

January 29, 2016

The Honorable Orrin Hatch
Chairman
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Johnny Isakson
United States Senate
131 Russell Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mark Warner
United States Senate
475 Russell Senate Office Building
Washington, DC 20510

ASN Comments Re: Bipartisan Chronic Care Working Group Policy Options Document

Dear Chairman Hatch, Ranking Member Wyden and Co-Chairs Isakson and Warner:

On behalf of the American Society of Nephrology (ASN) thank you for the opportunity to provide feedback and comments on the United States Senate Committee on Finance bipartisan Chronic Care Working Groups recent policy options white paper. ASN commends the working group for its continued bipartisan commitment in tackling these critical issues and for creating multiple opportunities for stakeholders to provide comments.

ASN is the world's leading organization of kidney health professionals, representing nearly 16,000 physicians, scientists, nurses, and health professionals who improve the lives of patients with kidney disease every day. ASN and the professionals it represents are committed to promoting policies and practices that are centered on advancing the care of Americans living with kidney disease, as well as simplifying patient access to optimal quality care, regardless of socioeconomic status, geographic location, or demographic characteristics.

The federal government has a unique role in financing kidney disease care. When a chronic kidney disease patient develops ESRD, they qualify by law for Medicare coverage regardless of their age. Yet, as these patients make the transition to ESRD, their risk of hospitalization and

death substantially increases. Although patients with ESRD make up 1% of the Medicare population they comprise over 6% of the total costs.

The society hopes that these comments in response to the working group's policy options white paper will contribute to the committee's efforts to identify thoughtful policies that improve outcomes for, and reduce costs related to, the care of people with complex chronic diseases.

In summary, ASN supports the following policy recommendations:

- 1) Expanding telehealth access for both home hemodialysis and home peritoneal dialysis
- 2) Permitting patients with ESRD to enroll in MA plans
- 3) Allowing patients with advanced kidney diseases to benefit from new and existing chronic care management payment codes
- 4) Developing Quality Measures for Chronic Conditions
- 5) Commissioning a Study on Medication Synchronization

As stated in ASN's previous comments to the Chronic Conditions Working Group in June 2015, any policy aimed at improving health care delivery should coincide with rigorous data collection on health care costs and health outcomes. Using prospectively defined "endpoints" and matched control groups to compare to those affected by the policy, these data can be used to evaluate the policy's effectiveness.

Expanding Access to Home Hemodialysis Therapy (Page 7):

ASN strongly supports the working group's proposal to expand Medicare's qualified originating site definition to improve access to care for home dialysis patients, especially pediatric dialysis patients. Expanding this definition to include free-standing renal dialysis facilities in any geographic area will be a significant benefit to many home dialysis patients. Telemedicine may be valuable for ongoing care of patients residing in rural areas, especially as a way of connecting them to nephrologists to avoid the need to travel in dangerous weather or prohibitively long distances.

Permitting patients and their physicians the option to participate in telehealth visits in some months – with in-person visits at least quarterly (every three calendar months) — may incentivize patients to adopt home dialysis as a treatment option. ASN believes that such telehealth interactions are appropriate when they 1) include a video interaction, 2) are supported by the transmission of clinical data that facilitates physician review and evaluation of patient treatment, and 3) are compliant with federal and state laws protecting privacy of patient health information.

An even more vital policy change, however, would be to allow a patient's home to be a qualifying site for telehealth. Eliminating the need for home dialysis patients to travel to an originating site to see their provider also would support those actively employed or seeking employment without sacrificing the appropriate level of clinical interaction. Pediatric patients often need to travel long distances for clinic, and telehealth would permit children to minimize school absences, decrease transportation costs, and decrease lost work days for parents.

ASN recognizes that appreciate the concern regarding clinical equipment; however, dialysis providers are able to work with patients to use iPads and other technologies to allow for video interactions and the transmission of clinical data in compliance with federal and state privacy

laws. ASN does not anticipate any significant costs associated with this policy change, as the vast majority of the infrastructure required for telehealth is already available.

Patient safeguards are essential for a patient population that requires ongoing, intensive treatment. First and foremost, both patients and physicians must retain the option to choose to conduct their monthly clinical assessment visit in-person if that more appropriately meets clinical needs in any given month. Secondly, if patients are able to participate in telehealth visits with authorized providers, the interval for a required in-person interaction should be at minimum quarterly; that is, patients should see their physician or other provider in person at least once every three calendar months.

ASN recommends that the Committee adopt its proposal to designate the renal dialysis facility as an originating site, and that the Committee also include the home as an originating site, for the purposes of home dialysis services.

