialysis facilities will incur an additional cost of complying with the new measures. For example, dialysis facilities will need to develop new programs to monitor the influenza status of their employees and encourage employee vaccination, and they will need to pay existing personnel or hire new personnel to conduct sufficiently detailed depression screening and pain assessments. While the increased weight of reporting measures increases the penalty for not complying with these new measures, ASN is not aware of an increase in the PPS payment to facilities to cover these additional costs.

ASN is concerned that the addition of new reporting measures will increase the financial burden faced by dialysis facilities and that this may lead to additional cost-cutting measures that could compromise the quality of care in other areas. If the QIP encourages facilities to incur added costs of new reporting measures at a time when reimbursement for dialysis care is being reduced, it will be important that CMS and others closely monitor for areas where the quality of care or access to care may be compromised.

Revisions to ICH CAHPS — Eligibility of Facilities with 30 or Fewer Patients

ASN supports CMS's proposal to exclude dialysis units with 30 or fewer survey eligible patients from the measure. Unfortunately, historically survey completion response rates are low among dialysis patients despite efforts by dialysis providers to implement efforts to encourage survey completion (patient and patient family education, helpers to assist in completion such as volunteers, nurses, social worker etc.). To increase the response rate, and allow smaller and midsized dialysis units to gain meaningful information about patient experience, ASN encourages CMS to consider validated translations of the ICH CAHPS into other languages beyond English and Spanish, shortening the survey, and return to annual rather than twice yearly administration.

While ASN notes that the survey is available in other languages, users have observed that these translations are suboptimal. For example, the Chinese version of the survey includes Chinese characters that ask "how often does your provider always...", which, when followed by "Always, Usually, Sometimes, Never" does not make sense. This raises concern that the Chinese ICH CAHPS surveys—and potentially other foreign-language versions of the survey—do not appear to not have been translated using an appropriately rigorous process.

ASN also reminds CMS that the mandate to administer the survey twice a year through an approved vendor will increase costs to the dialysis unit that are not reflected in the bundled payment. This burden will be felt by all sizes of dialysis units, but particularly by the mid to large units not in a large dialysis network or organization. Pursuant to this, ASN is concerned that administration twice per year will lead to survey fatigue (as, unlike the hospital CAHPS, dialysis patients tend to be the same individuals at six month intervals) and that the six-month timeframe will not allow for sufficient time for facilities to review their results and make meaningful interventions to improve CAHPS performance.

Anemia Management: Hemoglobin >12 g/dl

ASN commends CMS for removing this topped out anemia metric and appreciates the discussion provided regarding the coefficient of variation to determine when a measure is 'topped out'. As discussed in prior comment letters, ASN notes that the second criterion is an additional reason for removing the Hgb >12 g/dl metric. This criterion states: "performance or improvement on a measure does not result in better or the intended patient outcomes."

ASN thanks CMS for reporting the coefficients of variation for QIP measures and strongly encourages CMS to report these coefficients annually. ASN notes that, although not statistically indistinguishable (as is often the case with a sample size in the range of 5600), multiple other measures here appear 'topped out', including hypercalcemia and adult Kt/V, given coefficients of variation that are below 0.1. However, ASN is troubled by CMS' proposal that "even if we determine that a clinical measure is topped out according to the statistical criteria we apply, we will not remove or replace it if we determine that its continued inclusion in the ESRD QIP measure set will continue to set a high standard of care for dialysis facilities."

While there is a statutory requirement for inclusion of a measure of dialysis adequacy, this statement implies an arbitrary process may be applied to other measures. ASN encourages CMS to adhere to their reasonable methodology of a truncated CV of <0.1 for determining whether a measure is topped out rather than focusing on whether these values are 'statistically indistinguishable', stressing that statistical significance and clinical significance often diverge.

