ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

1725 I Street NW • Suite 510 • Washington, DC 20006
p 202.659.0599 • f 202.659.0709 • www.asn-online.org

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Donald Berwick, MD, FACP
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 314G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; End State Renal Disease Prospective Payment Final Rule – RIN 098-AP57
[CFR-1418-F]

Dear Administrator Berwick:

On behalf of the American Society of Nephrology (ASN), a not-for-profit organization of 11,000 physicians and scientists dedicated to promoting excellence in the care of patients with kidney disease, please accept this letter regarding the Medicare Program's End Stage Renal Disease Prospective Payment Final Rule. 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. ASN was pleased to have the opportunity to comment on the Proposed ESRD Bundled Payment Rule in December 2009. The society appreciates CMS' efforts to foster reform in the Medicare ESRD Program and promote high-quality, cost-efficient dialysis care.

ASN thanks CMS for incorporating many of the society's comments regarding the proposed rule into the final rule. ASN believes that the final rule generally reflects ASN's primary concerns, in particular, maintaining the integrity of the physician-patient relationship, including reasonable latitude for physicians in prescribing drugs and in ordering diagnostic laboratory tests.

We believe that CMS' interpretation regarding its authority and the scope of the bundle is appropriate and support the decision to delay implementation of payment of ESRD-related oral-only drugs under the ESRD PPS [define PPS] until January 1, 2014. We look forward to working with the Agency as it develops future rules and guidance related to their inclusion under the bundle. At this time, ASN submits the following comments regarding the final rule.

Physician Services (p. 138)

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

The Proposed ESRD Bundle (p. 40)

ASN agrees with the overall scope of the bundle, and CMS' decision to delay implementation of payment of ESRD-related oral-only drugs under the ESRD PPS until January 1, 2014. The advantages of the delay outlined by CMS are important to ensuring patient safety, facility preparedness, appropriate reimbursement, and most importantly adequate monitoring systems.

Further, ASN agrees with the agency's plan to exclude blood and blood products from the payment bundle, and strongly supports the Agency's plan to monitor the extent to which dialysis patients receive transfusions under the new ESRD PPS. The society believes that the decision to exclude these products is appropriate; however, ASN is aware that the separate payment could create a perverse incentive to provide blood transfusions instead of ESA therapy. It is of utmost importance to avoid transfusions in the dialysis population in order to not jeopardize these patients' prospects of receiving and maintaining a kidney transplant due to immune sensitization.

CMS should be able to identify instances where patients should be receiving ESAs but are not, and the society appreciates CMS' stated intention to monitor this element of care. In this regard, ASN suggests that CMS look at the lower hemoglobin limit for *all* patients receiving dialysis care, not just those who are receiving ESAs, under the Proposed Quality Improvement Program (QIP). Beyond the QIP, additional monitoring that occurs as close to real-time as possible will be important to protect against potential negative changes in practice patterns.

Monitoring the Impact of the ESRD Bundle

ASN thanks CMS for its commitment to monitoring the effects of ESRD bundling following implementation of the final rule. Vigilant monitoring of effects both anticipated and unanticipated will serve to mitigate any unforeseen barriers to quality care—and identify positive changes—that may arise as a result of provisions within the rule. The society stands ready to work with CMS as it develops this monitoring system, and respectfully requests a contact who can help ASN better understand the specific methodology and mechanisms CMS plans to use in these important efforts. Additionally, the final rule includes extensive use of the terms "comprehensive monitoring plan" and "appropriate plan of care" in relation to planned monitoring. ASN requests clarification on these terms as their interpretation has potential to direct overall monitoring activities.

CMS specifies numerous areas it will monitor—detailed in the table on the following page—and ASN is strongly supportive of these plans. ASN believes additional detail is essential to allow for careful planning and execution of the following monitoring efforts and, again, would appreciate the opportunity to collaborate with the agency in this regard.

