ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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Monday, June 22, 2015

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

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 input to the United States Senate Committee on Finance regarding analyzing the current law, discussing alternative policy options and developing bipartisan legislative solutions for improving care for patients with chronic medical conditions. ASN commends the Committee for its continued bipartisan commitment in tackling these critical issues. The society also thanks the Committee for its efforts to engage stakeholders and solicit feedback throughout this process.

ASN is the world's leading organization of kidney health professionals, representing over 15,000 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. We hope that these comments 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.

Kidney disease is responsible for high morbidity, high mortality and a substantial portion of the financial burden associated with chronic medical conditions. Over 20 million Americans have chronic kidney disease, including nearly 650,000 with end-stage renal disease (ESRD) who are treated with either dialysis or transplantation. More than 51% of patients with kidney disease have 5 or more chronic co-morbid conditions and more than 80% have 3 or more chronic co-morbid conditions. Consequently, approximately 25% of all Medicare dollars are spent on caring for patients with kidney disease. In 2012 CMS reported on the top five most costly triads of chronic illness; chronic kidney disease (CKD) was included in four out of the five with an average cost of approximately $60,000 per capita.

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

A significant portion of health care costs and health complications associated with ESRD occur during the transition from advanced CKD to ESRD, and, for patients with failing transplants, during the transition back to dialysis. Pre-ESRD care is typically provided in very different systems than dialysis care, which is based in the dialysis facility and is highly structured, or transplant care, which is based in the transplant center and is also highly structured. Policies that optimize care coordination in the months leading up to this transition could improve health, provide a better patient experience and reduce costs.

In summary, ASN provides policy recommendations in this letter focused on achieving the following goals:

1) Improve care coordination—especially during care transitions—for patients with advanced CKD and other complex chronic conditions through Medicare Advantage (MA) plan access and new care delivery pilot programs
2) Improve access to transplantation, the optimal therapy for most patients with ESRD from outcome and cost perspectives;
3) Permit patients with ESRD to enroll in MA plans
4) Reduce medication errors for complex, chronically ill patients
5) Utilize telemedicine and remote monitoring to more effectively manage co-morbidities and coordinate care for people with all stages of kidney disease.

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.

1. Transformative Policies that Improve Outcomes for Patients Living with Advanced CKD (question #2)

Currently, ACOs are tailored specifically to the general population while the forthcoming (as of July 1, 2015) ESRD Seamless Care Organization (ESCO) pilot is tailored to the specific needs of patients on dialysis. No programs or pilots exist that address the needs of individuals with advanced chronic kidney disease by promoting patient-centered care, smooth transitions of care and improved quality outcomes. ASN believes that the establishment of such pilots would fill a significant gap in care coordination for this chronically ill patient population—and lead to savings in the Medicare program. The months surrounding dialysis initiation cost between $20,000 and $30,000 per patient, and require patients to cross systems that do not communicate successfully. Although the forthcoming ESCO model is a positive and significant step towards improving care and reducing costs for the dialysis patient population, it will not encompass the clinically and economically significant transition period—nor do ESCOs include patients who have received a kidney transplant. While identifying patients with late-stage chronic kidney disease may pose a challenge, the society nonetheless believes this is an important goal and stands ready to work with the committee and the kidney community to develop solutions.

ASN proposes piloting of a "comprehensive CKD care delivery model". This care delivery paradigm is similar to but broader than the ESCO, as it will include patients with advanced CKD and focus on managing and slowing the progress of kidney disease and other complex chronic conditions that are common in patients with advanced kidney disease. Such a pilot model would build upon and borrow from many of the same concepts in the ESCO model, but expand the patient population included. Spearheading the care coordination efforts, a nephrologist would serve as the care leader for a population of patients from the time of their diagnosis of advanced CKD and would assume responsibility for their care—in partnership with other members of the care team, including dialysis providers—through the transition periods of dialysis initiation, transplantation or end-of-life care.

Nephrologists are specifically trained to manage multiple co-morbidities and, in a "comprehensive CKD care delivery model," the nephrologist and nephrology practice would assume primary responsibility of managing related comorbidities and coordinating patients' access to the multitude of other specialists needed to manage their complex conditions. Due to the complexity of the co-morbidities, many traditional primary care physicians (internists, family medicine) defer overall primary management to the nephrologist, but this is not universal. Effective management of co-morbidities is especially important for patients with earlier stages of CKD, during which proper care coordination by a nephrologist can help slow the progression of kidney disease towards ESRD as well as help prevent the advancement of co-morbidities that are caused or worsened by kidney disease, such as hypertension. Public accountability for quality and cost of services delivered, and a common financial system or shared financial goals across all sites of care included in the model would contribute to more patient-centered, cost-efficient care for those with advanced CKD.

