

January 26, 2015

The Honorable Fred Upton United States House of Representatives Chairman, Committee on Energy and Commerce 2125 Rayburn House Office Building Washington, DC 20515

The Honorable Frank Pallone United States House of Representatives Committee on Energy and Commerce 2125 Rayburn House Office Building Washington, DC 20515

Dear Chairman Upton, Ranking Member Pallone, and Representatives Harper, Johnson, Latta, Matsui, Walden, and Welch:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the draft legislation on advancing telehealth opportunities in the Medicare program.

ASN is the world's leading organization of kidney health and science professionals, representing more than 15,000 physicians, scientists, nurses, pharmacists, physician assistants, and other health professionals who improve the lives of patients with kidney disease every day. ASN and the professionals it represents are committed to providing the highest quality of care possible to the millions of Americans affected by kidney disease, regardless of geographic location.

ASN commends the Committee for seeking input and feedback from stakeholders on this important topic as part of its larger 21st Century Cures initiative. The society concurs that telehealth has significant possibility to facilitate better access to care and holds great promise for improving the health and quality of life for patients nationwide. Presently, Medicare provides reimbursement for Kidney Disease Education Services provided via telehealth, a service that ASN believes provides significant benefit to patients who would not otherwise receive this service.

That said, while ASN believes that telehealth may increase access to care for some patients and help improve care transitions, the society is concerned that telehealth may (in some instances) be used as an inappropriate substitute for face-to-face visits, or may be used to provide unnecessary care. The society therefore suggests careful consideration of the scope of the initial program and urges implementation of rigorous testing—ideally in the form of a randomized controlled trial—to ensure that the program or pilots achieve the intended goals.

Reflecting ASN's belief that a thoughtful expansion of telehealth opportunities is likely to benefit patients in the Medicare program, including those with chronic kidney disease (CKD) and end-

stage renal disease (ESRD) ASN submits the following comments regarding telehealth. In summary, ASN recommends:

- Permitting selected telehealth services to substitute for certain face-to-face encounters
- Rigorously testing every element of a telehealth program or pilot to ensure that the intended outcomes are being achieved, ideally in the form of a randomized controlled trial
- Learning from telehealth experiences in other settings—such as the Indian Health Service and the Veterans Affairs Administration (VAA)—and implementing successful elements or avoiding known challenges

More than 20 million Americans have kidney disease and are at risk for progressing to kidney failure, and nearly 500,000 Americans whose kidneys have failed rely on lifesaving dialysis. Kidney disease care is unique in that every American with kidney failure is eligible for Medicare coverage under the Medicare ESRD Program, regardless of age or income. 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.

Elimination of limitations on originating sites, including geographic limitations

ASN supports the proposal to eliminate existing limitations on what qualifies as an originating site, including geographic limitations to rural Health Professional Shortage Areas or counties outside of a Metropolitan Statistical Area. In particular, the society supports permitting patients' homes to qualify as originating sites for the provision of telehealth services. Although current efforts focused on bringing healthcare services to rural areas exist, the preponderance of specialty care—including kidney care and dialysis—is still delivered in urban areas. Lifting these limitations would facilitate patient access to care, eliminating the need to travel to interface with their nephrology care team. Furthermore, it would enable patients who live in urban areas but who have mobility challenges better access to healthcare.

Easier access to the nephrology care team could help people with advanced CKD—who typically require and benefit substantially from additional expertise that primary care physicians (PCPs) are not trained to provide—from progressing to kidney failure. According to CMS, more than 51% of patients with kidney disease have 5 or more co-morbid conditions. Effective management of these co-morbidities is especially important for patients with earlier stages of kidney disease, during which proper care from a nephrologist can help slow the progression of kidney disease towards kidney failure as well as prevent the advancement of costly co-morbidities that are caused or worsened by kidney disease, such as hypertension. Besides improving patient outcomes, facilitating patient access to subspecialists may contribute to long term cost-savings—particularly to the Medicare ESRD Program by preventing people from requiring dialysis.

Home dialysis is an important treatment option that offers patients significant quality of life advantages, including clinically meaningful improvements in physical and mental health. ASN, a member of the Home Dialysis Alliance, concurs with the Alliance that telehealth has the potential to not only improve access to home dialysis, but also to improve the care provided to these patients. The society joins the Alliance in encouraging the Committee to go designate the ESRD patient's home and dialysis facility as originating sites in statute. In doing so, the Committee would ensure access to this important treatment option for ESRD patients.

