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American Society of Nephrology Remarks Centers for Medicare and Medicaid Services ESRD Town Hall Meeting October 23, 2009

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 dialysis care and related services regardless of socioeconomic status, geographic location, or local demographic characteristics.

ASN applauds many aspects of MIPPA and the proposed payment rule as embracing true reform for the Medicare ESRD Program. However, we are concerned that in today's dialysis patient care and business environment, some aspects of the proposed regulations—in particular the inclusion of all 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 flexibility of the physician-patient relationship, which includes reasonable latitude for physicians in prescribing and in ordering diagnostic laboratory tests. We believe this approach provides optimal patient care.

Given the frequency of dialysis treatments, studies show that a vast majority of patients obtain their treatment at a facility as close to home as possible. Indeed for many patients with End-Stage Renal Disease (ESRD) and their physicians, there is little choice available in where to obtain dialysis within their region. In the current national environment for ESRD care, two organizations provide dialysis services to more than 60% percent of all dialysis patients. Moreover, vertically integrated dialysis companies provide the majority of manufactured dialysis equipment to dialysis facilities, and one of these organizations also owns and markets drugs commonly administered to patients on dialysis. Dialysis facilities of all sizes and types will likely encourage staff and physicians to operate with greatest efficiency under the new bundle. In some circumstances, expanded bundling of dialysis-related medications may lead to pressures to prescribe selected medications, based primarily on financial considerations.

Given this context, it is imperative that CMS ensure the Proposed Rule is focused on preserving the flexibility of the physician-patient relationship to ensure the most appropriate, personalized treatment is available to each individual. Specifically, the Rule must protect the ability to prescribe particular drugs. The Rule must ensure that all classes and types of drugs be readily accessible to all patients and providers, regardless of the facility in which they receive or provide care, nationwide. Because the choice of which drug is best often depends on incomplete data and not every patient follows the

norm, fixed regimens should not be based on algorithms using narrowly limited formularies. Since a demonstration project was not undertaken prior to passage of MIPPA and implementation of the proposed rule, ASN also encourages CMS to commission or collaborate on comparative effective research evaluating the complete range of drugs commonly used in care of patients with ESRD.

ASN is also concerned about maintaining flexibility in the ordering of diagnostic laboratory tests. Specialists caring for patients who are afflicted with a serious condition such as end-stage kidney disease often become the principal provider of care for that individual. Many nephrologists serve as the principal care provider for their dialysis patients. They often see the patients in the office setting outside of the dialysis unit. By including all diagnostic laboratory tests ordered by the MCP nephrologist in the ESRD bundled payment, CMS may discourage nephrologists from doing what is best for the patients they see on a frequent basis. ASN encourages CMS to include only tests which directly relate to ESRD in the bundle, and to develop an alternate method to enable nephrologists to order other important but unrelated laboratory tests. ASN encourages the Agency to work with the nephrology community to identify a list of ESRD-related diagnostic laboratory tests that will be covered by the bundled payment. This is especially important due to the fact that patients could face discriminatory practices related to charges for lab services and other formerly separately billable items and services.

Finally, the Society is concerned that CMS' statistical model has underestimated the complexity of providing dialysis service for pediatric patients. The model imposes substantial reductions in the payments for pediatric patients compared to the previous exception rates—rates that were based on accepted cost reports. If implemented, this model may severely impede pediatric dialysis centers' ability to continue to provide care to children nationwide.

ASN respects and appreciates CMS' willingness to collaborate with the renal community to address the important issues and challenges facing kidney disease patients and providers in order to offer the highest-quality care. The Society believes that CMS shares our view of the importance of the patient-physician relationship, including the opportunity to choose the most appropriate tests and medications, and believes that the Rule was not intended to diminish these vital aspects of care. In light of the Society's overall devotion to the patients its members treat, ASN looks forward to submitting a complete set of comments on the proposed rule. These would focus on maintaining the independent patient-physician relationship and nephrologist flexibility under the new bundled payment system. Again, thank you to CMS, Dr. Straub, and Dr. Blum for the opportunity to speak this morning.