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Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1418-P: Medicare Programs; End-Stage Renal Disease Prospective Payment System Proposed Rule

Dear Acting Administrator Frizzera,

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comment on the Centers for Medicare and Medicaid Services (CMS) Proposed ESRD Bundled Payment Rule. ASN is a not-for-profit organization of 11,000 physicians and scientists dedicated to promoting excellence in the care of patients with kidney disease. Foremost among ASN's concerns is the preservation of access to optimal quality dialysis care and related services regardless of socioeconomic status, geographic location, or demographic characteristics.

The ASN End Stage Renal Disease (ESRD) Bundling Task Force applauds many aspects of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), and the proposed prospective payment system (PPS) as embracing true reform for the Medicare ESRD Program. However, ASN is concerned that in today's dialysis patient care and business environment, some aspects of the proposed regulations—in particular the inclusion of certain drugs and diagnostic laboratory tests that were formerly separately billable in the proposed bundle—may have adverse unintended consequences. At this time more than ever, ASN strongly believes in the importance of maintaining the integrity of the physician-patient relationship, which includes reasonable latitude for physicians in prescribing drugs and in ordering diagnostic laboratory tests.

ASN respects and appreciates CMS' willingness to collaborate with the renal community to address the important issues and challenges facing dialysis patients and providers in order to offer the most accessible, highest-quality dialysis treatment. In light of the Society's overall commitment to ensuring patient safety and access, quality of care, and the patient-physician relationship, ASN submits the following comments regarding the Proposed Rule.

III. The Proposed ESRD PPS Bundle
D. Diagnostic Laboratory Tests and Other Items and Services (p. 46)

-See Also-

XIII. Proposed Implementation for the ESRD PPS
B1 Claims Processing

a. Laboratory Tests (p. 356)

- **CMS should develop a mechanism by which nephrologists may order non-dialysis related laboratory tests.**

CMS proposes to include all laboratory tests that are separately billed by ESRD facilities as of December 10, 2010, and laboratory tests ordered by a physician who receives monthly capitation payments (MCPs) for treating ESRD patients that are separately billed by independent laboratories, in the ESRD proposed payment bundle. ASN understands and supports the Agency's desire to encourage rational, judicious lab test ordering in the dialysis unit.

Specialists caring for patients who are afflicted with a serious condition such as end-stage kidney disease often become the patients' principal care provider. Frequently, it is in the best interest of the patient for MCP nephrologists to order non-dialysis related laboratory tests, emphasizing the role of the nephrologist as providing comprehensive care to dialysis patients. Including such tests in the bundled payment will provide a disincentive for nephrologists to order non-dialysis related laboratory tests during dialysis.
There are many lab tests that are not directly related to renal dialysis services but that may be beneficial for nephrologists to order during the dialysis procedure. These include hemoglobin A1C tests for management of diabetes, thyroid function testing, and transplant related laboratories (such as assays for panel reactive antibodies and histocompatibility testing). ASN is particularly concerned if included, the cost burden of transplant-related tests ordered by nephrologists could inadvertently provide a disincentive that might hinder patients' likelihood to consider or be considered for transplantation.

Allowing MCP nephrologists to order laboratory values that are not related to renal dialysis services will provide a more cohesive model of care, minimizing patient discomfort and maximizing quality, efficient, and cost-effective care for patients.

ASN believes that CMS did not intend to create the potential for unintended consequences on physician flexibility in ordering lab tests. Yet, the existing language creates a disincentive for MCP nephrologists to order tests that would be appropriate in the care of patients on dialysis. In order to protect the nephrologists' vital role as a principal care provider and dialysis patients' ability to access high-quality care, ASN encourages CMS to develop a mechanism by which nephrologists may order tests that are not directly related to the provision of renal dialysis services but are nonetheless medically necessary.

III. The Proposed ESRD PPS Bundle (p. 47)

-See Also-

XIII. Proposed Implementation for the ESRD PPS
B1 Claims Processing
b. Drugs and Biologicals (p. 357)

- **CMS should prioritize the maintenance of physician flexibility in prescribing and patient access to potentially medically necessary medications as it sets the products and services to be included in the bundled base rate.**

CMS proposes to include all drugs and biologicals formerly payable under either Medicare Part B or Part D used to treat dialysis patients, regardless of the route of administration, in the bundle. ASN recognizes that the existing composite rate payment system created an incentive to over utilize certain separately billable drugs, particularly erythropoiesis-stimulating agents (ESAs). ASN appreciates CMS' efforts to reconfigure the payment system to encourage more cost-effective, appropriate use of pharmaceuticals and is supportive of the Agency's work to implement this legislation. We recognize that this is a highly complex issue with no clear answers based on currently available information; we also recognize that bundling is a novel system of payment. If CMS moves forward with implementing the bundle as currently proposed, ASN urges the Agency to:

1) include only medications directly related to dialysis care, as highlighted in subsequent paragraphs;

2) maintain physician prescribing ability for any drug within a class;

3) defend patient access to multiple therapeutic options;

4) ensure scientific investigation of the relative safety and comparative effectiveness of various medications and approaches to dialysis care;

5) establish a system to track the effects of this approach and constitute an independent panel of stakeholders and experts to evaluate the tracked data, as outlined in greater detail elsewhere in this comment letter.

It will be critical to closely monitor and assess the effects of the new payment system to enable immediate modifications should the need arise. Adverse effects must be identified in real-time, not simply over years by changes or lack thereof in data such as USRDS.

If implemented for ESRD care, this would provide the first example of how such a system influences the care of chronic disease and may serve as a model for health care payment reform. The dialysis patient population would serve as the experimental cohort for the implementation of this proposed payment system. Foremost among ASN's concerns is the potential for adverse consequences for our dialysis patients in this unprecedented environment. Thus, it is important to weigh the potential risks and benefits of the proposed bundled payment system on this issue.

Ideally, a bundled payment system would enable physicians to prescribe the most effective type and quantity of drug regardless of reimbursement level. Such a system may allow market forces to drive the choice of the most effective medications from the perspective of quality and cost. Inclusion of drugs related to dialysis care may allow for the widest range of flexibility for physician prescribing if all medications are equally available for scrutiny from a value standpoint. This approach may encourage dialysis organizations to maintain broad, inclusive formularies, which could facilitate physicians' ability to consider multiple therapeutic options.

If dialysis-related drugs not currently covered by the composite rate are included in the bundled payment, then this may catalyze the judicious use of medications. However the feasibility of such a strategy may be difficult to implement in the current practice environment where dialysis facilities are not currently responsible for furnishing oral medications to their patients. We are worried about the impact on our patients if it becomes more difficult for them to obtain desirable drugs.

ASN is concerned that in some circumstances, the inclusion of drugs in the bundled payment that are not currently paid under the composite rate may lead to pressures to prescribe selected medications, based primarily on financial considerations. In a consolidated dialysis market that offers limited choice in locations to obtain care, expanded bundling may hinder physicians' ability to prescribe, and patients' ability to access, medications that are vital to the quality of their care. ASN would like to maintain the ability for renal dialysis drugs to be prescribed according to medical indications as best tailored by physicians for optimal patient care, and encourages the Agency to bear this goal in mind when determining which drugs to include in the bundled payment rate.

The Society is also aware that little is known about the comparative effectiveness of medications used in the provision of dialysis services. Changes in prescribing patterns related to inclusion of all drugs in the bundle may improve or worsen—or may not even alter—patient outcomes. Yet ASN is also concerned that there is a lack of a clear understanding of how expanded bundling of medications may impact patient outcomes.

Maintaining choice for patients on dialysis is also important, again to ensure equitable access to quality care and to preserve individual freedoms for a patient population whose autonomy is severely limited due to their chronic illness. Given the frequency of dialysis treatments, studies show that over 90 percent of patients obtain their in-center treatment at a facility as close to home as possible.[i] Indeed for many patients on dialysis and their physicians, there is *little, if any, choice* available in where to obtain dialysis within their region. In the current national environment for dialysis care, two vertically integrated dialysis organizations provide services to more than 60 percent of all patients, and one of these organizations also produces and markets drugs commonly administered to this population. Under the proposed bundled payment system, dialysis facilities of all sizes and types will likely encourage staff and physicians to operate with maximal cost-efficiency. The cost of certain types and classes of drugs used in the care of dialysis patients is high, and may in some cases exceed the bundled base rate payment. In turn, some facilities may perceive a need to discourage physician prescribing of potentially medically useful drugs in an area where scientific evidence is sparse. Because the choice of best drug often depends on incomplete data and not every patient follows the norm, fixed regimens should not be based on algorithms using narrowly limited formularies. This will restrict availability of care to patients, and will significantly affect the autonomy of the patient–physician relationship.

ASN believes it is logical to only include those medications that are pointedly related to renal dialysis care in the bundled payment. This implies that medications administered in the dialysis unit that are not specifically related to dialysis services should not be included. For example, if CMS determines to include antibiotics in the bundle, ASN believes the antibiotic should be included if used for a dialysis catheter infection, but not if being used to treat bronchitis, pneumonitis, cellulitis and other infections not directly related to ESRD or dialysis. CMS should develop a mechanism to code for specific use of medications to include or exclude from the bundled payment appropriately. In addition, certain medications are frequently administered to patients on dialysis, but are not necessarily related to their renal dialysis care. ASN believes that such medication classes, such as anti-hypertensive medications and medications used to treat diabetes, are not appropriate to be included in the bundled rate payment.

