ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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September 24, 2010

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

Re: CMS-3206-P: Medicare Program; End-Stage Renal Disease Quality Incentive Program [RIN 0938-AP91]

Dear Administrator Berwick,

On behalf of our 11,000 physicians and scientists, the American Society of Nephrology (ASN) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) End-Stage Renal Disease Quality Incentive Program Proposed Rule. 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.

ASN strongly supports CMS' goal of monitoring the quality of care provided to patients with end-stage renal disease (ESRD). In the context of a novel bundled payment environment, evaluation of quality and unencumbered access to dialysis services and prescribed medications will be of utmost importance. However, given the scientific evidence currently available, the society has reservations about some aspects of the proposed regulations. As the first pay-for-performance program in a Medicare fee-for-service program, the Quality Incentive Program (QIP) is fundamentally an experiment. Further, it is an experiment in a realm of medicine for which nephrologists are still developing evidence-based guidelines for patient management. As such, ASN offers the following overarching suggestions regarding the QIP: A) because of limited evidence supporting the QIP measures, the three finalized measures should be subject to replacement by new measures when scientifically validated performance targets are developed; B) the QIP should be redesigned to account for facility-level differences in case-mix; C) in the interim, careful monitoring in as close to real-time as possible will be crucial to the success of the QIP by minimizing adverse unintended consequences, including compromises in access to care.

Limitations Supporting Current QIP Measures

Recognizing the vital importance of preserving access to necessary medications and providing adequate renal replacement therapy to patient well-being, the society applauds Congress and CMS' efforts to monitor these areas. Based on currently available information, the three QIP measures selected are reasonable. However, ASN wishes to call attention to the limitations of the scientific evidence upon which the QIP measures are based. Specifically, none of the current QIP measures reflect care that falls solely under provider influence, nor has it ever been prospectively demonstrated that achieving these clinical targets leads to improved clinically important patient outcomes. The society recognizes that CMS is mandated by Congress to implement a QIP, and must select quality measures based on currently available information. Yet, the society believes it is important for CMS to acknowledge the scarcity of scientifically validated performance targets and create opportunities to change and replace these QIP

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measures in the future as new evidence becomes available in support of higher-priority and scientifically validated targets.

Indeed, a recent report on performance-based accountability systems for public services by the RAND Corporation cautions that "in many sectors, there is not a sufficiently strong evidence base to provide scientific evidence to would-be performance-based accountability systems adopters and providers." [1] This report highlights general lessons regarding performance measures and highlights several key points about their selection, concluding that: 1) performance measures should focus on measures that matter; 2) measures should treat service providers fairly (e.g., service providers should be able to influence the criteria of interest), and 3) performance measures that focus on a single absolute threshold score should be avoided. The report goes on to include specific recommendations regarding implementation and evaluation that the society believes are relevant to consider with regard to future roll-out and monitoring of the QIP.

Notably, performance measures are fundamentally different from consensus-based clinical guidelines. While guidelines may legitimately recommend certain treatment goals, they are rarely appropriate as "all-or-nothing" performance measures.[2] At this time, no proven causal association exists between improving the quality measures selected in the QIP and improved patient outcomes in terms of morbidity and mortality. Indeed, evidence for improved outcomes and efficacy of several drugs and therapies commonly used in the treatment of dialysis patients is limited and there are no universally-recognized, validated quality metrics. In general, ASN is concerned that incenting providers to achieve performance targets that have not been validated could potentially lead to unintended consequences for patients.