As patients progress towards kidney failure, a "comprehensive CKD care delivery model" would emphasize preparation for the optimal form of kidney replacement therapy, addressing the fragmentation that often characterizes the transition of care onto dialysis. Improved care coordination for CKD patients would improve outcomes and reduce costs: slowing the progression of kidney disease, educating patients about their choices, planning for pre-emptive transplant (before starting dialysis) or selecting the most appropriate modality type and environment, planning and initiating the most suitable vascular access type, and formulating conservative therapy and palliative care plans where appropriate.

Some of the elements ASN believes would contribute to more patient-centered, cost-efficient care for those with advanced CKD and other chronic conditions include:

- Patient and family involvement with care focusing on the needs of the patient rather than on any single provider, facility or site of care
- Integrated knowledge flow across systems (including inpatient and outpatient) as well as knowledge of the patient, care plan, and best practices and processes available to all, allowing for effective hand-offs and smooth transitions.
- Consistent patient preference-focused education with real-time information translated on the patient's level to gain maximum usability of information. Such education can facilitate living donor transplantation and home based dialysis therapy to keep patients independent.

Besides improving the transition of care from CKD to ESRD, ASN anticipates that a "comprehensive CKD care delivery model" would facilitate practices with considerable positive implications for patient outcomes and costs, such as improved medication reconciliation and management (please refer to section on medication reconciliation). Additionally, by including post-transplant patients within the scope of this model, there would be inherent incentives to promote transplantation for the greatest number of patients possible who are candidates.

By effectively implementing a seamless coordinated patient-centered system of care, patient-important outcomes such as decreased need for acute medical services and emergency room visits, decreased unnecessary tests and procedures, improved advance care planning, timely referral for specialized care including transplant, and overall improved patient outcomes can be achieved for patients with complex chronic disease (CKD) leading to a decrease in overall cost of care. ASN would welcome the opportunity to continue discussions and provide more detail regarding how the society envisions a "comprehensive CKD care delivery model" could improve patient outcomes and reduce costs to the Medicare system.

2. Improving access to kidney transplantation to optimize outcomes and minimize costs (general bipartisan goals)

The chronic conditions working group solicited ideas for policies that improve care transitions, produce stronger patient outcomes, increase program efficiency and overall reduce the growth of Medicare spending. ASN believes that improved access to transplantation, including pre-emptive transplant, would directly help achieve these goals.

Patients with CKD progressing to the point of ESRD have two treatment options; transplantation or dialysis. Ideally, patients will receive pre-emptive transplants and never require dialysis. Kidney transplantation is the treatment of choice for eligible patients and compared to dialysis, markedly improves survival (Wolfe, NEJM 1999), reduces risk of chronic medical conditions that complicate ESRD, and improves quality of life. Besides the survival and health outcomes benefits of transplantation over dialysis, kidney transplantation is one of the most cost-effective interventions. One live kidney donation has been estimated to lead to an increase of 2-3.5 quality adjusted life-years for recipients and a net health care savings of $100,000 [Klarenbach et al, CMAJ 2006]. The less time recipients spend on chronic dialysis prior to transplant the better their post-transplant outcome; patients transplanted before ever needing dialysis (pre-emptive transplant) being the optimal goal [Mange, NEJM 2001].

The costs in the first post-transplant year are approximately double those of the 1-year cost of care for a dialysis patient and the break-even for transplant versus dialysis is about 30-36 months [SRTR annual report 2012]. Longer-term transplant costs are $25,000/life-year compared to approximately $60,000-$80,000/life-year for dialysis patients [SRTR annual report 2012]. While almost all the dialysis related costs are borne by Medicare, many transplant recipients return to the work place after transplant where they are often eligible for private insurance.

Patients can obtain kidney transplants from one of two donor sources; either a live donor (biologically or non-biologically related) or a deceased donor. Live donor kidneys survive longer (half-life about 15 years) compared to kidneys from deceased donors (half-life about 10 years) [SRTR annual report 2012]. Live donor transplantation is associated with shorter lengths of hospital stays and fewer hospitalizations overall.