ASN contends it is extremely important to set up a monitoring system to ensure that under this new payment system patients and physicians maintain access to the wide range of drugs that are available and appropriate. As discussed in greater detail elsewhere in this comment letter, ASN also proposes the creation of an independent board comprised of dialysis community stakeholders that provides oversight and reports concerns as they arise. ASN envisions that such a board would have a voice that is heard at all levels within the Agency and has consequential influence if it recognizes issues that are concerning within the novel practice environment.

Thus, ASN applauds the desire of CMS to be innovative in its approach to cost containment for medications. We also believe that bundling may be effective, but only if there are substantial safeguards to patient access, physician prescribing, and inclusion of appropriate drugs in the bundle as detailed above. Most importantly, because the ESRD bundled payment system is experimental and no demonstration project was completed, a process must be established to monitor medication use in real-time to ensure no adverse effects of the bundle on patient care and outcomes. This monitoring requires clearly delineated metrics, which are likely to be more inclusive than quality measures.

XIII. Proposed Implementation for the ESRD PPS
B1 Claims Processing
b. Drugs and Biologicals (p. 357)

- **In the interest of protecting patient access to medically useful products, CMS should propose a standard national method for dialysis facilities to establish prospective contracts with multiple traditional and mail-order pharmacies for the furnishing of renal dialysis drugs.**

CMS also proposes that "ESRD facilities would be required to furnish drugs formerly covered under Part D and any other self administered ESRD-related drugs to beneficiaries either directly or under arrangement." The Society is concerned that CMS has underestimated the potential complexities in this care transition. The burden of developing an on-site pharmacy that complies with state licensing requirements is substantial, especially in the limited amount of time prior to the implementation of the bundled payment system. Indeed, CMS states a belief that "many ESRD facilities would forego the process of becoming licensed as a pharmacy and instead, furnish renal dialysis drugs formerly covered under Part D under arrangement with a licensed pharmacy." Especially for smaller dialysis units, the complexity of implementing an on-site pharmacy may leave them no choice but to furnish drugs "under arrangement," even if that pharmacy is not conveniently located for patient access.

Patients with chronic illness already dedicate the time equivalent of a part-time job to obtaining dialysis treatment. They often wake as early as 4 a.m. to travel to, obtain, and complete their care—which leaves them physically exhausted—eight hours later. Some are blind, lack one or more limbs, or are otherwise markedly physically disabled, and are therefore reliant on others for transport to various centers of care. Patients on dialysis often lack the financial resources and physical capacity to seek out a contracted pharmacy in addition to their existing responsibilities and ASN is concerned that this demand may impede patients' ability to access crucial medications. Furthermore, ASN is apprehensive that patients who reside in rural areas may be disproportionately adversely affected by this aspect of the Proposed Rule, contributing to health disparities between urban patients.

In addition to concerns about patient access, ASN is concerned that CMS does not propose a uniform mechanism by which facilities will order, bill, and track drugs furnished "under arrangement." Prospective contracting for these drugs under the bundle would be immensely challenging and potentially disruptive to patient care if it places dialysis facilities in financially precarious situations. Although CMS indicates that a facility may establish arrangements with multiple pharmacies in the interest of patient access, developing numerous contractual arrangements may be extremely difficult for smaller facilities due to these complexities.

In the interest of preserving equitable patient access to medications under the new payment system, ASN urges CMS to propose a standard national method for dialysis facilities to establish prospective contracts with multiple traditional and mail-order pharmacies for the furnishing of dialysis-related drugs, regardless of the size of the dialysis provider

- **It is imperative that CMS institute a system to monitor and evaluate the impact of the ESRD PPS.**

Expanded bundling of dialysis-related medications is likely to result in changes in physician prescribing patterns. Due to the dearth of data on the outcomes and effects of the drugs commonly used in the treatment of dialysis patients, it is unclear whether a change in payment policy will be to the benefit or detriment of patient outcomes. Also, as described in greater detail elsewhere in this letter, ASN supports the use of certain patient- and facility-level payment adjustors. However, the Society is apprehensive that such adjustors may potentially create a perverse incentive for providers to cherry-pick, or preferentially select patient populations that qualify for greater remuneration through these adjustors. Such selection forces may create differential access to care for dialysis patients.

Given the Society's dedication to ensuring patient access, physician flexibility, and overall quality of care, ASN believes it is imperative that CMS establish a prospective monitoring system to study the impact of the bundled payment system on access to care, and utilization of dialysis-related medications and services that may be important in preserving patient health. ASN envisions CMS would contract with an entity to develop a system that collects and evaluates data to identify shifts in practice patterns and changes in patient outcomes in as close to real-time as possible. ASN suggests it will be necessary for the contractor to track dialysis-related medication utilization, patient lab data, closure of dialysis units, unit case-mix, and dialysis patient mortality data. Additional measures may also be needed to evaluate any potentially adverse consequences of the new bundled payment system. The data collected by the contractor should also be made available to the nephrology and research community for review and analysis in a timely fashion. That said, ASN is concerned that the Agency—or any contracted entity—possesses no baseline data by which to determine whether patient care is actually better or worsened under the new

bundled payment system. CMS and its contractor may wish to consider developing a baseline using data collected during the transition period, during which some facilities will adopt the bundled payment and others will maintain the current method of payment—though confounding variables could be significant. Alternatively, CMS and its contractor may wish to retrospectively monitor changes.

The engagement of multiple outside bodies in the monitoring process is vital to protect the health of our vulnerable patient population. While the 2003 Medicare Modernization Act (MMA) obligated the Agency to conduct a demonstration project to analyze the impact of a bundled payment system, CMS did not ultimately carry out the project. The fact that there is no existing information on the potential effects of bundled payments on patient care speaks to the need for an independent body to provide oversight as the new payment system is rolled out across the country. As such, ASN proposes that CMS form an external oversight board comprised of a diverse group of dialysis community stakeholders, including patients, physicians, nurses, and providers. This board would review the contractor's reports to ensure that the data is transparently presented and is analyzed as objectively as possible in as close to real-time as is possible. Furthermore, it would ideally possess the authority to exert influence on CMS policy to remediate any negative changes in availability or quality of patient care identified.

- **Given the impact of the bundled payment system on practice patterns and the dearth of data on optimal care of renal dialysis patients, it is vital that CMS support comparative effectiveness research in this area.**

It is imperative that changes in practice and prescribing patterns under the proposed bundled payment system do not result in unintended adverse effects on patient safety or quality of care. In the short term, developing an active monitoring and evaluation system is vital to achieving this goal. Yet this new payment system—particularly its proposed pay-for-performance measures—highlights the vacuum of evidence within nephrology about the impact and effectiveness of treatments used in the care of dialysis patients.

Especially in light of the new payment model, it is crucial that physicians have access to prospective studies that examine the relative safety and effectiveness of the range of pharmaceutical products and renal replacement therapies. The availability of this data is important not only to protect patient well-being, but also to enable physicians to feel comfortable prescribing the most cost-conscious drug under the bundled payment.

Given CMS' influence in shifting prescribing patterns and drug utilization via the bundled payment system, ASN contends the Agency must also assume responsibility for ensuring the completion of comparative effectiveness research on the therapies for ESRD that have been targeted for financially-based performance measurement.

Although many components of ESRD care require greater evidence, ASN generally encourages implementation of comparative effectiveness research on the following four classes of drugs, which are tenets of dialysis patient care: Phosphate binders, intravenous iron, vitamin D derivatives, and cinacalcet. More specifically, ASN would hope to see comparative effectiveness research on products for which the prescribing patterns are likely to change under the bundle, including studies listed on the following page.

- Bone and mineral metabolism and parathyroid hormone (PTH) drugs
    - Effectiveness of vitamin D vs. cinacalcet
    - Effectiveness of oral vs. intravenous vitamin D therapies
    - Effectiveness of different active vitamin D therapies, or analogs
    - Effectiveness of calcium carbonate vs. calcium acetate as phosphate binding agents
    - Outcomes between patients receiving cinacalcet and no cinacalcet

- Anemia management drugs
    - Intensive intravenous iron-based strategies vs. Intensive ESA-based strategies for anemia management

- Optimal dialysis dose

- Volume of nutritional supplements

- Cardiovascular disease prevention
    - Lipid control
    - Blood pressure control and monitoring

ASN also encourages the Agency to support research on different combinations of therapy in addition to single drug comparators. This may include, for instance, a study examining the effect of cinacalet plus calcium binders versus vitamin D plus non calcium binders, or a study comparing an ESA plus oral iron against ESA plus intravenous iron. This is especially important because single drug studies have generally not shown patient-level outcome benefit in the kidney disease population.

Comparative effectiveness research is also needed to evaluate drugs that are commonly used in the care of dialysis patients but whose effect in that specific population has not been evaluated. In the interest of patient safety, CMS should also support studies that compare the safety and relative effectiveness of these medications within the dialysis population.