ASN notes that these data can still be collected and the metric restored if there is a change in care delivery. The society also observes that, as noted in Table 23 of the proposed rule, fistula use achieves the TCv while catheter use does not. Because these are co-dependent metrics, they may be best considered in tandem when making this determination.

If CMS continues maintaining topped out variables, ASN urges that the agency not to force a normalized distribution to set scores that result in penalties; rather, the society suggests that a clinically appropriate threshold be set that does not require that some facilities received low scores within a specific metric such that sufficient leeway is allowed within care metrics to permit individualized care without penalizing the entire facility. This is consistent with overarching tenet number three above and is an essential aspect to the delivery of personalized patient care and individual patient safety.

Exclusion Criteria for Measures that Require Monthly Assessment

In the current proposed rule, both that the adult and pediatric hemodialysis adequacy measures exclude patients treated at the facility fewer than two times during the claim month. As stated in prior comment letters from the ASN and as consistent with previous and existing ESRD policy, ASN urges that CMS raise this threshold to **seven** in a month. This allowance is critical for dialysis facility workflow, particularly in months where the first two treatments may fall on a Saturday and a holiday Monday for example. Additionally, clinical laboratories that receive specimens from dialysis facilities cannot receive specimens from every facility on the same days; these need to be spread out over the course of the month.

ASN urges that CMS adopt the following global exclusions for the Kt/V and other measures that are applicable on a monthly basis:

- Beneficiaries who die within the applicable month;
- Beneficiaries who receive fewer than 7 treatments in a month;
- Beneficiaries receiving home dialysis therapy who miss their monthly in-center appointment when there is a documented good faith effort to have them participate in such a visit during the applicable month;
- Transient dialysis patients.

Implementing a Risk-Standardized 30-Day All-Cause Hospital Readmissions Measure (SRR)

As noted in prior comments, ASN is overall a strong supporter of the concept of SRR measure as an important indicator of patient care. However, the society is unable to support the measure as currently proposed and continues to urge that CMS work collaboratively and transparently with stakeholders to develop the optimal SRR measure for inclusion in the QIP. While ASN applauds the dry run of this measure, the society also notes that the measure steward did not respond publicly to feedback items over a process of two years, but rather, when unsuccessful with the TEP process, cites the authority granted by section 1881(h)(2)(B)(ii) of the Act, which allows for an exception to the National Quality Forum endorsement process.

In the current document, CMS implies that the major reason for the TEP's non-endorsement of the proposed measure was that the SRR did not risk adjust for the nephrologist. ASN is disappointed in the manner in which the proposed rule presents the lack of consensus regarding this proposed metric. As based on statements from TEP members both during face-to-face

meetings and in extensive communications to the measure development team from the TEP members following the face-to-face meetings, non-inclusion of physician factors was not a significant reason for a lack of support from the TEP.

The major reasons the TEP did not support the metric were: 1) Composition of denominator, which the Chair of the TEP urged should be based on all eligible patients in the dialysis facility rather than those who had been admitted, as this provides for a far more robust measure; 2) Mechanism for allowance of the dialysis facility to have opportunity to intervene in the care of the patient following discharge; and 3) Issues with the statistical model and adjustment strategies. These concerns and others have not been publically addressed by the measure steward. ASN continues to strongly encourage transparency, particularly when using an exception to the rule that a metric should be endorsed prior to inclusion in regulation.

ASN offers additional concerns with the proposed SRR measure below, and notes important inconsistencies with other measures in the current proposed rule, specifically the NHSN Bloodstream Infection measure. ASN urges that, in the spirit of collaboration and transparency encouraged in the rulemaking process and particularly when using an exception to the usual measure development process to incorporate a measure into the QIP, CMS respond to the individual points raised in these specific queries regarding the SRR principles and methodology.

Defining Hospitalization

The society believes that clarification is required regarding how bedded outpatients and observation admissions are counted in the SRR. With recent rule clarifications by CMS affecting this trend across hospitals, ASN is concerned that the SRR dry run did not adequately capture the effect of the rapid increase in the number of bedded outpatients that previously would have been defined as admissions.