In particular, the society wishes to register that controversy persists regarding optimal management of anemia among patients with kidney disease. Over the past decade the nephrology community's definition of quality anemia management has changed significantly. Although the initial indication for erythropoiesis-stimulating agents (ESAs) was to raise hemoglobin levels sufficiently to avoid blood transfusions, the focus quickly shifted from partially restoring hemoglobin in early safety studies to normalizing hemoglobin levels—despite a lack of rigorous evidence demonstrating any benefit or absence of harm of targeting higher hemoglobin levels. The results of several recent landmark studies in conjunction with a re-analysis of older studies prompted an intense re-evaluation of the reasons for the failure to recognize the potential harms associated with ESAs (which include increased risks of stroke, heart attack, and death).[3,4,5] These publications have lead to congressional inquiry and US Food and Drug Administration (FDA) hearings which resulted in drug safety advisories, suspension of marketing, and black box warnings.[6,7] Had the current QIP been in place several years ago with the hemoglobin targets promulgated in clinical practice guidelines at that time, performance-based payment may have prompted excess deaths instead of improving patient care. For this reason, ASN believes caution must be exercised for all QIP performance measures that lack evidence demonstrating benefit on hard clinical endpoints.

Nonetheless, the society does believe that the new bundled payment system and the 10 g/dL hemoglobin floor CMS proposes for hemoglobin seems reasonable, and will likely prevent future ESA over- or under-dosing issues of this magnitude; the society supports these new policies until they can be revised with better scientific evidence. Importantly, however, recently-published evidence published does raise questions about the safety of a 10g/dL safety and deserves consideration.[8] This recent development highlights the society's conviction that all quality measures, including the 10g/dL floor, should remain subject to change as better scientific evidence becomes available.

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ASN recognizes that CMS is required to implement a QIP that holds facilities accountable to performance standards—and looks forward to working with the agency to fulfill this important yet difficult responsibility. Improved quality of care may lead to improved quality of life for the patients ASN's members treat—a shared goal of CMS and the society. With these perspectives in mind, ASN offers the following comments according to key components of the QIP:

1. Quality measures

As previously noted, ASN believes that the new bundled payment system and the 10 g/dL hemoglobin floor CMS proposes for hemoglobin will likely prevent future ESA over- or under-dosing—and supports these new policies until they can be revised with better, more recent scientific evidence. However, the society is concerned that the quality measures selected may penalize facilities with a large percentage of patients in whom it can be difficult to achieve the specified outcomes, including those with HIV or malignancies as well as facilities that serve patient populations that tend to be non-compliant, transient, or without the most appropriate vascular access. These latter three characteristics are most common among socioeconomically or medically disadvantaged patient populations—such as those with high rates of mental illness or substance abuse. In certain areas of the country, particularly in regions with disadvantaged patient populations, it is difficult to achieve the most desirable intermediate quality metrics (such as hemodialysis adequacy and hemoglobin level) despite the best efforts of nephrologists. Several studies have demonstrated that adverse selection of such patients occurs in the setting of undue incentives.[9,10,11]

Defining quality based on these intermediate quality metrics does not take into account variation between compliance level and vascular access across patient populations, nor does it reflect the efforts of nephrologists and other providers to provide high-quality care. Accordingly, the society strongly encourages CMS to implement case-mix adjustments when calculating performance scores. These adjustors would go a long way towards accurately portraying the quality of care offered in the unit and preventing penalization of facilities that serve the most difficult patient populations.

In particular, ASN is deeply concerned that application of these new quality measures without adjusting for case mix may result in more stringent acceptance standards in some units, and that non-compliant (or otherwise difficult to treat) patients may be more likely to be involuntarily transferred out of facilities. This is especially of concern for cities and regions with significant numbers of disadvantaged, or otherwise difficult to treat populations, as it may not be feasible for providers to meet these standards due to factors beyond the control of nephrologists or dialysis facilities. Preservation of equal access to nephrology care for all patients, regardless of geographic location or socioeconomic status, must be a foremost goal for the agency under the QIP; besides instituting case-mix adjustors, CMS should establish mechanisms to monitor patient access patterns in advance of the January 1, 2012 QIP start date. Please refer to ASN's more detailed comments on case-mix adjustment below.