Finally, ASN is also concerned that a new payment system may have an adverse impact on research on new therapies, as new drugs are typically more costly and may therefore be disadvantaged for selection under a bundled payment. This may reduce the incentive to perform research in the kidney disease population. If CMS implements the bundle as proposed, it should consider strategies to prevent any deleterious consequences on research and development or the advancement of science in the nephrology arena.

ASN recognizes that the Agency does not commonly engage in research and development-related activities or comparative effectiveness research. However, the Agency should seek to partner with other organizations such as the National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), the Food and Drug Administration (FDA), and academic institutions to conduct these crucial studies.

XIII. Proposed Implementation for the ESRD PPS

A2. Limitation on Beneficiary Charges under the Proposed ESRD PPS and Beneficiary Deductible and Coinsurance Obligations (p. 352)

- **CMS should limit patient co-payment responsibility to 20 percent of the base rate payment, as making patients responsible for increased costs due to adjustments to the base rate—such as outliers—may represent a substantial increase from current financial obligations and could hinder this fragile, chronically ill patient population's ability to continue obtaining dialysis treatment.**

CMS proposes to include cost of all drugs and biologicals formerly payable under either Medicare Part B or Part D used to treat dialysis patients in the bundled rate. The Agency also proposes that a 20 percent beneficiary coinsurance that would be applicable to the total ESRD PPS payment, including any adjustments such as those for case-mix, geographic wage index, and outlier services. Shifting drugs that were formerly paid under Part D—a tiered, capped co-payment system—and adding lab services into the bundle has the potential to significantly increase the co-payment amounts owed by patients relative to their current responsibility. ASN is concerned that this financial burden may constitute a major barrier to accessing adequate care for many patients.

While it is difficult to estimate the implications of the 20 percent co-insurance proposal under the bundled payment due to variance in beneficiaries' coverage, ASN believes the effect on some patients may be substantial.

For instance, the proposed policy could result in a sizeable cost for patients who currently have Part D coverage of oral drugs, and it may be the first time some of these patients are responsible for any co-payment for such medications. The co-payment amount under Medicare coverage may also significantly exceed the current co-payment responsibility of patients who currently have private coverage. Similarly, patients who do not have prescription drug coverage from any source will receive coverage under Medicare Part B, which may may result in an increased co-payment responsibility. Finally, patients who are currently dually-eligible for Medicare and Medicaid may experience the greatest co-payment increase of all.

In the event that the Agency should move forward with implementing the bundle currently outlined in the Proposed Rule, ASN strongly recommends that CMS seek alternatives to implementing the 20 percent co-payment responsibility for the total until the Agency has identified a method to eliminate its potentially negative impact on patient access.

ASN also objects to the Agency's proposal that patients would be responsible for paying for adjustments to the bundled base rate—such as patient- and facility-level adjustors and outlier payments—in their 20 percent co-payment amount. Under this proposal, an African American woman may, for example, face a higher out-of-pocket cost than a white male due to outlier payments. This sets a dangerous precedent for discrimination on the basis of race and gender in health care and federal policy. For some patients, this would create a significant financial obligation that may hinder their ability to access care. ASN strongly encourages the Agency not to make patients responsible for increased costs due to adjustments to the base rate, but rather limit all patients' co-payment responsibility to 20 percent of the base rate payment.

III. The Proposed ESRD PPS Bundle
E. Home Dialysis Patients (Method I and II) and Self Dialysis Training
2. Self Dialysis Training (p.54)

-See Also-

VIII. Cost Regression Used to Develop Proposed Payment Adjustment Factors
B. Proposed Patient-Level Adjustments
4. Onset of Dialysis (New Patient Adjustment) (144)

- **Providing payments specifically for home training is essential to preserve patient and provider choice to select the most appropriate treatment environment.**

For some patients, certain dialysis therapies or environments may be more appropriate than others to promote the highest quality of care and lifestyle. ASN is committed to preserving patients' ability to choose their preferred location of dialysis and would like to maintain the ability for patients to make this choice under a new bundled payment system. As such, ASN appreciates CMS' stated goal of encouraging home dialysis and applauds the Agency's assignment of a single base rate regardless of modality for adults.

However, ASN is concerned that inclusion of training for home dialysis under the proposed bundled rate payment may not be consistent with this goal. ASN believes that a bundled payment system should not reward providers for offering one form of dialysis over another. Rather, the system should reward those centers that foster patient choice in modalities and locations of dialysis.

Physicians, dialysis providers, and other medical staff must dedicate a significant amount of time and resources to provide safe and comprehensive home dialysis training for hemodialysis and peritoneal dialysis (PD). Indeed, CMS and MedPAC have recognized the additional costs incurred in providing this training on multiple occasions. In the 2008 Report to Congress, the Agency also acknowledged that the present payment amount for home dialysis training, which has not been updated since 1983, is insufficient to cover the actual cost of training.

ASN is concerned that elimination of discrete compensation for home dialysis training may create a disincentive for providers to offer the training. Instead of supporting those units that offer home dialysis training, the Proposed Rule would provide compensation at the same rate as units that do not provide home dialysis options.

The provision of adequate payments specifically for home training is essential to ensure that dialysis providers are able to preserve patient and provider choice to select the most appropriate treatment environment. As such, ASN recommends that the Agency to create a "home dialysis training" adjustor that provides higher payments at *any* time during a patient's treatment that he or she elects to undergo home dialysis training. Given CMS' acknowledgement that existing payments for home dialysis training are insufficient, in the interest of protecting patient choice and safety, ASN encourages the Agency to calculate the payment adjustor for home dialysis training using the best available information based on actual resource requirements.

IV. Unit of Payment (p. 58)

- **CMS' decision to provide payment per unit of payment will encourage patient compliance and clinical flexibility.**

As stated in the Proposed Rule, CMS "proposes to establish an ESRD PPS which relies on a per treatment unit of payment." CMS further proposes to maintain the current payment system that allows ESRD facilities to be paid up to three treatments per week, unless medical necessity justifies more than three weekly treatments. ESRD facilities treating patients on peritoneal dialysis or home hemodialysis would also receive the payments for up to three treatments for each week of dialysis, unless medical necessity justified the furnishing of additional treatments.

ASN believes that a per treatment unit of payment system provides an incentive to ESRD facilities to encourage their patients to refrain from skipping treatments and affords an appropriate level of clinical flexibility in treating patients. CMS rightly states that they are concerned that a monthly ESRD PPS would provide no incentives for discouraging skipped treatments. ASN believes that the proposal appropriately aligns a per treatment unit of payment with patient care and compliance.

A per treatment unit of payment system also benefits ESRD patients by providing a reasonable degree of flexibility to receive treatments in more than one facility when necessary due to hospitalization or personal or work-related travel. As CMS highlights, approximately 19 percent of out-patient dialysis patients incur an interruption of service or receive their treatments at more than one facility during the month. The proposed per treatment unit of payment ensures that patients receive treatments at ESRD facilities/locations without restriction. ASN encourages CMS to maintain its commitment to the current Medicare policy, giving patients the ability to receive additional treatments where medically appropriate.

VIII. Cost Regression Used to Develop Proposed Payment Adjustment Factors (p. 120)

- **A differential payment system that promotes selective patient enrollment based on payment levels provided by CMS may generate perverse incentives and result in variability in quality of care.**

ASN strongly believes that access to renal replacement services for all patients must be preserved. However, the Society is concerned that the facility and patient level adjustors in the Proposed Rule may generate perverse incentives and promote adverse selection. The Society understands that the proposed facility and patient level adjustors are meant to mitigate those risks but respectfully submits that these sections of the Proposed Rule are flawed for several reasons.

First, the proposed predictors, identified by the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) analyses, are based on incomplete data. UM-KECC primarily focuses on identifying the costliest patients to dialyze based on drug and laboratory costs, expenses that could be manipulated by the providers and drug industry to optimize reported costs in order to maximize CMS payments. We suggest that case-mix adjustors identified by this approach will poorly predict actual costs. The current rule may particularly disadvantage small providers that are unable to use a large network to promote selection of the most "lucrative" patients. This may further promote consolidation in the dialysis industry in some geographic areas and limit patient choice and competition nationwide.

Second, philosophically, ASN is concerned by a differential payment system that promotes selective enrollment or disenrollment of high cost patients based on the payment levels provided by CMS. In addition, risk selection may also promote variability in care quality that will not be transparent to patients or nephrologists. Although ASN understands that adjustors will be included in the final rule precisely in order to reduce the incentives for patient risk selection, the Society believes that CMS needs to have continuous and careful evaluation of the consequences of the adjustors on adverse selection and to determine if the adjustors effectively predict health utilization and dialysis costs. The Agency may need to use data collected during the implementation of the proposed bundle to develop robust risk adjustors that meet the equity requirements. Since ESRD treatment operates under competitive model, empiric data from analysis of managed care suggests adverse selection is more than a theoretical concern.