Opportunity to Affect Care

ASN believes that it is important that the dialysis facility have the opportunity to impact readmission before being held accountable for readmission. If a discharged patient is readmitted prior to being seen at the dialysis facility, the facility would not have had the opportunity to intervene to prevent the readmission. This serves for both readmissions within 48 hours as well as readmissions from other healthcare settings (for example, if a patient is receiving dialysis at a rehabilitation center rather than at their home facility following hospital discharge). Although ASN acknowledges that the model developed by He and colleagues, by attempting to adjust for hospital effects, could potentially account for some rapid readmissions, this model has substantial limitations and is inadequate to account for this issue. ASN notes that a system where the dialysis unit is not accountable for these rapid readmissions, which occur before the facility had the opportunity to affect care, has far greater validity than the proposed adjustment strategy.

Denominator Total

Similar to the decision made with the NHSN Bloodstream Infection metric, where the number of catheters (the major cause of access-related bacteremia) does not determine the denominator but rather the number of patients determines the denominator, ASN feels that the number of discharges should not be the determinant of the denominator, but rather that the number of readmissions should be based on the total number of patients treated in a facility. This structure is far more representative of overall quality of care and far less vulnerable to one or two patients with extensive comorbidity within an otherwise outstanding facility.

For example, if a provider has a dialysis facility with 50 patients, and there is one patient who is readmitted repeatedly while no one else is hospitalized, that facility's performance will appear to be very poor and it will be declared a low quality unit; in actuality, the facility is nearly perfect except for one patient. ASN notes that, in these cases, the SRR becomes interpretable without simultaneous accounting for the hospitalization rate. Given that reducing readmissions also has been shown to reduce first admissions, ASN believes that a change in the proposed SRR denominator would allow for a more robust single measure of quality that will further motivate improved clinical care and have additional benefits while maintaining reasonable parsimony within the QIP.

Denominator adjustment

ASN is also concerned with the possible lack of validity with the methods behind the double random effects model (stage 1) and how this is impacted by communities where there is only 1 major hospital and/or 1 major dialysis facility versus those where there are many of one or both. ASN believes this information must be addressed before finalization. The society is also concerned that use of the less conservative fixed effects model, despite the statements made by He et al in their methods paper regarding difficulty identifying lower performing small facilities, appears inappropriate for the overall purpose of the measure given the assumptions required for this model.

In fact, the use of a fixed effects model and statements supporting this methodology are contradicted by the use of a random effects model for the ARM for the NHSN measure. ASN encourages consistency in statistical adjustment strategies to promote both transparency and validity, and, for this particular metric, feels that the methodology is inappropriate for the clinical setting. Furthermore, the society believes that, in order to instill confidence and validity in the model, the measure must reduce the number of variables included and focus on more clinically plausible variables. For example, ASN suggests that BMI derived from the 2728 form should not be used, as these data, despite having statistical significance, are essentially uninterpretable given the heterogeneity of weight (wasting and anorexia, edema, etc...) at the time of dialysis initiation, inaccuracy of data entry on the 2728, and lack of face validity for the association between BMI at dialysis initiation to at a rehospitalization occurring at a potentially distant time point that can be years later. This same point holds for the STrR, where there is even greater dependence on 2728 from variables for case mix adjustment.

Numerator Questions

ASN is concerned that the numerator, which relies on accurate determination of planned admissions, uses codes from a non-ESRD population to determine these and urges validation of these codes in the ESRD population. This could be done with detailed examination of samples of patient-level data from the dry run.

ASN is also greatly concerned that the types of admissions do not consider ESRD-specific patient management. Given that this metric addresses a very specific population, the society suggests tailoring this list to include nephrology-related patient care measures. For example, where does a PD catheter placement or omentectomy fall into on this list, vascular access creation, transfusion for a transfusion dependent patient (which is typically done in hospitals)? Clarification of how observation/bedded outpatient status is handled may be helpful for better understanding this question.