CMS proposes not to include patients who are not receiving ESAs in the calculation of anemia management scores. ASN is concerned that this may create a perverse incentive to withhold ESA therapy in some cases, or to administer blood transfusions—which will be paid separately from the bundle—instead of ESA therapy in some cases. As such, ASN proposes that CMS assess the lower limit (10 g/dL) for **all** patients receiving dialysis care. In addition, the society strongly supports CMS' efforts to track blood transfusions under the new bundled payment system. It is of utmost importance to avoid transfusions in the dialysis population, in order to not jeopardize these patients' prospects of receiving and maintaining a kidney transplant due to immune sensitization. ASN urges CMS to take all possible steps to monitor both minimum hemoglobin levels (10 g/dL) as well as blood transfusion rates among all dialysis patients regardless of whether they receive ESAs.

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In summary, based on currently available evidence, ASN supports the use of the quality measures outlined in the ESRD Final Rule—but strongly encourages the agency to maintain flexibility to adjust or replace these measures as new evidence becomes available that may better reflect provider efforts to provide the highest quality of care.

2. Payment reductions

Safety-net and other independent or stand-alone dialysis units often provide a significant portion of dialysis care to disadvantaged or otherwise difficult to treat patient populations. In the interest of maintaining access to care for these individuals—as well as maintaining a diversity of providers to promote patient choice in where to receive dialysis care—ASN wishes to understand the impact of the proposed payment reductions on these safety-net and other not-for-profit facilities. The society appreciates that CMS has provided an estimate of the number and location of other facilities it projects will receive reductions based on other characteristics (such as small versus large and rural versus urban). ASN believes it is also important to estimate the influence of payment reductions by facility type (e.g., large dialysis organizations (LDOs) versus independent facilities). This is particularly necessary because the latter often serves a relatively large percentage of the patient populations in which it is inherently difficult to achieve quality metrics. The data used for assessing the quality of care should be appropriately weighted to reflect the actual potential of the unit to achieve the targets. Achieving sufficient dialysis and hemoglobin levels in all patients is a shared goal of nephrologists and CMS, but CMS should account for factors in specific units' patient populations that may influence their performance scores in its calculations.

ASN is also concerned that quality data from facilities with few patients may be skewed due to the small sample size, thereby negatively (or positively) affecting their overall performance score. In these small units, just one patient falling outside of the anemia or hemodialysis adequacy target ranges could result in performance scores that do not necessarily correlate with the quality of care provided. It is possible that the small-facility adjustor CMS created in the ESRD PPS final rule would compensate for payment reductions that are the result of skewed data. If this is the case, the society requests that CMS provide evidence demonstrating this effect—and if it is not the case, ASN strongly urges CMS to address this issue in the final rule. For instance, the agency may wish to consider removal of statistical outliers more than a certain number of standard deviations from the mean in all facilities (small or large) in either direction, in order to achieve a better sense of overall performance—and moderate the focus on a single absolute threshold score.

3. Performance Standards

CMS proposes to set the performance standard for each facility as the lesser of a) the performance of that provider or facility on each measure during 2007 or b) the national performance rates of all providers/facilities for each measure in 2008. ASN is supportive of CMS' proposal to hold facilities accountable to standards specific to their patient populations. Given the variability of patient characteristics across regions and facilities, it is most reasonable to compare facilities to their own patient population rather than a national average.

The goal of the QIP should not be to rank dialysis units based on performance standards, but rather to bring every unit up to its highest level of function. Therefore, the society believes that facilities should be measured against their potential, not against each other. The Scientific Registry of Transplant Recipients (SRTR) database within the transplant community could serve as a model: each transplant center's "expected" and "observed" outcomes are compared against one another. The poorly-functioning units stand out because their "observed" outcomes are significantly different than their "expected" outcomes.

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This model permits reflection of the subtle but important difference that, for instance, a unit with a 93 percent one-year graft survival rate may be providing higher quality of care than a facility with a 95 percent one-year graft survival rate because the first unit transplants higher-risk patients.