Allowing End Stage Renal Disease Beneficiaries to Choose a Medicare Advantage Plan (MA) (Page 9):

ASN strongly supports the working group's proposal to allow ESRD patients the choice to consider whether joining a MA plan versus enrolling in traditional Medicare. As the working group outlined in its white paper, under current law, people who develop kidney failure are not permitted to enroll in MA plans. ESRD is the only pre-existing condition that renders people ineligible to participate in this program. As the committee also outlined in its white paper, the Medicare Payment Advisory Commission (MedPAC) has recommended that Congress eliminate the restriction against ESRD beneficiaries enrolling in MA plans to provide ESRD beneficiaries with the same freedom of choice and access to improved coordinated services as other Medicare-enrolled individuals. Permitting patients with ESRD equitable access MA plans would enable them to benefit from greater care coordination, and aligns directly with the aims of the chronic care working group.

ASN also notes that this policy change may benefit patients with ESRD who receive a kidney transplant in terms of maintaining coverage for the immunosuppressive drugs needed to keep their kidneys healthy. Traditional Medicare does not provide coverage for kidney transplant recipients who are under age 65 starting 36 months after their transplant, which can create hardships for patients struggling to purchase the drugs themselves. Patients who enroll in an MA plan would not face this 36 month coverage issue and would be ensured access to their immunosuppressive drugs.

The society also notes that critically, ESRD patients who enroll in MA plans should still have the data regarding their care and outcomes incorporated into the U.S. Renal Data Service (USRDS) database, as is standard in traditional Medicare. This database is an essential tool for the kidney and research community to assess, understand, and improve practice patterns and outcomes among this vulnerable patient population over time. The society also urges that, in order to preserve patient choice and flexibility, networks not be limited to a single dialysis organization in a given MA plan or region.

Improving Care Management Services for Individuals with Multiple Chronic Conditions (Page 11):

ASN applauds the working group for its consideration of developing new high-severity chronic care management payment codes. The federal government has a unique role in financing

kidney disease care. When a chronic kidney disease patient develops ESRD, they qualify by law for Medicare coverage regardless of their age. Yet, as these patients make the transition to ESRD, their risk of hospitalization and death substantially increases. Although patients with ESRD make up 1% of the Medicare population they comprise over 6% of the total costs.

In many ways patients with ESRD epitomize the complex, high-severity patients the working group seeks to address with these proposed new codes. Patients with advanced kidney diseases almost always have multiple other serious chronic co-morbidities, including diabetes, hypertension, peripheral vascular disorders, and heart failure, and commonly receive care from multiple specialists. More than 50% of patients with chronic kidney disease have 5 or more other co-morbid conditions, and chronic kidney disease is included among 4 of the 5 most costly chronic condition combination triads in the Medicare program (CMS Office of Information Products and Data Analytics, August 2014). As such, they could especially benefit from the proactive, comprehensive care coordination that the new proposed high-severity codes would offer—providing them superior quality of life, fewer hospitalizations, and better long-term health.

However, current CMS practices exclude patients with End-Stage Renal Disease (ESRD) from eligibility for the existing CCM codes during the same 90-day period during which they receive standard—and lifesaving—dialysis care. This exclusion was not legislatively mandated, but rather, implemented during the CMS rulemaking process. ASN strongly believes that patients with kidney disease deserve equitable access to CCM services, and would be among the most likely to benefit from the new high-severity codes. ASN hopes that Congress will ensure that CMS ensures that the kidney patient community is eligible to receive this important benefit.

ASN commends the working group for considering these important new codes, and welcomes discussion with members of the working group concerning why ASN believes these codes would be of particular benefit to patients with kidney failure.

Addressing the Need for Behavioral Health among Chronically Ill Beneficiaries (Page 12):

ASN supports the working group's decision to include mental and behavioral health issues for chronically ill patients. As the working group indicated in its white paper, behavioral health problems can hinder the successful management of patients with chronic conditions and lead to a lack of adherence and compliance to treatment and medication regimens, and overall, result in negative patient outcomes. Patients with kidney disease often experience psychological issues, and estimates suggest that approximately 20 percent of maintenance dialysis patients suffer from depression. ASN commends the white paper's attention to behavioral health and stands ready to discuss this issue with the working group.

Increasing Convenience for Medicare Advantage Enrollees through Telehealth (Page 16):

In concept, ASN supports the working group's recommendation to permitting Medicare Advantage (MA) plan to include in certain telehealth services in annual bid amounts. As stated above, ASN believes that providing kidney patients with the opportunity to use telehealth would be beneficial. However, ASN would recommend that the working group does not make this permanent, and would recommend rigorous testing during implementation so that it is certain that the program is successful. As the working group knows, once something is locked into statute, it is difficult to change, making this testing and gathering of data critical.