Area for Proposed Monitoring	Reference in Final Rule
General Implementation	
Incidence of transfusions among dialysis patients	Page 44, 768
Anemia	Page 44-45, 47-48
Bone loss and mineral metabolism associated with the provision of calcimimetics and phosphate binders	Page 82
Utilization of renal dialysis items and services to ensure the quality care continues to be provided	Page 89, 95, 97
Vascular Access	Page 93
Overall monitoring: tracking measures to monitor utilization and measure outcomes, specifically to track and report patient levels of calcium, phosphorus and parathyroid hormone	Page 98
Cherry Picking Patients: "We do not agree that the inclusion of co-morbidities as payment adjustments will lead to "cherry picking" of patients…we believe that our continued monitoring will identify the few ESRD facilities that do not provide appropriate care."	Page 289, 394
Hemoglobin	Page 813
Drugs and Biologicals	
Drugs and biologicals to identify those that are being used for ESRD-related conditions	Page 115
ESRD drug categories included in the ESRD Base Rate but may be used for dialysis and non-dialysis purposes	Page 116 - Table 5
Anti-seizure drugs and biologicals for the treatment of ESRD	Page 122
Extent of transfusions in dialysis patients after implementation of the ESRD PPS	Page 122, 137
Home dialysis utilization (and training support)	Page 153, 154, 448,468
How the updated training add-on adjustment relates to changes in the proportion of ESRD patients on home dialysis modalities	Page 187
ESRD facilities that do not provide an appropriate plan of care	Page 322, 399
Prevalence of any co-morbidity diagnoses recognized for the co-morbidity payment adjustment	Page 354, 397, 399
Evidence of decreased access to renal dialysis services by racial or ethnic groups	Page 417
Payments under the ESRD PPS and the location of new facilities to determine if changes in the criteria that qualify ESRD facilities as being low-volume are warranted	Page 470, 474, 480, 485, 498

Outlier payments: - identify patterns of increased utilization of outlier services, and any associated outlier payments across ESRD facilities - "we intend to monitor outlier payments for any unusual trends in outlier payments for all patients, including home dialysis patients who self-administer ESAs"	Page 589, 596, 606-607
Cost structure of the ESRD industry and the labor-related share of the ESRDB market basket. Should this be ESRD rather than ESRDB?	Page 638, 647
Claims to see if additional laboratory tests should be added.	Page 724
"We intend to further evaluate beneficiary protections under the ESRD PPS related to oral drugs. We note that we are developing monitoring procedures that we will discuss in the future."	Page 730
Disparities based on Race and Sex	
Impact of patient sex on cost	Page 300-301
Onset of dialysis adjustment to determine if there is an increase in the number of individuals who become entitled to Medicare prior to the 90-day waiting period as a result of receiving home dialysis training	Page 319
Access to care	Page 417, 420
Inappropriate care based upon race and ethnicity	Page 426
Ongoing analysis of race and ethnicity data to detect and monitor for trends in health disparities	Page 441
Intend to complete the studies required under MIPPA and ACA that will assist us in identifying and monitoring health disparities on the basis of race or ethnicity	Page 444-445
Changes in the number and characteristics of patients who have been involuntarily discharged from their ESRD facility	Page 767
Claims	
Bacterial pneumonia on claims	Page 345-346
ESA claims	Page 204-205, 770

ASN wants to highlight the importance of tracking trends in access, practice and prescribing patterns as they relate to patient care. ASN also wishes to call attention to the importance of monitoring levels of calcium, phosphorus and parathyroid hormone prior to addition of the oral-only drugs to the ESRD PPS in 2014. It will be important to have information about these levels to study any changes that may result from including oral only drugs in the bundle.

The decision to delay inclusion of oral-only drugs is applauded by ASN; however, the delay could result in amplified risks for unintended consequences upon their inclusion. ASN looks forward to working with CMS to develop ways to identify both positive and potential negative effects leading up to their inclusion under the bundle 2014.