Although ASN recommends that CMS use facilities' own data as a performance standard baseline (intra-unit comparisons), if the agency determines to use historical national average data as a performance score baseline, ideally, CMS would rely on data closest to the current time period. Practice patterns have evolved considerably in the past several years, especially in light of randomized controlled trials results (beginning with CHOIR and CREATE in 2006 and continuing through TREAT in 2009) as well as the FDA Risk Evaluation and Mitigation Strategy (REMS) for ESAS, instituted in 2010. [12, 13,14] While recognizing the challenges of rapidly obtaining data, it is important to bear in mind the significant limitations of older data when determining performance standards that will determine payment reductions. ASN encourages CMS to use the most recent data available as the facility baseline.

The society suggests that CMS may also wish to consider determining performance scores at the patient level rather than the facility level. Under such a model, each patient would be held against his or her own scores from previous time periods. This would capture provider efforts to—or failure to—improve individual patient care. A total performance score could be calculated for each patient, with a mean patient score developed across the facility.

The society is also concerned by CMS's proposal that floors for the performance standards will never be lower than those set for the previous year. The science regarding ideal hemoglobin targets is still not definitive—and several randomized clinical trials (RCTs) have used 'lower' hemoglobin targets without obvious adverse effects. Patient population dynamics also change over time. For instance, older and sicker patients increasingly utilize dialysis services; dialyzing 80- and 90- year olds is no longer uncommon, though would have been relatively rare just a decade ago. Given that the science in this arena is still evolving, ASN believes it is unrealistic for CMS to expect that outcomes will necessarily improve over time. Again, the RAND report notes that "performance-based accountability systems are sufficiently complex that initial success is indeed rare, and the need for modification should be anticipated."

In addition, the society urges CMS to establish a formal way to evaluate the appropriateness of these metrics—leaving open the option to change the floors proposed or finalized levels in light of new evidence. The definition of optimal quality care will almost inevitably change over time as new data emerge, and CMS should permit flexibility to reflect these changes as it sets floors for performance standards in the future. For instance, fixed-dose ESA therapy has recently received attention as a strategy to balance the risks and benefits of ESAs.[15] Fixed-dose strategies would require different measures that are not hemoglobin-based. If this or any another groundbreaking treatment approach is validated in an RCT, CMS should be able to quickly alter quality measures to reflect the new findings.

4. Performance Scores

CMS proposes to weight the Hemoglobin Less Than 10 g/dL measure as 50 percent of the total performance score. Based on currently available evidence, ASN believes this is an appropriate decision, as this floor will incentivize providers to provide the optimal level of ESAs to keep patients healthy and maintain their quality of life by discouraging underdosing.

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However, given the variability in the patient populations dialysis facilities serve, CMS should use a case-mix adjustor for calculating performance scores based on these measures—which are influenced a great deal by patient factors. Case-mix adjusted, intra-unit comparisons would provide the most accurate representation of care quality and prevent unintended consequences. For example,in a small dialysis facility with a few patients with hemoglobinopathies, achievement of a hemoglobin >10g/dl would not only be difficult to achieve in these patients but also potentially harmful if high doses of ESA are administered to try to meet this target.[15] Further, if case-mix adjustment is not used, this small dialysis unit (when compared to the national average) would likely not be able to meet the QIP anemia target and may consider discharging these patients from their unit. As the agency has recognized the importance of case-mix adjustments to determine accurate payment for ESRD care under the bundle, the society would recommend case-mix adjustment when calculating performance scores.

5. Performance Period

CMS is mandated by the Affordable Care Act to implement payment reductions for dialysis services beginning January 1, 2012, and the agency proposes to select all of calendar year 2010 as the initial performance period. ASN is concerned that many facilities are not aware that the care they provide today will be evaluated—and potentially subject to payment reductions—two years from now. As CMS has yet to finalize the performance standards, it seems unreasonable that facilities would be penalized for patient results that were largely (or wholly) recorded prior to the finalization of the QIP. Consequently, it would not be possible for facilities to attempt to achieve the standards. The society is troubled that CMS would set a precedent of creating *ex post facto* regulations and strongly urges the agency to reconsider this proposal. ASN proposes that CMS instead make the first half of 2011 the performance period–assuming the agency publishes the final rule in 2010—and conduct data processing during the final six months of 2011.