Other Specific Comments

ASN also encourages CMS to clarify how unsuccessful kidney transplants would be addressed in this measure in the 6 months following the transplant. ASN recommends that unsuccessful

kidney transplants should not reflect on the dialysis facility; rather these reflect the transplant (and transplant complications) and therefore these patients and readmissions should be excluded from both the denominator and numerator. This is similar to the attribution of peri-transplant transfusions to the transplant rather than to the dialysis unit in the proposed STrR. This allowance is important to unintentionally compromise access of patients with delayed graft function to dialysis or discourage transplantation.

In conclusion, ASN strongly recommends against incorporating the proposed SRR measure to the QIP.

Standardized Transfusion Ratio

ASN applauds CMS for proposing the STrR for inclusion in the QIP and read with interest the proposed measure methodology. Similar to the SRR, ASN believes that this is a measure with great potential to help patients and a measure that may be meaningful for assessment of adequate anemia management. ASN encourages CMS to solicit further feedback on the proposed metric and looks forward to collaborating with CMS on refining this proposed metric prior to its implementation. Specifically, ASN offers the following comments:

While appreciating the simplicity of using similar adjustment to the SHR, ASN notes that transfusions represent only a small fraction of hospitalizations and urges CMS to consider inclusion of other critical adjustment factors that are more closely linked to anemia and transfusion events, either in the general population or in the dialysis population, including more proximate factors to the transfusion event. This would require utilizing comorbidity data derived from claims data for use in adjustment in this proposed metric and has the benefit of avoiding issues with validity and relevance of data derived from the 2728 forms, such as baseline body mass index. Such an approach is undertaken in the proposed SRR measure.

ASN encourages that CMS place a limit on the number of transfusion events that a single patient can contribute, suggesting that 4 events each year is a reasonable number. This represents the fact that very frequent transfusions likely represent conditions such as recurrent bleeding from chronic intestinal arteriovenous malformations that may be resistant to other treatments, or active receipt of chemotherapy, presence of bone marrow malignancies, or non-dialysis related diseases like sickle cell anemia that may not be captured in Medicare claims with only a 1-year look back window. These conditions likely would not be amenable to treatments that the dialysis facility can institute.

NHSN Healthcare Personnel Influenza Vaccination Reporting Measure (NQF #0431)

ASN concurs that monitoring influenza vaccination among healthcare personnel at dialysis facilities is an important goal. Preventing transmission of influenza is a particular concern for patients receiving dialysis due to their frequent interaction with healthcare workers and their susceptibility to developing severe illness from viral infections such as influenza.

ASN is concerned, however, about defining “qualifying healthcare personnel” as persons who work at a dialysis facility for at least one day. This appears to be a departure from the measure as recommended by the National Quality Forum (NQF), which only includes personnel working at a facility for 30 days or more. The NQF recommended a 30 day requirement as opposed to a one-day requirement due to “... substantial concern from the pilot project’s Steering Committee regarding the feasibility for healthcare institutions of determining the vaccination status of healthcare personnel present at the facility for only one day.” The ASN shares this concern, and notes that very few employees are likely to work at a facility for less than 30 days.

Pediatric Peritoneal Dialysis Adequacy Clinical Measure

ASN, along with the American Society of Pediatric Nephrology (ASPN), agrees and supports a clinical measure focusing on peritoneal dialysis adequacy for pediatric patients.

Transition Reporting ICH CAHPS Clinical Measure (NQF- #0258)

CMS proposes to implement an ICH CAHPS clinical measure in PY 2018. ASN agrees that this measure would have value from a patient perspective, but recommends decreasing the proposed weight of the ICH-CAHPS measurement to avoid penalizing dialysis units that provide safe, high quality care.