B. Proposed Patient-Level Adjustments

- **The data CMS employed to determine the proposed patient-level case-mix adjustors may not capture the most costly variables in patient care.**

ASN appreciates the recognition by CMS that specific patient subgroups require resource-intensive treatment and supports CMS' proposal to adjust certain ESRD facility reimbursements based on case-mix adjustors. However, as discussed previously, ASN is concerned that data used by UM-KECC to derive case-mix adjusted payment rates for individual patients are limited to composite rate and separately billable services, which may incompletely capture the most costly variables in ESRD patient care. ASN believes the costliest patients are those who require frequent or prolonged hospitalizations, where the assigned chair remains empty, resulting in no payment and little flexibility in reducing the substantial fixed costs associated with dialysis.[ii] An alternative approach to identify case-mix adjustors that capture significant variation in renal replacement therapy costs would be to determine predictors of hospitalization frequency and duration. ASN is concerned that the omission of these often costly aspects of patient care renders the entire model intrinsically flawed. The Agency may be overlooking facilities that face significantly higher than average expenditures to provide patient care due, for instance, to patient population that require frequent hospitalizations or extensive staff assistance.

ASN supports the use of appropriate patient-level case-mix adjustors to prevent closure of dialysis facilities with disproportionate numbers of high cost patients that could occur without additional reimbursements. These facilities are the most likely to serve the most vulnerable populations. However, the Society is concerned that CMS ensure the adjustors do not create perverse incentives to cherry-pick a specific patient populations that maximizes profits and inhibits access to care for other patient group. As previously discussed, ASN believes that CMS must establish a system to identify unintended consequences of the case-mix adjusted models that limit patient access to quality ESRD care.

Finally, the process by which dialysis facilities gather data to document case-mix must be feasible and easily executable. A complex, administratively resource-intensive system would disadvantage the very facilities CMS intends to support through this measure. For example, variables like the diverse disease states identified by ICD-9 codes, which are included in the proposed patient case-mix adjusted models, are not readily available to independent dialysis facilities. ASN encourages the Agency to bear these concerns in mind when developing mechanisms to document case-mix information and when finalizing the patient characteristics that qualify as case-mix adjustors. Despite these reservations, ASN believes that some degree of

case-mix adjustment accounting for variance in patient-level cost of care is preferable to none whatsoever.

2. Patient Sex (p. 135)

- **Patient gender may be an appropriate case-mix adjustor, but highlights the need for a monitoring system to detect any adverse impact on patient access.**

Based on the information provided by CMS in the Proposed Rule indicating that facilities that treat more female patients face higher dialysis treatment costs, ASN would support the Agency's proposal to provide higher reimbursements for their care through a patient-sex adjustor. However, ASN's previously discussed concerns regarding a differential payment system based on individual patient characteristics, and the potential for cherry-picking and higher co-payments for patients that qualify for adjustors, are of particular importance with regard to this adjustor.

4. Onset of Dialysis (New Patient Adjustment) (p. 144)

-See Also-

E. Home Dialysis Patients (Method I and II) and Self Dialysis Training
2. Self Dialysis Training (p.54)

- **CMS should develop a "home dialysis training" adjustor that provides higher payments at *any* time during a patient's treatment that he or she elects to undergo home dialysis training, and eliminate new patient adjustor in favor of other adjustors that address the root causes of higher costs during the first four months on dialysis.**

ASN concurs with CMS that in general "individuals who have been newly diagnosed with ESRD have higher costs in the first 4 months of dialysis," and appreciates the Agency's efforts to reimburse these costs. Home dialysis is an effective and increasingly popular treatment environment that may enhance quality of life for some patients.

In its discussion of the first four months of dialysis, CMS states that a large contribution to costs during this time may be due to training patients and their caregivers to perform home dialysis, both in-center and at home. However, data show few patients begin home training within the first 120 days of treatment. 85 percent of patients who initiate home hemodialysis training, and many patients who initiate home peritoneal dialysis training, do so after having received treatments in a dialysis center for at least four months, in order for the patient to become acclimatized to dialysis treatments. As such, costs associated with home dialysis training are most commonly incurred several months after a patient receives an ESRD diagnosis and initiates dialysis. A mistimed payment adjustor may create a disincentive for providers to offer the training option, thereby limiting options for renal replacement therapy. Given ASN's dedication to preserving patient choice and access to care, the Society recommends that the Agency create a "home dialysis training" adjustor that provides higher payments at *any* time during a patient's treatment that he or she elects to undergo home dialysis training.

CMS provides data that demonstrate higher dialysis costs in the initial months of dialysis treatment. However, because the majority of increased costs during the first four months on dialysis may largely be the result of hospitalizations and higher drug utilization related to patient race, ASN believes that these costs may be better captured by mechanisms other than the proposed 120-day new patient adjustor, such as an adjustor for patient race. The Society also reiterates its concern that CMS has not specifically included risk of hospitalization in its consideration of case-mix adjustors. Given these concerns, as well as the Society's desire not to excessively reduce the base payment rate due to a proliferation of adjustors, ASN encourages CMS to eliminate new patient adjustor in favor of other adjustors that address the root causes of higher costs during the first four months on dialysis.

5. Co-Morbidities (p. 145)

- **ASN questions the accuracy of the data used to calculate co-morbid adjustors and encourages CMS to re-calculate these measures with after verifying the data quality. The Agency should also provide evidence of the independence of the predictors of cost examined in the model.**

CMS proposes a co-morbidity adjustment based on the Agency's finding that listed co-morbidities, defined by ICD-9 codes, are predictors of variation in payments for ESRD patients. ASN recognizes that the presence of co-morbidities may affect the cost of providing care. Beyond ASN's fundamental concerns about the use of any differential payments, ASN is concerned that the co-morbidity case-mix adjustors proposed by CMS lack predictive power and may duplicate costs associated with other variables. Indeed, CMS reports that it obtained different results from different regression models, and different results when adding a race adjustor to the analysis. This suggests that the co-morbidities for which CMS proposes to provide adjustments are not actually independent—and the Agency provides no evidence of its efforts to ensure the independence of these variables.

- **CMS should ensure that data required documenting eligibility for patient-level adjustors be readily available to coders in dialysis units prior to implementing the proposed bundled payment system. The Agency should also collaborate with the renal community to identify co-morbid conditions that are predictors of hospitalization.**

CMS also acknowledges that "the available data did not identify use of resources by individual patients" and it therefore relied on a "facility-level regression model to estimate the relationship between patient characteristics and cost." ASN is concerned that there is little basis to associate facility-level costs with individual patient co-morbidities, as other factors—such as staffing mix and group-purchasing practices—are likely to have greater impact on dialysis facility costs.

ASN is further concerned that dialysis units cannot capture the ICD-9 codes listed in the proposed rule. In its analysis to determine co-morbidities that patients have which warrant case-mix adjustors, CMS captured patient characteristics using co-morbidities and diagnoses from multiple sources, including the Medical Evidence Form 2728 and ICD-9 codes. Because coders at dialysis units do not have access to a patient's complete medical records, ASN questions if patient level data for the co-morbidities listed in Table 14 of the Proposed Rule will be available to dialysis providers. If not, "real life" application of the proposed model may be impractical. The administrative burden of collecting data this breadth of sources would be immense for dialysis units, particularly smaller, independent facilities. Without a mechanism to associate costs with

co-morbidities at the individual patient level, CMS should refrain from implementing the co-morbidity adjustment. As proposed, the adjustor is based on potentially inaccurate patient characteristic data and facility-level information with questionable predictive power for variance in costs to provide dialysis to individual patients.

Although the intent of payment adjustors is to provide financial support to facilities with the most resource-intensive patients, the burden associated with collecting co-morbidity data may potentially disadvantage these very facilities. Therefore, CMS should limit case-mix adjustors to data that is simple and easily obtainable. Without a clear mechanism to provide coders at dialysis units, or other locations, the co-morbidity data necessary to fully and accurately complete the claims forms, and ensure the validity of the co-morbidity data used to conduct its analysis, the Agency should refrain from implementing proposed new co-morbidity adjustments. In the future, however, ASN would appreciate the opportunity to work with CMS to identify co-morbid conditions that influence the cost of providing care, and methods to make patient information readily accessible to coders in dialysis units. In particular, ASN would encourage CMS to examine patient co-morbid conditions that are predictors of hospitalization.

ASN acknowledges that HIV/AIDS status is a generally complex and difficult issue to address due to privacy protection concerns. CMS reports that inclusion of HIV/AIDS in the model increases its explanatory power, and data provided by the agency also indicates that that an HIV/AIDS adjustor would give "higher payments for patients who are substantially more costly to treat." The Agency also acknowledges logistical challenges to implementing an HIV/AIDS adjustor. Dialysis facilities are required by state law to maintain patient confidentiality and some may therefore be unable to comply with reporting HIV/AIDS diagnoses on individual patient claims. ASN recognizes the administrative difficulties associated with maintaining patient HIV/AIDS status confidentiality as well as with identifying the presence of certain co-morbidities in lieu of access to complete patient medical records.

ASN notes reservations about exclusion of a payment adjustor for HIV/AIDS, as it may place facilities with a high prevalence of HIV/AIDS patients at great financial risk. This may jeopardize access to care for this patient population as well as others who dialyze at such facilities. This is especially of concern for patients who dialyze in inner-city environments.