6. Public Reporting

ASN appreciates CMS' commitment to transparency and openness in the provision of dialysis care and agrees with this principle. ASN is also aware that CMS is bound by statue to make performance under the QIP available to the public and looks forward to collaborating to develop meaningful and easily understandable methods of public reporting. Recognizing that transparency efforts must be executed in a way that is both accurate and meaningful from a patient perspective, the society stands ready to work with the agency in this important—yet challenging—effort.

Literature suggests that there are numerous potential limitations when quality reports are published; the public often does not understand them, distrusts them, and fails to make use of them. There are few, if any, randomized controlled trials that assess the effect of public reporting specifically on quality.[16] The value of publicly reporting quality information is largely undemonstrated and public reporting may have unintended and negative consequences on health care. Even in settings where there is an established link between process measures and outcomes, it is unclear how best to employ public reporting, particularly due to the potential for adverse selection as a result.[17,18] For instance, a propensity toward not performing a percutaneous coronary intervention (PCI) on higher-risk patients due to fear of public reporting of high mortality rates has been identified as a possible explanation for differences in patients undergoing PCI in one state.[19] While the society believes that transparency is important, ASN has concerns these about the proposed public reporting measures and associated goals for the reasons expressed above. In the context, society believes the complexities of public reporting suggest that developing this component of the QIP is an area of opportunity for collaboration between CMS and the nephrology community. The proceeding paragraphs highlight three specific areas the society wises to address with CMS in greater detail: case-mix adjusting, the specific goals of sharing performance score

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information, and working with stakeholders to develop meaningful, easily understandable presentation methods for patients.

As discussed earlier, because of variation in patient compliance and characteristics, performance scores are not necessarily an accurate reflection of the quality of care providers offer at a facility. Accordingly, the society believes that public reporting of facility-level performance scores without any indication of case-mix is problematic, as it omits vital contextual information about the significant variance in patient populations between facilities. As elaborated above, it is imperative that CMS create case-mix adjustors to account for this monumentally influential factor. Indeed, CMS recognizes this variation in the ESRD Final Rule and institutes patient-level adjustors to account for the differences between facilities' patient populations when making payments. ASN believes it would be unreasonable to prompt patients and the public to compare facilities' performance scores without providing them complete contextual information about patient population variance. Overall, the society is concerned that the QIP data without case-mix adjustors may be limited value for patients, and at worst paint a distorted picture of the quality of care available at certain facilities—underrating some and overrating others.

Recognizing that MIPPA requires CMS to publicly report performance scores, ASN encourages the agency to provide additional clarification on the specific goals of public reporting beyond meeting the statutory requirement. Especially in the absence of case-mix information, the society believes that it may not be appropriate for patients to use performance scores in determining where to access care. The society suggests that CMS work with ASN members and the renal community to obtain a better understanding of the needs and limitations of the many stakeholders and make improvements to the public reporting system prior to its implementation.

In particular, ASN strongly encourages CMS to set aside funding to conduct consumer testing with patients on dialysis to determine the best format and presentation method to enable patients to understand and meaningfully interpret the publicly reported data. CMS also notes that it will provide "appropriate comparisons of providers and facilities to the national average with respect to such scores," and the society suggests that developing methods of meaningful comparison for patients is another activity that would best be conducted collaboratively between the agency and the nephrology community. Given the inherent complexity of the quality measures themselves and the calculation performance score, ASN looks forward to working with CMS to clarify the specific goals of sharing performance score information with patients and develop ways to make quality data information "user friendly."

7. Future QIP Considerations

As previously discussed, ASN is troubled that few quality metrics exist that reflect provider effort to improve patient outcomes—yet the society recognizes the need to identify metrics to use within the context of the QIP now and in the future.