To date, experience with Consumer Assessment of Healthcare Providers and Systems surveys have been mostly in the acute care setting (H-CAHPS). In this environment, the care delivery is overwhelmingly focused on an acute and transient need and the relationship between the care team and patients is not long term, but rather centered on relaying discrete information and education. Translating measurements from the acute care setting to the complex chronic disease management setting may lead to unexpected adverse outcomes such as prescribing dialysis sessions that minimally meet other QIP measures, but are not appropriate for individual patients (shortening dialysis sessions to please the patient), or not pursuing critical conversations (such as continuing to pursue healthy life style changes and compliance concerns with resistant patients) to avoid poor ratings at the risk of causing increased adverse outcomes.

ASN agrees that Nurse and Provider/Doctor communication is important to the patient experience and can contribute to improvements in patient-centered outcomes, but ratings on surveys are impacted by many variables that do not reflect quality of care delivered, particularly in the management of chronic, non-curable disease. Other proposed measures such as the standardized readmissions rate that adequately reflect the complexity of a patient's illness and standardized mortality rates may be more accurate reflections of appropriate patient-centered care. Additionally, data shows that just 53% of patients on dialysis are capable of completing forms for patient-reported outcomes. Another concern is the ability of many patients with ESRD and psychiatric or behavioral health diagnoses or cognitive impairment to accurately interpret the value of care delivered. This demonstrates the diverse and numerous limitations of generalizing the responses received from a selected sub-group of patients to the true experience of all patients receiving care in the dialysis facility.

Finally, ASN is concerned about the methods by which the achievement and benchmark goals are determined. ASN encourages CMS to outline the method for review and comment. While ASN certainly appreciates that aligning the ESRD QIP measures with other VBP initiatives—such as those for hospitals—may lead to a standardized approach, we urge CMS to recognize that the appropriate weighting of the measures may be different in the successful management of complex chronic disease versus the management of acute episodic illness. Expectations of acute care experiences can be quite different than chronic care experiences, especially when the interaction with the care team is long term, frequent and often with unsolvable medical issues. Although most patients requiring maintenance dialysis have a trusting relationship with their dialysis care team, their ongoing disease process rarely results in total health recovery – leading to disappointment and at times stressed relationships with care teams. In addition, in-center hemodialysis requires patients to interrupt their lives at least three times a week to travel to and from the dialysis unit and receive their treatment. Their frustration

with this burdensome life style could very well be reflected in their scoring. These issues inherent to ESRD could result in lower CAHPS scores for dialysis units and not reflect the quality of care delivered. Therefore, ASN recommends decreasing the proposed weight of the ICH-CAHPS measurement to avoid overly penalizing dialysis units that provide safe, high quality care.

Screening for Depression and Follow-Up Reporting Measure (NQF #0418)

ASN supports this measure in concept and believes that a depression/mental health measure is important for patient satisfaction and overall health. Depression is common among ESRD patients, with prevalence estimates ranging from 20-37%. Depression in ESRD patients has been shown to be associated with increased morbidity, mortality, and increased risk of hospitalization. Therefore, ASN believes that it is important to consider assessing depression as increased recognition of depressive illness that is subsequently appropriately treated can lead to improved patient outcomes. However, the society suggests that further study is needed to demonstrate that screening for depression and subsequent intervention improves patient outcomes. In particular, it is unclear which depression screening tool should be used and which treatments are best for ESRD patients. As a result, ASN recommends that CMS not implement this measure until further clinical research examining the role of screening for depression in dialysis patients and the effect of treatment on patient outcomes becomes available.