However, nephrologists and dialysis providers do not prescribe a differential dialysis treatment regimen for HIV/AIDS patients based on their disease status. This suggests that HIV/AIDS status may actually be a surrogate for other costly patient characteristics, such as African American hyporesponsiveness to ESAs or for increased rates of hospitalization among individuals with advanced AIDS. As such, ASN again encourages the Agency to consider implementation of adjustors for race and to examine other patient co-morbid conditions that are predictors of hospitalization, as these may obviate the need for an HIV/AIDS adjustor.

However, were CMS to proceed with instituting a payment adjustor for HIV/AIDS, ASN suggests that the Agency make this a facility-level, rather than a patient-level, adjustor. The Society believes this may alleviate concerns of potential compromise of individual patient privacy. Additionally, ASN would encourage CMS to re-calculate the effect of HIV/AIDS on cost after adding patient race to the model.

6. Race/Ethnicity (p. 145)

- **In the interest of protecting access to care in population centers whose demographics are dominated by one race/ethnicity, CMS should include patient race as a patient-level adjustor.**

In the Proposed Rule, CMS states that the analyses of "race and ethnicity data demonstrate associations between these patient characteristics and facility level composite rate costs and patient level separately billable payments." Indeed, CMS presents evidence suggesting that race may explain cost variability in patients more effectively than other proposed adjustors, such as co-morbidities.

ASN maintains fundamental reservations about a payment adjustor that sets a precedent of formalizing differential healthcare costs for African Americans or other racial/ethnic groups in policy. As previously discussed, the Society is uncomfortable with a differential payment system that may promote adverse patient selection. ASN also notes that such a policy may encourage providers to misidentify racial/ethnic status to qualify for greater payments.

If CMS were to move forward in implementing such an adjustor, the Agency may wish to consider the expansion of racial/ethnic categories to minimize the potential for "gaming" and to better account for patients of mixed race. Patients who are unwilling or unable to provide race/ethnicity information based on these categories would not be eligible for an adjustor. ASN also proposes that because race appears to be more predictive of costs than co-morbid conditions, CMS should eliminate the co-morbid adjustors to prevent provision of duplicate payments. Replacing the co-morbidity patient-level adjustors with a measure of race may also obviate the need for CMS to reduce the base rate to maintain budget neutrality. Again, it will be imperative for the Agency to constantly monitor and evaluate for adverse selection practices or other unintended negative consequences on patient care quality and availability. This is a challenging yet vital duty.

Despite these significant reservations, on the basis of the data provided by CMS and on the likelihood that race is a surrogate for other costs associated with co-morbidities, ASN believes that in the interest of protecting access to care in population centers whose demographics are dominated by one race/ethnicity, patient race should be included as a patient-level adjustor.

Higher costs associated with self-reported race are not evenly distributed across the population; rather, they are typically concentrated in locations the where the population is primarily comprised of one demographic group. Accordingly, many facilities serve communities of color. The bundling of higher costs associated with a particular race or ethnicity that were formerly separately billable, such as greater ESA use in the hyporesponsive African American population, will have a dramatic negative influence on facilities that care primarily for patients of that race or ethnicity. Lack of an adjustor to account for racial/ethnic variation in costs may potentially negatively influence access to care for a significant number of patients.

For instance, many dialysis facilities provide a large percentage of their total treatments to African-American patients, particularly in certain regions of the country. In some areas, these facilities also predominately serve Medicare patients. Facilities with a majority of African-American patients also tend to be urban, and ASN is concerned that the new bundled payment system not inadvertently jeopardize access to care for economically disadvantaged minority communities.

CMS excludes a case-mix adjustor based on race in the Proposed Rule, primarily citing concern that "race/ethnicity is not objectively measured" because it is "commonly based on self-reported information." ASN disagrees with the position that self-identified race data are less reliable than ICD-9 or other administratively reported data. In fact, multiple studies contend that self-reported race/ethnicity is the "criterion standard," as it is accepted in the U.S. census and numerous other settings as an accurate reflection of race/ethnicity. In contrast, race/ethnicity data in medical records are commonly based on provider observation and inference.[iii,iv] Since 2003, patient self-report of race/ethnicity has been the preferred method of collecting this information in the Veteran's Affairs (VA) administration.[v] Indeed, utilization of patient self-reported race is a crucial step toward minimizing opportunities for providers to game the payment system by recording inflated numbers of costly demographic groups.

Based on the information currently available, instituting a race/ethnicity adjustor is an important—and feasible—course of action to maintain access to care. The Society welcomes the opportunity to discuss this issue, as well as other potential adjustors, in greater detail with CMS. For instance, the Agency may also wish to consider an adjustor for socioeconomic status (SES). Such an adjustor may encourage dialysis providers to establish facilities in disadvantaged communities. SES cannot be gamed, and may help abrogate race/ethnicity, self-reported race, and other privacy issues.

7. Modality (p. 195)

- **Maintaining equal payments regardless of modality is an effective strategy to preserve patient and provider choice.**

ASN appreciates and supports CMS' proposal to maintain equal payments for PD and hemodialysis. The Society believes that PD is sometimes a good option for those patients desiring and deemed eligible for home dialysis and applauds CMS for preserving patient ability to choose among the various dialysis modalities, either in-center or at home.

8. Outliers

- **CMS' proposals regarding outlier payments are generally sensible and will assist facilities to provide adequate care for costly patients, but should be evaluated and adjusted periodically.**

Overall, ASN believes that CMS' core proposals for outlier services are satisfactory. The Society's general concerns regarding the inclusion of certain drugs and lab services in the bundle also apply to outlier payments insofar as CMS proposes that dialysis facilities would be responsible for furnishing or making available these items and services. Yet as the Agency implements the Proposed Bundle, practice patterns, and therefore costs, will change. ASN is particularly concerned that these payment changes could limit access for vulnerable ESRD patient populations and promote unintended, perverse incentives for patient cherry-picking. As such, CMS must re-calculate adjustors periodically to ensure they reflect the changes in reported cost of care for these patient populations and ensure ongoing equity in access for all ESRD patients.

VIII. Cost Regression Used to Develop Proposed Payment Adjustment Factors
C. Proposed Facility-Level Adjustments
1. Wage Index (p. 206)

- **The absolute amount of labor reimbursement should remain the same in 2011 as in 2007, adjusted for inflation. In future years this measure should be updated to reflect additional labor costs associated with the inclusion of formerly separately billable items and services in the bundled payment.**

Under the Proposed Rule, CMS proposes that the labor-related share of the proposed bundle (38.16 percent) will be significantly lower than the share under the current rate (53.711 percent). ASN recognizes that that with the addition of the cost of separately billable items and services, the percent of the total payment attributable to labor costs logically decreases, if the assumption that the separately billable services have no associated labor costs is valid (please refer to the following paragraph). Although ASN does not have data to assess whether the percentage of labor share within the bundle is correct, the Society wishes to state its belief that the absolute amount of labor reimbursement remain the same, adjusted for inflation for 2011.

Furthermore, CMS claims that "no [additional] labor costs [are] associated with the separately billable portion of the proposed market basket." However, ASN believes assumption may not be valid and is not supported by data in the Proposed Rule. The current labor share was "developed from the labor-related components of the ESRD composite rate market basket," and CMS used calendar year (CY) 2007 data to determine the proposed labor-related share for the bundled payment system. Given that the CY 2007 data could not account for costs attributable to the separately billable services, CMS does not have the data to assess any change in labor costs associated with separately billable services. ASN believes it is vital that the Agency re-calculate the base rate as soon as data from the new payment system becomes available in 2012 to reflect actual labor costs.

In light of the Society's dedication to preserving patient access to care and choice in selecting dialysis providers, ASN is concerned that failure to reassess the labor share under the bundled payment system would have a negative financial impact on dialysis providerst that may challenge their ability to continue providing dialysis care. For instance, CMS proposes that ESRD facilities will either dispense drugs directly or contract with a pharmacy. This approach requires additional staff time to monitor drug purchasing and utilization that was not previously necessary and therefore not reflected in the 2007 data. Similarly, should a unit establish an in-house pharmacy, labor will be required to stock, maintain, and inventory to provide new services. CMS also proposes that ESRD facilities will be responsible for all billing associated with lab tests and services, another mandate that will increase labor costs to implement. Bundling lab services with other ESRD services for payment purposes would require a much more detailed level of documentation than in the current system. Moving forward, ASN encourages CMS to account for these significant changes in labor used in the provision of dialysis care.

2. Low-Volume Adjustment (p.223)
b. Defining a Low-Volume Facility

- **CMS should provide a detailed review of its methodology for selecting facilities for low-volume status, and should verify that facilities identified as low-volume meet the criteria of providing fewer than 3,000 total treatments of *all* payer types.**

ASN's foremost priority is the preservation of patient access to quality care. As such, ASN appreciates CMS' willingness to consider a payment adjustor to account for higher costs of providing ESRD care in underserved areas. Given the information provided by CMS in the Proposed Rule, ASN believes an adjustment for low treatment volumes is reasonable. However, it is vital that CMS take into account all treatments regardless of payer to set the low-volume threshold. ASN requests that CMS conduct a more detailed review of facilities it identifies as low-volume to be sure the data used yields results that are accurate and consistent with the intent of the policy.