Live donors have to take off time from work to donate and often have associated travel costs as well. For many, the financial hardship (out-of-pocket costs estimated to be over $5,000/donor) associated with live kidney donation can be a barrier to potential candidates [Klarenbach AJT 2014]. This can result in the intended recipient losing an opportunity for a pre-emptive transplant and needing dialysis therapy for several years before a deceased donor kidney is available. Patients without live donors must be wait listed for a kidney from a deceased donor. The disparity between the number of candidates being waitlisted and the supply of suitable deceased donor kidneys has continued to widen. At present over 100,000 patients are on the waiting list for a deceased donor kidney and the average waiting time is 5-7 years [SRTR annual report 2012]. Most patients need to receive dialysis treatment for much of the time that they spend on the waiting list.

When kidney transplants fail (approximately 5,000 per year in the US), most patients return to dialysis; only about 10% of patients with failing transplants get pre-emptively re-transplanted [USRDS 2010]. Patients transitioning from transplantation to dialysis are a particularly vulnerable population with a death rate of about 25% within 2 years of needing dialysis [Gill KI 2007]. This morality risk among transplant failure patients is attributable to the combined burden of longstanding kidney disease, its associated comorbidities as well as chronically weakened immunity from anti-rejection medication use. A coordinated care strategy involving tailored transplant management, concomitant preparation for timely initiation of dialysis (including modality selection and access placement) and optimal treatment of CKD-related complications is essential to mitigate the risk this unique population faces.

Despite the clear outcome and cost-saving benefits of transplant, several barriers exist that limit access to transplantation for the ESRD population, including:

1. Lack of education among patients with advanced CKD as to optimal ESRD treatment options
2. Late referral for CKD care by primary care physicians
3. Late referral to transplant centers by kidney specialists
4. Delayed access to transplantation for racial and ethnic minorities (for instance, African Americans constitute 12% of general US population but 30-35% of the ESRD population)
5. Lack of access to transplant centers for patients living in remote/underserved areas
6. Financial barriers to living donation (average out-of-pocket costs for living donors exceed $5,000)

ASN proposes the following policy options that could help make transplantation more accessible to all eligible patients with ESRD, including:

1. Tasking the Centers for Medicare and Medicaid Services to explore strategies to incentivize nephrologists to refer patients with advanced CKD to transplant centers for pre-emptive transplant evaluation
2. Testing a "comprehensive kidney care delivery model" for CKD patients at all phases of care, including kidney transplant recipients and those with failing transplants returning to dialysis (please refer to section on comprehensive kidney care delivery model)
3. Expanding access to pre-and post-transplant care for geographically disadvantaged kidney recipients and kidney donors through telemedicine (please refer to section on telehealth)
4. Eliminating barriers for potential live kidney donors
    a. Prohibiting life, disability, and long term care insurance companies from denying or limiting coverage and from charging higher premiums for live organ donors;
    b. Clarifying that live organ donors may use FMLA time to recover from donation surgery and testing involved in their donation
    c. Providing reimbursement for out-of-pocket costs related to undergoing live kidney donation

In summary, ASN believes that these policy options to increase kidney transplantation rates strongly align with the bipartisan goals of the chronic conditions working group, particularly in terms of producing superior patient outcomes, improved quality of life and reducing the growth in Medicare spending.

3. Improvements to Medicare Advantage Plans for Patients Living with Multiple Chronic Conditions (question #3)

Under current law, people who develop kidney failure are not permitted to enroll in Medicare Advantage (MA) plans. ESRD is the only pre-existing condition that renders people ineligible to participate in this program. However, 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, aligns directly with the aims of the chronic care working group.

4. Reducing Medication Errors for Patients with Chronic Kidney Disease

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. 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). These medications may interact with each other and often are processed differently in the body depending on the level of kidney function. 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. However, the literature suggests that patients frequently lack this needed medication coordination (Barnes et al, Pharmacotherapy 2015). Currently, although e-prescribing is common, little ancillary information accompanies prescriptions. Specifically, the pharmacist dispensing medications often is unaware of the patient's level of kidney function, and they may not even know whether a patient has kidney failure and is treated with dialysis.

While relatively limited, the existing literature suggests that policies and programs that improve the availability of patients' kidney function to pharmacists have considerable cost savings potential. In one study, the number of incorrect doses prescribed was significantly improved when information on kidney function was available (Erler et al, BMC Fam Pract 2012), while a retrospective study described a cost

savings of over $2 million at a single hospital over a decade after computerized kidney dosing assistance was initiated (Chertow et al, JAMA 2001).

A 2006 Institute of Medicine report suggested that there were at least 1.6 million adverse drug events and opined that this was likely a marked underestimate. This report specifically cited patients with kidney disease as a population requiring further study. Systems to facilitate communication regarding patients' kidney function (eGFR) to pharmacists with all prescriptions, and between nephrologists and pharmacists, would be a prime opportunity for future study.