Pain Assessment and Follow-Up Reporting Measure (NQF #0420)

ASN supports a measure to assess pain in ESRD patients in concept, which is a crucial factor in patients' quality of life and well-being. Studies have shown that pain is among the most frequently reported symptoms in patients with ESRD. Weisbord et al. (CJASN July 2014) recently showed that pain was independently associated with abbreviated hemodialysis treatments, emergency room visits, and hospitalizations. Therefore, ASN believes that it is important to consider efforts to effectively recognize and treat pain and potentially improve patients' quality of life and overall health. However, insufficient data exist regarding the management of pain in ESRD patients for CMS to make definitive recommendations to providers. For example, there is no pain assessment tool for ESRD patients that have been validated in the existing literature. Similarly, strategies for chronic pain management in ESRD patients must be investigated. Therefore, ASN recommends that CMS not implement this measure until further research investigating the complexities of assessing and treating pain in ESRD patients becomes available.

QIP Scoring Methodology

For 2018, CMS proposes to revise the scoring methodology to assign measure scores on the basis of two domains: Clinical Measure Domain (CMD) and Reporting Measure Domain (RMD), which would both be divided into subdomains of Safety, Patient and Family Engagement/Care Coordination, and Clinical Care.

ASN appreciates the effort to stress clinical measures over reporting measures. That said, ASN is concerned that the proposal devalues actual reporting of the reporting measures and somewhat arbitrarily assigns values and subcategories to clinical measures which appear forced.

Under CMS' proposal, a facility could lose 40 points for failing to report but achieves little for full reporting. If CMS feels that the reporting measures have importance, then they should be at

least weighted in part as such, with positive rather than negative weighting for adhering to these reporting demands. With regard to the distribution of points for the clinical measures, this is difficult to comment on as the measures themselves are not fully delineated. Overall, ASN suspects that although patient experience is very important, the ICH-CAHPS measure is over-emphasized given the fact that no studies have shown an association between scores on the ICH-CAHPS and meaningful domains of quality. The society would favor lower weighting of ICH-CAHPS, lower weighting of the NHSN measure (which is complicated by issues related to reliable reporting), higher weighting on the vascular access measures, and continued inclusion of the reporting measures in the weighting system. Critically, as discussed above, the scoring system must provide sufficient margins that individualization of care remains possible.

Stratifying ESRD QIP Measures for Medicare-Medicaid Enrollees (Dual Eligibility)

ASN agrees with CMS that patients receiving dialysis who are eligible for both Medicare and Medicaid (“dual-eligible”) may be different in important ways and have different needs than patients who are not dual-eligible. ASN commends CMS for its interest in examining issues specific to potentially vulnerable patient populations and for exploring how to improve the quality of care they receive. Stratifying QIP measures according to whether a beneficiary is dual eligible could be an important first-step toward understanding the specific needs of this population and improving the quality of care delivered.

However, ASN strongly recommends that any stratified QIP measure be used purely for investigative purposes. In particular, ASN opposes the use of QIP scores stratified by dual-eligible status as a means of adjusting facility payments. If a stratified QIP score were to be used as a basis for payment adjustment, facilities could be held accountable to separate quality standards for their dual-eligible beneficiaries compared to non-dual-eligible beneficiaries. This could reduce the incentive to provide high quality care for both patient groups and reinforce disparities in quality of care.

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 recommends that CMS:

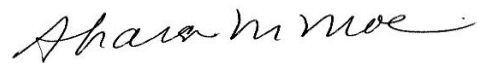
- Work transparently and collaboratively in measure development and specifications.
- Aim for parsimony in the QIP and other grading systems. Specifically, developing and implementing fewer measures that focus on the most meaningful items for patient care is a far better strategy than diluting both the QIP and the attention of dialysis providers with numerous measures of less substantial importance.
- Diligently avoid incentives to compromise individualized patient care in order to obtain a more favorable the QIP.
- Monitor the effects of the PPS on access to care, including the ability of ESRD beneficiaries to obtain promptly prescribed oral medications covered under Medicare Part D.
- Not implement the SRR measure to the QIP until several serious concerns with the measure have been addressed.

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

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

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

Sincerely,

A handwritten signature in cursive script that reads "Sharon M. Moe".

Sharon M. Moe, MD, FASN
President