ASN is aware that demonstration projects mandated by the Medicare Modernization Act were repealed in subsequent legislation. However, the society remains cognizant that pilot projects to determine the effects of the regulatory changes on patient management and outcome have not been conducted. As such, the society believes that the real time monitoring CMS outlines in the final rule will be critical in safeguarding patient safety and ensuring the highest level of patient care. Accordingly, ASN looks forward to both learning more about CMS' plans to monitor the new payment system, and to collaborating with the agency to refine and implement this system.

Home Dialysis (p. 145)

ASN thanks CMS for its decision to adopt a payment adjustor for home dialysis training for both hemodialysis (HD) and peritoneal dialysis (PD) modalities if the training occurs after the first four months of start of dialysis. Providing an additional payment after the first four months for home dialysis training is an appropriate policy that preserves patient and physician flexibility in selecting the optimal treatment environment and renal replacement therapy method. In addition, ASN appreciates the decision to pay the same amount for home dialysis as in-facility treatment, as we believe this will facilitate consideration of all options when selecting modality and treatment environment and promote home dialysis where appropriate.

Unit of Payment (p. 189)

While appreciative of CMS' intention to encourage use of home dialysis and the decision to maintain the same base rate per treatment for PD as HD, ASN believes that the agency could better achieve this goal by removing the medical justification for more than three treatments per week. Frequent dialysis is not just for the sickest patients; for many relatively healthy patients, it is crucial to preserving their quality of life and well-being. Besides the substantial number of home patients who dialyze more than three times per week, many in-center patients also benefit from dialyzing more frequently. Unless data becomes available that demonstrates that dialysis treatments more than three times per week fails to improve outcomes, CMS should pay for more than three home treatments per week.

At present, Fiscal Intermediary/Medicare Administrative Contactors (FI/MACs) cover more than three sessions per week. ASN is concerned that the new policy may prompt some FI/MACs to rescind existing coverage for frequent dialysis for some patients. Furthermore, to facilitate optimal patient-physician latitude in selecting the most appropriate plan of care, the society encourages CMS to remove the requirement for medical justification for more than three treatments per week

Co-Morbidities (p. 327)

ASN supports CMS' proposal to adopt six of the eleven originally proposed co-morbidity case-mix adjustors. ASN appreciates the agency's further investigation of the ICD-9 codes eligible for the co-morbidity payment adjustment following the comment period, and supports its decision to reduce the number of ICD-9 codes eligible for the co-morbidity payment adjustment to eighty-eight codes. (See Table 22 p. 359) The society concurs with CMS that the six diagnostic categories that correspond to the ICD-9 codes are appropriate selections from a provider standpoint; providers should be aware of these conditions as part of routine care and the number of associated ICD-9 codes is manageable. This will mitigate our concerns that ESRD facilities may be burdened to identify all of the many ICD-9 codes originally proposed that would have needed to be recognized for a payment adjustment.

CMS states that it will require a documented radiographic diagnosis in the patient's clinical or medical record, in order for an ESRD facility to be eligible for the co-morbidity payment adjustment for the bacterial pneumonia infection category (p. 345). ASN requests that CMS clarify how providers should code for pneumonia that is radiographically documented. While a culture could be considered, they are not typically performed in the dialysis unit. More often than not, nephrologists are unable to obtain a sputum culture that is positive for a specific pathogen; for instance, a patient may cough up a contaminant or already be on antibiotics when he or she arrives in the dialysis unit. Because both X-ray and sputum

cultures are not readily available to nephrologists, how a nephrologist should indicate how the diagnosis of the co-morbidity was determined remains unclear. The society looks forward to clarification from CMS in future administrative issuance.

ASN also supports CMS' elimination of Hepatitis B as a co-morbidity diagnostic category adjustment due to insufficient evidence, and encourages the Agency to revisit this potentially important co-morbidity in the future. However, as CMS examines this and other additional co-morbidities in the future, ASN encourages the Agency to again weigh the administrative burden potentially associated with any diagnostic category.