Further, ASN also believes that under a comprehensive CKD care delivery model, nephrologists and their partners in care would establish more closely coordinated communications systems with pharmacists in order to properly dose medications, leading to fewer patient rehospitalizations and lower costs to the Medicare system.

5. Use of telehealth, remote monitoring, and strategies to increase chronic care coordination in rural and frontier areas

ASN believes that patients at every stage of kidney disease—from those with early-stage CKD who may be at risk to progressing, to those who are on dialysis, to those who have received a kidney transplant—may be uniquely poised to benefit from expansion of telehealth opportunities. As delineated earlier, effective management of these co-morbidities is especially important to slowing the progression of kidney disease as well as preventing the advancement of costly co-morbidities that are caused or worsened by kidney disease. Besides improving patient outcomes, facilitating patient access to subspecialists via telehealth technologies may contribute to long term cost-savings—particularly to the Medicare ESRD Program, by preventing people from requiring dialysis.

The current system, outlined in Section 1834(m) of the Social Security Act, creates a series of hurdles for practitioners wishing to incorporate these technologies into their practices. In order to qualify for reimbursement for visits by video conference, each interaction must meet a series of requirements. First, the patient must be located at a statutorily defined "originating" site, which does not include the patient's home. Second, the services must be provided within a rural Health Professional Shortage Area (HPSA), a county outside a Metropolitan Statistical Area (MSA) or be part of a federal telemedicine demonstration project. Finally, the services can only be provided by a statutorily defined list of approved practitioners.

These restrictions create a system that disincentivizes providers from adopting new technologies, and discourages innovators from developing new devices that will never be reimbursed. Additionally, the statute categorically prevents the reimbursement of "store and forward" technologies, such as remote patient monitoring devices, that would allow providers to more closely track their patients' condition.

In particular, telemedicine and remote patient monitoring technology may be valuable for ongoing care of those in rural areas, especially as a way of connecting rural home dialysis patients to nephrologists to avoid the need to travel in dangerous weather or prohibitively long distances. This technology would also be extremely useful as a mechanism to obtain the expertise of the subspecialist/nephrologists to patients who have no nephrologists in their area by allowing real-time knowledge sharing and handoffs/coordination of care with the primary provider.

In addition, while some states (eight as of Monday, June 15, 2015) have signed on to a Telemedicine Interstate Medical Licensure Compact allowing expedited licensure for physicians seeking to practice medicine (telemedicine) across state lines, most physicians see the prolonged and arduous process of obtaining additional state licensures for telemedicine as a barrier, thus limiting access to those in rural areas.

ASN urges the Committee to adopt practical and beneficial reforms that would allow dialysis patients to access telehealth services that could provide improved outcomes and lower costs. As an initial step, we recommend that the Committee include the home as an eligible "originating" site for the purposes of home dialysis services;

1. Allow CMS to reimburse telehealth services throughout the country, regardless of an area's health shortage status;
2. Allow greater flexibility in what providers can bill for telehealth services;
3. Allow for standing waivers of the monthly Medicare face to face requirement for physicians billing for care management of dialysis patients in the home when appropriate conditions are met including the use of remote monitoring technologies; and
4. Create a reimbursement mechanism for remote patient monitoring technologies.
5. Expand the Telemedicine Interstate Medical Licensure Compact to all states.

ASN believes that these reforms would provide a significant improvement over the current system. The society is also open to working with Congress, along with the larger kidney and telemedicine communities, to develop additional reimbursement approaches outside of the current 1834(m) rubric or to remove the barriers to expand the use of telehealth and remote monitoring to care for dialysis patients.

Conclusions

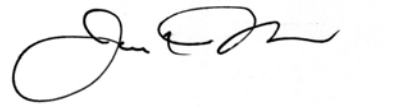
Patients with kidney failure are among the most complex and most expensive patients in medicine. Enhanced care coordination, including policies to minimize medication errors, slow the progression of kidney disease, and improve transitions of care between CKD and ESRD (and into kidney transplantation)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

ASN reiterates that all of the proposals described in this letter—and other reforms to the Medicare program—need to be tested during implementation in a rigorous manner with prospectively defined endpoints, similar to a clinical trial. What intuitively makes sense does not always withstand study; these and other changes to the Medicare program cost money and need to be proven worthwhile.

The society thanks the Committee and the working group for their interest in chronic conditions and for the opportunity to provide input regarding opportunities to improve patient outcomes and reduce costs. ASN stands ready to answer any questions the Committee may have and looks forward to continuing to work with Committee in order to support thoughtful, appropriate adoption of policies that advance these goals.

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,



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