- **CMS should consider strategies to reduce incentives for "gaming" to qualify for the low-volume adjustor, in addition to the proposed 25-mile distance and common ownership clauses.**

In the event that CMS moves forward with the application of the low-volume adjustor as currently proposed, ASN is concerned that the 3,000 patient per year threshold may encourage "gaming" the system. Specifically, if there is a significant difference between the base rate and the amount paid to facilities that qualify for the low-volume adjustor, there may be a perverse incentive to withhold care to patients if doing so would elevate the total number of patients treated above the threshold, negating the facility's eligibility for the adjustor. CMS must also differentiate "low volume" units, which serve disadvantaged or sparsely populated areas, from "underutilized units," which have been generated by oversaturation of a region by dialysis providers.

Given the deleterious impact on patient access this type of gaming may cause, CMS should consider strategies to prevent these situations. One alternative strategy the Agency may wish to consider is stratified differential payment to all units based on treatment volumes. Facilities would receive greatest renumeration for the first 1,000 treatments; slightly less payment for 1,000 to 2,000 payments, and finally less for 2,000 to 3,000 treatments. Therefore, facilities that provide more than 3,000 treatments would receive slightly larger payments for the first 3,000 treatments but slightly smaller payments for treatments beyond that number than they would have received otherwise. This approach would not change the total amount paid to facilities but may reduce the potential for gaming that may occur under the current proposal.

ASN believes that the 25-mile minimum distance between facilities under common ownership is a reasonable geographic requirement. ASN concurs with CMS that this would create a disincentive for commonly-owned ESRD facilities to establish multiple low volume facilities in close proximity in order to capture additional revenue through the low volume adjustment.

4. Rural Facilities (p. 231)

- **CMS should re-evaluate the necessity of a rural facility adjustor following its reassessment of the data for low-volume facilities**.

The Society appreciates CMS' consideration of a payment adjustor that addresses the relatively higher costs of providing care where it otherwise may not be available and agrees that a low-volume facility adjustor is a sensible approach on many levels. Every dialysis unit manages fixed costs, challenging smaller facilities to offset these costs though economies of scale. ASN's perspective believes these pertain to many rural units.

It is unclear to the Society whether CMS took these types of costs differentials into account in its original determination of whether rural units warrant a payment adjustor. Similarly, ASN respectfully questions whether defining every facility not located within a Metropolitan Statistical Area (MSA) as rural reflects the variation in degree of geographical isolation—and therefore cost—between providers that are not located within an MSA. It seems possible that significant cost differences exist between facilities classified as rural, which are dozens or hundreds of miles further from an MSA, compared to rural facilities closer proximity to an MSA. The assumptions in the Proposed Rule do not account for this variation. Given issues with the data validity used to calculate the low-volume adjustor, the Society is, by extension, skeptical of the data used to determine that rural facilities do not warrant a payment adjustor. As such, the Society is concerned that under the current Proposed Rule, some rural facilities may not receive adequate reimbursement to continue to provide dialysis services in remote areas, resulting in compromised patient access to care. ASN therefore encourages the Agency to reassess data for rural facilities following its reassessment of the data for low-volume facilities.

IX. Pediatric Patients (p. 240)

- **ASN encourages CMS to consider postponing the application of the bundled payment system to the pediatric population until more accurate data can be collected and the actual costs of caring for this vulnerable population can be analyzed in more detail by the Agency.**

ASN is concerned about how proposed payment changes may affect pediatric patients with ESRD. Reducing the pediatric case-mix adjustor (CMA) for facility reimbursement from 1.62 to 1.199 or below could lead to an unintended consequence of pediatric ESRD patients losing access to necessary and appropriate treatments. The unique needs of children and adolescents may have been underestimated by CMS' regression methodology used in the ESRD Proposed Rule. CMS previously has recognized the higher cost of dialyzing children, both in the granting of pediatric dialysis facility exceptions to reimbursement and in the provision of the temporary pediatric CMA of 1.62 in 2005. Pediatric dialysis units with exception, most of which are associated with children's hospitals, were granted higher facility rates based on their actual costs in their Medicare cost reports, including higher personnel staffing, higher costs of pediatric-specific dialysis disposable equipment, and higher costs of support for home care of children and their caregiver families. Data from pediatric units provide the best assessment of costs for pediatric-specific services. Importantly, these highly specialized centers are regional referral centers, providing services for children and families from very large geographic areas. Use of the proposed pediatric CMA will inevitably lead to elimination of the pediatric facility exceptions and will reduce the cost adjustment needed by many pediatric facilities to remain operational or to at least provide the services that are necessary for safe and effective treatment of children.

Without pediatric dialysis units, our children and adolescents with ESRD will not have access to the specialized dialysis care that they need and which has been the driving force for improvement in outcomes and advances in dialysis treatment for this unique group of patients. Furthermore, the proposed lower pediatric CMA adjustors of 1.199 or less will be a disincentive for adult units to continue to provide dialysis for the few children who are geographically unable to be cared for at a pediatric center.

Pediatric patients account for just less than 0.6 percent of the prevalent dialysis population and only about 0.2 percent of dialysis Medicare beneficiaries. The unique services provided in pediatric dialysis units are vital for the care of this small, vulnerable population. Children and adolescents under the age of 18 are not yet fully developed and are dependent on adults to provide age-specific supervision and care during dialysis treatments and for home care. The smallest and youngest children require at least one-to-one nurse or home caregiver care during HD or PD treatments to ensure safety and efficacy. Children receiving dialysis range in size from 3 kilogram (kg) newborns to 90 kg teenagers, so require a wide variety of specialized dialyzers, blood lines, and other supplies, most of which are expensive and only made by one or at most two vendors. Ancillary pediatric personnel are both required and essential to pediatric dialysis, not only in dealing with the smallest children, but also in dealing with adolescents, who have significant problems with dialysis, including behavioral adjustment, adherence to dietary restrictions and medications, and maintaining school performance.

The proposed ESRD CMA for pediatrics is based on a statistical regression model that is likely flawed due to the to the small number of pediatric patients used in the data analysis and to missing and incomplete cost data for pediatric dialysis units. The current CMS model may not fairly represent the actual data from cost reports of pediatric dialysis units and is distorted by the pediatric patients dialyzed in adult units, whose facility costs represent the adult costs of those units and not pediatric specific services. In addition, methodology for estimating separately billable services for pediatric patients was based on a small sample with limited statistical power and is missing significant data from under-reporting of separate pediatric claims. The proposed modifier does not take into account pediatric specific costs, co-morbidities and other special needs of the pediatric ESRD population, so is severely undervalued. Pediatric patients almost never have the co-morbidities designated in the proposed ESRD bundled payment system, but do have pediatric-specific co-morbidities, including renal osteodystrophy, growth retardation, developmental delay, deafness, seizure disorder, rare genetic diseases and other organ system disorders. Dialysis nurses, dietitians, social workers, Child Life Specialists, tutors, and psychologists with specialized pediatric training and expertise are required and essential for the care of children and adolescents.

CMS should use a single category CMA for pediatric patients. Using multiple payment categories to adjust for age, modality and adult co-morbidities unnecessarily complicates the proposed ESRD bundled payment system for pediatric dialysis patients (Table 33, p. 260). The proposed pediatric rates are lowest for the youngest patients (less than 13 years of age), which is completely contrary to and does not account for the technical complexity and high cost of staffing and specialized supplies involved in dialyzing this group of children. Assigning a single pediatric CMA regardless of modality will allow pediatric nephrologists and families to choose the right dialysis modality for each child. Currently, about 50 percent of pediatric patients are treated with home PD. The technical aspects of providing home PD support for parent caregivers and for adolescent self-care patients lead to higher costs and appears undervalued by the proposed modality-based formulas. The acceptable co-morbidities stated in the proposed ESRD bundled payment system (diabetes, alcohol/drug dependence, etc) are for adults and do not often apply to children. Common pediatric ESRD co-morbidities are not addressed, including pulmonary

hypoplasia, developmental delay, failure to thrive, seizure disorder, deafness, congenital heart disease, other solid organ transplantation, and renal osteodystrophy of growing bones. Most pediatric dialysis patients would not be classified as having co-morbidities using the proposed ESRD bundled payment system list.

The pediatric CMA should be based on a separate pediatric-specific analysis of actual costs, including data for the majority of patients who are dialyzed in pediatric dialysis units and including pediatric-specific co-morbidities, and not on the proposed regression methodology, which has flaws when applied to such a small population with incomplete data. We request that CMS work with leaders of the pediatric dialysis community to consider an analysis that would include all aspects of the cost for pediatric dialysis patients to determine an appropriate pediatric CMA. We anticipate that such an analysis will result in a more accurate pediatric CMA than currently proposed, and be more in line with reimbursing actual costs to the country's vital pediatric ESRD facilities. CMS may want to consider postponing the application of the bundled payment system to the pediatric population until more accurate data can be collected and the actual costs of caring for such a vulnerable population can be analyzed in more detail by CMS.