Race/Ethnicity Adjustor (p. 409)

Similarly, ASN believes that it is appropriate for CMS to delay finalizing a decision regarding a race-ethnicity adjustor, and supports the decision to re-evaluate the extent to which this would be appropriate when more data becomes available. Besides supporting examining race/ethnicity neutral biological factors and other patient conditions that may result in increased treatment cost, the society wishes to reiterate its comment that the Agency may also wish to consider socioeconomic status (SES) in its future analyses. Until more complete data becomes available, the society strongly requests that CMS monitor access, practice, and prescribing patterns under the ESRD PPS to ensure that the new system does not result in unintended adverse effects on patient safety or quality of care—or on the viability of facilities that serve predominantly minority populations. As such, ASN appreciates CMS' intent to monitor for evidence of decreased access to renal dialysis services by race/ethnicity, and looks forward to learning more about the agency's methodology for doing so.

Diagnostic Laboratory Tests (p. 127)

The society thanks CMS for its decision to create a billing modifier to provide for a separate payment when a nephrologist orders a lab test that is not ESRD-related. Preserving nephrologists' ability to order these tests will minimize patient discomfort, protect vascular access, and enable nephrologists to serve as primary care providers to the patients they see on a frequent basis. ASN also thanks CMS for providing the list of 53 ESRD-related labs, which the society believes is comprehensive and will facilitate nephrologists in providing optimal patient care.

Implementation (p. 681)

ASN supports CMS' decision to delay implementation of payment of ESRD-related oral-only drugs under the ESRD PPS until January 1, 2014. The society agrees with CMS that this period will enable the agency to better determine the impact of their addition to the bundled payment—and any unintentional consequences that might ensue on quality of care. In particular, the society wishes to reiterate its concern that more than half of all beneficiaries currently rely on the low-income subsidy under Medicare Part D to help cover their co-pay responsibility. These individuals will no longer have the support of the low-income subsidy as of January 1, 2014. By generating a new co-pay for ESRD patients, ASN is concerned that this step may impede some patients' ability to pay for their dialysis care. Non-composite rate labs—which were formerly fully covered by Medicare—will be paid under the bundle as of January 1, 2011, further contributing to the new co-pay burden for patients.

Many patients on dialysis live on fixed incomes and for some, additional costs would constitute a severe hardship. The society understands that patients who currently use more than the average amount of ESRD services will have lower co-payments under the bundle—but is troubled that patients who currently use less than average services will face higher co-payments which may be challenging for them to cover.

ASN appreciates that CMS has proposed to assess the impact of this shift on patients and ESRD facilities during the transition period, and that the agency has already begun outreach efforts with State Medicaid Agencies to address financial concerns related to patients who are dual-eligible. The society would appreciate the opportunity to learn more about the steps CMS is taking in this regard and requests that the Agency share contact information for a staff person with whom ASN can communicate.

The society appreciates CMS' recognition that small and independent facilities may be at a disadvantage to the largest national dialysis chains because they are less capable of aggressively negotiating drug prices. Recognizing that the agency is not proposing a national standard for establishing contracts with pharmacies for the purposes of obtaining ESRD-related drugs and biologicals, ASN nonetheless encourages CMS to monitor these arrangements to ensure that monopoly laws are not violated.

Finally, ASN requests that CMS clarify what will happen to a facility that pays for medications which are not administered—and for which they did not receive a co-pay—because a patient did not show up for an appointment.

Conclusion

The new ESRD PPS described in the final rule is a significant departure from historical payment and incentive structures; ASN believes its implementation presents a unique opportunity to improve the quality, delivery, and cost of dialysis patient care. The society looks forward to working with CMS to ensure the highest quality of care and access in this unprecedented payment environment, and thanks the agency in advance for its willingness to consider this letter of guidance regarding the final rule.

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

Sincerely,

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