CMS notes that it will be developing measures that "reflect performance goals widely recognized by the ESRD medical community as demonstrating high quality care." Nephrologists currently use numerous metrics on a day-to-day basis to evaluate the health of their dialysis patients. However, patient factors and compliance have significant influence on almost all of these metrics—for instance, albumin levels, phosphorus, calcium, vascular access, transplant wait listing status, and immunizations. Achieving performance targets for all of these factors are sometimes also beyond the control of the patient or dialysis facility. For instance, obtaining the most desirable vascular access may be delayed due to a lack of interventional nephrologists or qualified vascular surgeons in the region. Higher serum albumin is strongly associated with improved patient outcomes, however, there is little evidence that specific interventions can improve serum albumin. Higher phosphorus is associated with poorer outcomes and

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while nephrologists administer medications to lower phosphorus, patient noncompliance is typically the reason for persistently elevated phosphorus. Even while the KDOQI Clinical Practice Guidelines set forth targets for mineral metabolism, anemia, blood pressure, and other measures, they have been criticized as being opinion-based—and potentially influenced by pharmaceutical companies which fund these guidelines.

Holding nephrologists to standards which are based on expert opinion and not hard science creates a dangerous precedent. In the absence of hard study outcomes (rather than observational or patient-reported outcomes) ASN believes it is difficult to identify quality metrics certain to reflect, and improve, the quality of care. Consequently, ASN suggests that CMS consider supporting efforts to generate necessary evidence in this arena. For instance, the agency may examine the Children's Oncology Group model of improving care over time. In the COG, every child with cancer is entered into a protocol and, through studying which patients do better over time, survival rates have improved. While translation of this model to the ESRD environment is neither direct nor problem-free, the approach may warrant consideration as a cost-effective method to generate evidence.

Given the society's concerns with lack of evidence around the effect of changing lab values on patient outcomes—and the degree to which compliance patient factors may influence certain results—ASN suggests that the agency consider, among other things, measuring the frequency of lab test ordering of some values rather than assessing the values themselves.

However, currently, most units measure parathyroid hormone (PTH) levels monthly or, in the most stable patients, quarterly. Clinical studies suggest that failure to treat hyperparathyroidism early makes it more resistant to medications and thus more likely to require surgery to treat. As such, ASN suggests that CMS measure PTH lab values as well as the rates of parathryoidectomy. In addition, because there is some trial data that supports Kt/V as a measure of dialysis adequacy, the society believes that this is a reasonable quality metric to consider pursuing. Literature also suggests that frequency of interdisciplinary sit-down patient rounds improve patient care and are associated with better patient outcomes, including an increased chance of meeting the albumin target, decreased hospitalization, and decreased risk of mortality.[20] While this is based on observational data, a future prospective study on sit-down patient rounds could yield a meaningful quality measure that reflects provider interventions for the QIP.

ASN recognizes that CMS will be developing additional measures in the future and, while the society has some reservations about the lack of availability of robust, scientifically validated evidence on which to base quality measures, ASN stands ready to collaborate with CMS to address these challenges.

Conclusion

On behalf of ASN, thank you for your willingness to consider these comments for the QIP Proposed Rule. The society's members are committed to providing the best possible care and believe monitoring the safety and accessibility of dialysis services is vital in this effort. ASN believes that there remain many challenges in developing an evidence-based system that accurately reflects the quality and availability of care offered in dialysis facilities nationwide. Nonetheless, the society offers several issues and recommendations to consider in this letter and hopes these comments will prove helpful. ASN would be pleased to discuss this letter with CMS if the agency would like to continue addressing the challenges highlighted. The Society also encourages CMS to engage the kidney community to address how this new pay-for-performance system will be updated in future years, and welcomes the opportunity to discuss this issue now and in the future.

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Again, thank you for your time and consideration. To discuss ASN's comments, please contact ASN director of Policy and Public Affairs, Paul C. Smedberg, at (202) 416-0640 or at psmedberg@asn-online.org.

Sincerely,

Sharon Anderson, MD, FASN
President, American Society of Nephrology

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