Developing Quality Measures for Chronic Conditions (Page 22):

The society appreciates the working group tackling such an important issue for overall patient quality, and would recommend that this section be included in the current CMS ESRD Quality Incentive Program (QIP) and Prospective Payment System (PPS). Meaningful measures that truly affect outcomes, shared decision-making and care coordination between transitions are critical in the care of complicated patients. As stated above, patients with kidney disease have a dramatic increase of hospitalization and/or death during the transition from CKD to ESRD. Measures and coordinated care during this tenuous time could have a dramatic impact on patient care as well as overall economic savings. The months surrounding dialysis initiation cost between \$20,000 and \$30,000 per patient, and requires patients to cross systems that do not communicate successfully. The society stand ready to help answer any questions the working group or committee may have and thanks the working group once again for the inclusion of this important topic.

Establishing a One-Time Visit Code Post Initial Diagnosis of Alzheimer's/Dementia or Other Serious or Life-Threatening Illness (Page 24):

ASN is strongly supportive of the working group's recommendation for CMS to implement a one-time visit for patients to discuss the severity of their diagnosis and what they should expect in the future. The work group requested comments on which diseases should be eligible for this one time visit. ASN believes that patients with kidney disease would be among the most likely patient population to benefit—and among the most likely patient population to see decreased costs associated with downstream treatments as a result.

Helping patients to understand the progression of their kidney disease is a critical component in building patient-centered care, better health for individuals, and reduced expenditures to the Medicare program. There are many types of kidney disease and a nuanced approach/conversation can help patients understand how they can slow their disease progression, preventing the need for costly and time-consuming dialysis for as long as possible. Every year a Medicare beneficiary with kidney disease is able to live before initiating dialysis, it both grants that patient greater independence and quality of life and saves the Medicare program the approximately \$90,000 annual average per-patient cost of dialysis. Furthermore, this visit would be an excellent opportunity to educate patients regarding other treatment options such as transplantation or home dialysis.

As stated above, ASN commends the working group for considering new CCM codes, and request again that any new code developed include patients with kidney disease.

Providing Flexibility for Beneficiaries to be Part of an Accountable Care Organization (Page 27):

As the working group notes, beneficiaries who receive at least one primary care service from any physician within an ACO are assigned to that ACO if the beneficiary receives a plurality of his or her primary care services from specialist physicians. ASN appreciates that the Chronic Care Working Group is considering recommending that Medicare fee-for service beneficiaries have the ability to voluntarily elect to be assigned to the ACO in which their main provider is participating. ASN supports this concept and recommends that, if finalized, this policy also permit patients who receive a plurality of their care from specialists participating in an ACO to elect to participate in that specialist's ACO.

Many patients with advanced kidney disease interact primarily with their nephrologist, with the nephrologist filling the role of primary care provider. Enabling these patients to elect to enter their nephrologists' ACO would help facilitate their access to the enhanced care coordination that the ACO provides in concert with the physician who oversees the majority of their complex, costly care. ASN supports this proposal and encourages the working group to permit patients to select participation in an ACO in which their specialist physician participates.

Study on Medication Synchronization (Page 29):

ASN supports the working group's proposal to commission a study on medication synchronization for Medicare Part D drugs. Patients with kidney disease are at particularly high risk for medication related problems that contribute to adverse patient outcomes and high cost (Manley et al, Am J Kidney Dis 2003). Because many medications are removed from the body by the kidneys, it is essential to account for kidney function when dosing drugs. As the working group observed, the major gap in safe medication prescribing occurs when patients cross systems. Patients with chronic kidney disease are prescribed complex medication regimens; the average dialysis patient takes 19 pills per day (Chiu et al, CJASN 2009).

Identifying and resolving medication-related complications, particularly among patients with multiple chronic conditions who require multiple medications, is an important objective both in terms of patient outcomes and cost of care. As such, ASN is supportive of this proposed study and hopes that such a study will help underpin the development of programs that both improve the lives of patients with kidney disease, lead to fewer re-hospitalizations, and provide considerable cost savings.

Conclusions:

Patients with kidney failure are among the most complex and most expensive patients in medicine. Enhanced care coordination, including policies to minimize medication errors, slow the progression of kidney disease, and improve transitions of care between CKD and ESRD are important clinical and economic considerations and ASN hopes that these comments are helpful as the chronic conditions working group continues to review and develop legislation.

The society thanks the Committee and the working group for their interest in chronic conditions and for the opportunity to provide comments on the working group's bipartisan policy options document, and stands ready to answer any questions the Committee may have.

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

Sincerely,



Raymond C. Harris, MD, FASN
President