VII. Development of Budget-Neutral ESRD Bundled Base Rate
E. Calculation of Transition Budget-Neutrality Adjustments (p. 107)

- **An additional transition payment adjustment is not required by MIPPA and counteracts the Congressional intent of a transition period.**

Under the Proposed Rule, dialysis facilities may elect to adopt fully bundled payments beginning January 1, 2011, or to "phase-in" bundled payments over a four-year transition period. CMS believes that "each provider would likely choose the option that is most financially beneficial to them," thereby causing total payments between 2011 and 2013 to be greater than the amount of payments that would have been made under the current ESRD composite rate payment system. In the interest of budget-neutrality as mandated by MIPPA, the Agency proposes that it must impose an additional 3 percent reduction to all payments made to dialysis providers during the transition period.

However, this proposal is based on a misinterpretation of MIPPA. The plain reading of MIPPA clearly applies same payment adjustments related to the ESRD bundle—the 98 percent budget neutrality requirement and the market basket updates—to the transition period, but does not mention any additional payment reductions. Imposing this payment reduction during the transition period would not only counteract the intended benefit of choosing which payment system to adopt between 2011 and 2014, it would effectively penalize facilities for having two options available to them. This proposal is contrary to Congress' original intent to allow dialysis facilities to adjust to the new payment system.

- **CMS should reconsider its proposal to impose a transition payment adjustment, as the current proposal may have an adverse impact on quality and availability of patient care.**

ASN is concerned about the potential negative ramifications a 3 percent reduction in payments may have on dialysis facilities that are small and medium-sized or independent. These units may not possess the resources to make the most appropriate election, potentially preventing them from continuing to provide care. ASN believes that the ability to exercise choice is an integral component of high-quality care. In an already consolidated market for dialysis care, the Society

is concerned that the 3 percent cut may cause further reduction of provider diversity—and, by extension, further reduction in patient and provider choice regarding the optimal treatment plan and environment.

ASN is also concerned that the proposal poses a serious threat to the the overall quality of dialysis care during the transition period and beyond. Specifically, the proposed 3 percent payment reduction may compromise patient care by reducing the ratio of patient-to-nursing, technologist and other support staff in the dialysis unit. A treatment that normally requires three hours to complete can easily require five hours in a unit that is short-staffed. This contributes not only to patient dissatisfaction and lower quality of life, but also to costly high staff turnover rates. Moreover, reduced budgets may push dialysis center administrators to shift the balance of staff from more qualified and experienced individuals to less experienced persons, such as technologists. In sum, financial pressures on dialysis units directly impact the quality of patient care.

ASN notes concern that the 3 percent reduction may particularly disadvantage the quality of care for rural dialysis patients. Facilities in these areas are typically more challenged than their urban counterparts to remain financially viable due to higher costs for patient transport, staff salary, and facility maintenance costs. As such, the 3 percent payment reduction poses an even greater threat to access and quality for patients who dialyze at these facilities.
Overall, ASN urges CMS to re-examine its legal authority to impose a 3 percent payment reduction during the transition period. The Society further encourages the Agency to weigh the potential unintended consequences on patient care this reduction may cause.

XV. Quality Incentives Program (QIP)

MIPPA requires the Secretary to develop a quality incentive program (QIP) that will result in reduction of payments to providers of services and dialysis facilities that do not meet or exceed a total performance score based on performance standards for specified measures. In the Proposed Rule, CMS provides its initial model for the QIP, which identifies three specific measures to be used for the calendar year 2012 payment reduction.

ASN is grateful for the opportunity to comment on the proposed QIP at this time. The Society also notes that CMS intends to issue a subsequent proposed rule, and it appreciates CMS's attempt to inform the public as early as possible regarding the measures on which the performance standards will be based. ASN, however, would like to emphasize the necessity for a comment period following the Proposed Rule on QIP that CMS plans to put forth because the specifics on implementation and other aspects of the program remain unclear in this current conceptual model.

C. The ESRD Quality Incentive Program as Authorized by Section 1881(h) of the Act

1. Proposed Anemia Management and Dialysis Adequacy Measures

- **If an intermediate outcome is targeted for performance improvement it should be tightly linked to clinically important patient outcomes. ASN urges CMS to take caution when implementing performance measures in knowledge areas that have yet to be determined and oversimplifying for the sake of implementing standards.**

ASN applauds CMS on its efforts to include an ESRD QIP, however, there are several important limitations that deserve further consideration prior to moving from the current public reporting system to one that also includes financial incentives. First, general tenets from the quality improvement literature indicate that if an intermediate outcome is targeted for performance improvement it should be tightly linked to clinically important patient outcomes. If it is not, efforts to meet those performance targets by providers will not result in improvements in patient outcomes, and may even result in harm as unintended consequences. For example, efforts to target higher hemoglobin levels over the past decade occurred despite the lack of high-grade evidence that increasing hemoglobin levels would result in improvement in patient outcomes. However, several randomized, controlled trials have failed to demonstrate a benefit to targeting high hemoglobin levels. Conversely, studies suggest that doing so may increase the risk of serious adverse events.

Such cautionary experience should provide pause prior to escalating the motivation provided by prior legislation that established anemia monitoring/reporting in the ESRD Core Indicators Project, ESRD Clinical Performance Measures, and Dialysis Facility Compare. The current Proposed Rule seeks to intensify prior incentives for anemia management by now including financially-based motivation through a payment reduction plan for targeting an intermediate clinical outcome prior to consistent, high-grade evidence that demonstrates doing so will result in improved patient outcomes. As such, ASN believes that prior to the institution of finally-based incentive QIP strong evidence must support use of any proposed intermediate measures.

Although ASN offers initial comments here, the Society is unable to provide more detailed comments until review of the subsequent proposed rule that CMS plans to issue.

CMS proposed to adopt three performance measures for the first QIP performance period:

I. Anemia Management

- The percentage of patients at a provider/facility whose hemoglobin levels were less than 10 g/dL.
- The percentage of patients at a provider/facility whose hemoglobin levels were greater than 12 g/dL

ASN acknowledges that MIPPA requires CMS to develop quality incentive measures of anemia management that reflect the labeling approved by FDA for such management. However, ASN urges caution since at the present time, the hemoglobin range to target with ESA therapy to optimize patient outcomes is unclear. Indeed, the hemoglobin target levels proposed (within 10-12 g/L) are based on current FDA labeling guidelines whose purpose is to balance safety and therapeutic benefit. The

upper limit seeks to minimize harm from ESA-related toxicity while the lower limit seeks to achieve a minimum hemoglobin level below which patients are presumed to have suboptimal outcomes. However, more recent evidence from the Trial to Reduce Cardiovascular Events with Aranesp Therapy (TREAT) suggests that this minimum level for some CKD patients could be as low as 9 g/dL. Future efforts through prospective trials to address this gap in our knowledge will be limited by the proposed QIP unless specific exemptions are obtained.

Even if the optimal hemoglobin range were to be determined, additional levels of complexity are not considered with the proposed quality measures for anemia with upper and lower bound limits. There is substantial variability in hemoglobin levels over time despite vigorous attempts to maintain levels within specified ranges (supportive evidence includes the relatively low proportion of <50% of patients meeting this requirement despite current efforts through DFC). Hemoglobin cycling, blood loss, iron deficiency, systemic inflammation, and other factors further complicate maintenance of hemoglobin levels within narrow ranges.

Many ESRD patients with hemoglobin levels <10 g/dL have resistance to ESA therapy; this resistance is often secondary to systemic conditions such as inflammation.
Imposing a quality incentive that withholds payments if a larger proportion of patients have lower hemoglobin risks cherry-picking by facilities/providers whereby they would resist admitting patients who are anticipated to have difficulty in achieving the hemoglobin targets.

The Society applauds CMS for taking care to propose that the anemia QIP will be applied only to those dialysis patients who are receiving ESA therapy. However, ASN urges CMS to consider a window for ESA use and study what the appropriate length of the window should be (3, 6, or 12, months).

Greater efforts to achieve any future evidence-based measures should be considered (i.e. change numerator of anemia quality measure to include those within specified target as well include those for whom appropriate adjustments were made in an attempt to achieve target, such as prescribing intravenous iron for iron deficient, or increasing ESA dose for below target hemoglobin, etc.) rather than laboratory value based measures alone when assessing performance.

II. Hemodialysis Adequacy

- The percentage of hemodialysis patients at a provider/facility whose urea reduction ratio (URR) is 65% or greater.

At present, there is a lack of strong, high-grade evidence to support the dialysis adequacy quality measure. However, ASN believes that it represents a fair and reasonable population target given the available evidence and experience. However, further clarifications will be necessary for certain subgroups including patients who receive more frequent in-center hemodialysis (i.e. 4-6 times per week) and those with significant residual renal function as they may require a lower per-treatment dose of dialysis to maintain similar levels of Kt/V.

2. Performance Standards for the ESRD QIP Measures

- **ASN strongly encourages CMS employ facility-specific performance rates as the standard throughout the duration of the QIP.**

In the Proposed Rule, CMS provides an explanation of how the performance standards for the specific measures will be set. Specifically, CMS addressed the "Special Rule" which would use the lesser of facility-specific performance rates or a standard based on national performance rates for the initial year of the QIP. ASN strongly encourages CMS employ facility-specific performance rates as the standard throughout the duration of the QIP. CMS also notes in the Rule that the proposed hemodialysis adequacy measure would asses hemoglobin values in patients who receive treatment at a provider or facility, not those treated at home. Additionally, according to CMS, the proposed hemodialysis adequacy measure would not assess hemoglobin values in pediatric dialysis patients.

I. Performance Rate Standard

For the first payment withhold in 2012, the current proposal would use one of three years (2007, 2008, 2009) as the base utilization year. However, with the ongoing publication of results of randomized controlled trials starting from late 2006 (Correction of Hemoglobin and Outcomes in Renal Insufficiency) and continuing through 2009 (TREAT), it is highly likely that the clinical practice of anemia management is evolving over the three possible base-utilization years. It is arguably unfair to use yardsticks created from data from a time when practice was evolving to institute payment withholds for providers and facilities that differ only slightly from the practice during that period.

A reading of the rules suggests that after the initial year of the QIP, the thresholds that would be used to define quality standards would be based on the national average for the measure. Although this approach reduces the bias from single or limited measurements, several limitations remain, as described below:

- The national averages may not reflect the optimal care for the measure in question.
- When using a proportion of patients for a given quality measure, small volume facilities are more likely to fall outside the range with change in the measure for a very small number of patients.
- Assuming the QIP is accurately and continuously updated to reflect current clinical practice, judging facilities using the distribution for a measure at any given point in time would present a moving target for the facilities and would not be fair. As it changes from time to time, it would provide a financial disincentive to change practice should new evidence emerge that would otherwise have led to change. That is, the earlier facilities change practice in light of new data, the more likely it is that they will differ from the normal distribution, and thus risk payment withhold.

Facility-Specific Rates should be implemented as the performance standard base throughout the duration of the QIP and should not cease as the standard after the initial year. It is not quite clear from the Proposed Rule how CMS will determine

these rates. ASN strongly encourages CMS to address this issue in the forthcoming rule.

II. Home Dialysis and Pediatric Dialysis

The appropriate dose of hemodialysis is not determined by where dialysis is performed (home or in-center), but instead by the dialysis regimen being utilized. Thus, if hemodialysis is performed at home three times per week, then criteria for judging hemodialysis adequacy, based on the URR parameter (>65%), should be the same as three times per week in-center hemodialysis.

However, if the hemodialysis schedule is non-traditional (i.e. short hemodialysis for six times a week) whether it is performed at home or in-center, the appropriate criteria is currently unknown. Some investigators have advocated the use of the "standard Kt/V or sdKt/V" parameter, but this criterion has not been rigorously validated. Because of this uncertainty, facilities/providers should not be held to any standards at this time in regards to non-traditional hemodialysis.

If standards are absolutely required, then CMS may consider converting the URR to a Kt/V parameter for hemodialysis schedules that are greater than thrice weekly. The desired Kt/V would then be 1.20 multiplied by three and divided by the number of sessions per week. For example, for hemodialysis performed six times per week, the required Kt/V would be 1.2 x 3 / 6 = 0.6.

For PD patients, a total (renal and peritoneal) weekly Kt/V urea of 1.7 is an appropriate target.

ASN requests that CMS consider the comments made by the American Society of Pediatric Nephrology (ASPN) when considering issues specific to pediatric dialysis.

3. Performance Period for the ESRD QIP Measures

CMS states that it is considering all or portions of 2010 as the performance period.In general, ASN encourages CMS to adopt a performance period that reflects current clinical practice and remains consistent with the evolution and changes made to such practice. Furthermore, there should be enough time (at least one year) between the first publication of the final QIP rule and the beginning of the performance period.

4. Methodology for Calculating the Total Performance Score for the ESRD QIP Measures

- **ASN strongly urges CMS to adopt a scoring scheme that deducts points only from outliers instead of broader proposed point reductions.**

CMS proposes a 10 point scale for each of the three measures, with a scoring methodology that subtracts two points for each two percentage point increment range that the provider or facility's performance falls from the standardASN does not agree with the proposed methodology for calculating the total performance score. ASN strongly urges CMS to adopt a scoring scheme that deducts points only from outliers instead of the wide-range implementation suggested. Such a scheme would recognize the limitations of our current knowledge and would determine if

achieving the goals for the intermediate measures as defined today will hold the test of time to meaningfully impact patient outcomes.

The importance of this issue is clearer when one juxtaposes how CMS has developed the scoring system, particularly for the anemia measure. When using the national average for the distribution of hemoglobin levels as a starting point from which payment withholds would begin, it will apply to at least 50 percent of facilities. Indeed, this is evident from Table 42 in the Proposed Rule – fifty percent of facilities had greater than 42 percent of patients with hemoglobin levels greater than 12 g/dL and would be affected, at least in part, by the proposed payment withhold. Given the likely instability of data for the anemia measure and that clinical practice is evolving, it would be more appropriate to apply payment withholds only to outliers (i.e. those outside two standard deviations from the mean for the quality measure) rather than create a system that is likely to affect more than 50% of the dialysis facilities.

As mentioned previously, ASN strongly recommends that performance evaluation, and thus point assignment, also be based on the process of care or actions made by the provider or facility rather than on laboratory results alone. There are too many confounding variables to assess performance that is based only on laboratory parameters. An analysis of what steps were taken to correct any abnormal values related to the specified measures should be the goal of the QIP scoring method, as this would better reflect quality of care.

Application of Payment Reductions Using the Total Performance Score

- **ASN urges CMS to establish a reliable, extensive, and ongoing monitoring system for the proposed QIP including the measures and standards being used as well as a real-time monitoring of the roll-out and consequences of the program.**

According to the Rule, CMS plans to implement a sliding scale of payment reductions up to two percent. ASN recognizes that CMS is required to develop a payment reduction system linked to the QIP. However, ASN cannot provide comment specifically addressing the proposed application of payment reductions as the Society does not support the scoring methodology. ASN would like to reiterate that payment reductions result from a provider or facility scoring as outliers with respect to the specified measures as well as a provider or facility failing to provide the appropriate process of care rather than small variability from the national average for the quality measure.

Moreover, ASN understands the current circumstances and obligation CMS has to develop a QIP linked to payment reductions, but the Society would again like to point out the hazards of so doing. All measures and standards specified for the QIP should be very closely linked to clinically important patient outcomes. If they are not, efforts to meet those performance targets by the providers may result in harm and unintended consequences. Currently, these intermediate endpoints do not necessary reflect what is best for the patient. The same concern applies even to measures that CMS may consider in the future, like measures of mineral metabolism. Therefore, ASN urges CMS to establish a reliable, extensive, and ongoing monitoring system for the proposed QIP including the measures and standards being used as well as a real-time monitoring of the roll-out and consequences of the program.

6. Public Reporting of Measures

- **CMS should publicly report only measures that are meaningful and within a dialysis provider's control.**

CMS seeks comment on how to make provider or facility performance available to the public. ASN understands that CMS is required to establish a procedure for making information regarding performance under the QIP available to the public. ASN urges CMS to only make public data that is within the provider or facility's control and evaluates valuable measures. ASN has mentioned throughout this section, the Proposed QIP does not fit this criterion, and thus should not be publicly reported as it currently reads.

- **CMS Should Consider Other Potential Quality Measures for the Forthcoming Rule**

ASN believes that any quality incentives program should consist of measures that improve patient care, and the Society encourages CMS to create a QIP that works toward this goal. Given the concerns expressed throughout this section, ASN would like to provide other measures for quality that CMS should considered when drafting the forthcoming rule on the QIP.

I. Optimal Vascular Access (hemodialysis – incident vs prevalent patients)
   - Arteriovenous fistula vs arteriovenous graft vs catheter

II. Immunizations
   - Influenza– It is recommended that ESRD patients be immunized against the seasonal influenza virus at least annually; the repetitive need for this immunization makes it an attractive measure of quality of care of dialysis patients. However, this needs to be balanced against the increased reporting requirements that would be an unfunded mandate and particularly burdensome for smaller providers.
   - While immunization against hepatitis B and pneumoccus are also recommended for dialysis patients, they are not administered annually and thus may not commensurate with the vision for the quality measures such that it can be applied repetitively to the prevalent cohort of patients.

Given the current conceptual model, ASN urges CMS to strongly consider the Society's remarks pertaining to quality measures and advancing knowledge, performance standards and evolving practice, performance score and evaluating outliers, and payment reductions based on process of care. Again, ASN is grateful for the opportunity to comment on the proposed QIP at this time, and the Society looks forward to commenting on the forthcoming QIP Proposed Rule.

On behalf of ASN, thank you for your willingness to consider our comments for the Proposed ESRD Bundled Payment Rule. Our members are committed to providing the best possible care and want to ensure that nephrologists have the necessary flexibility and information to treat patients safely and effectively to preserve their quality of life. We believe that our recommendations in this letter will prove helpful in formulating an efficient new payment system that promotes accessible, high-quality patient care. ASN would be pleased to discuss these comments and recommendations with the Agency if it would be helpful. The Society also encourages CMS to engage the kidney care community to address how this new payment system will be updated in future years, and welcomes the opportunity to discuss this issue.

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,

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President

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