Both kidney transplant recipients and living kidney donors would be well-served by expanded telehealth options. Kidney donor follow-up consultations, mandated by both Medicare and the United Network for Organ Sharing, typically comprise a simple well-patient visit for which donors must bear the costs of a day off work and travel; were patients' homes to be designed as originating site, many of these consultations could easily be provided via telehealth. Similarly, telehealth encounters for postoperative/post-discharge transplant patients has the potential to reduce rates of readmissions, leading to improved patient outcomes, as well as a cost-savings to Medicare.

Selection of telehealth services

ASN strongly supports the concept of permitting selected telehealth services that are substitutions for an in-person visit. As described above, substituting certain face-to-face visits with telehealth interactions would likely connote quality of life benefits as well as reduced expenditures for patients receiving CKD, ESRD, and transplant-related care.

For instance, nephrologists presently provide at least one face-to-face interaction with their dialysis patients each month to receive the Monthly Capitation Payment (MCP) for the continuous care of home dialysis patients. ASN joins the Home Dialysis Alliance in acknowledging the importance of in-persons visit for home dialysis patients, but believe that a telehealth visit should be allowed to meet this face-to-face requirement in some situations, such as for those patients who are relatively healthy or who have to travel long distances to see their provider. Allowing a telehealth visit to substitute for a face-to-face MCP interaction may help increase access to home dialysis as a treatment option for ESRD patients, and ASN encourages the Committee to consider adjusting the monthly face-to-face mandate to quarterly, substituted by monthly telehealth visits.

ASN also commends the Committee for considering allowing CMS to select telehealth services that would reduce readmissions or other costly elements of care. ASN agrees that telehealth has significant potential to reduce overall spending and understands the imperative for fiscal responsibility and understands the goal not to increase any expenditures. However, the society encourages that the program focus first on patient access and quality of care, with expenditure reduction as an important, but secondary, goal.

The peer-reviewed literature already provides excellent evidence that certain services are highly likely to reduce costs. For instance, Erickson et al (J Am Soc Nephrol 25: 2079–2087, 2014) found that one additional provider visit to dialysis patients in the month following hospital discharge was estimated to reduce the absolute probability of 30-day hospital readmission by 3.5%. At current Medicare reimbursement rates, providing one additional patient visit in the month following hospital discharge could lead to nearly 32,000 fewer hospitalizations per year, and \$240 million per year saved. Erickson et al concluded that incentives for closer outpatient monitoring following hospital discharge could lead to substantial cost savings. Permitting telehealth reimbursement for physician visits following dialysis patients following hospital discharge appears to have significant potential to reduce rehospitalizations in patients undergoing hemodialysis.

ASN strongly believes that rigorous testing to evaluate whether telehealth services are achieved their intended goals is imperative. The society suggests the use of limited trial runs in the manner of a randomized clinical trial: one group of Medicare patients is allowed to receive care

via telehealth while another highly similar group is restricted to presently-available face-to-face interactions. Pre-specified patient outcomes and cost metrics would be analyzed and the cost-saving/readmissions-preventing hypothesis verified in close to real-time. Although there is wide consensus that telehealth has the potential to improve patient access, reduce hospitalizations, and reduce costs, these hypotheses remain unproven and therefore must be closely evaluated.

Remote patient monitoring and store-and-forward technologies

ASN also encourages the Committee to adopt language that allows for flexibility in the definition of what technologies qualify as telehealth services under the law. Specifically, ASN also suggests that the Committee expand the definition of "telehealth Services" to include "remote monitoring" or "store-and-forward" technologies. The current definition of telehealth is limited to an interactive audio and video telecommunications system that permits real-time communication between a healthcare professional, at the distant site, and the beneficiary, at the originating site. While real-time communication offers real and important benefits, this limited definition fails to encompass a breadth of new technologies that are widely available and can enhance care delivery and patient monitoring. Including "remote monitoring" and "store-and-forward" technology in the definition of telehealth would empower patients and healthcare professionals to share more data, in real-time, facilitating patient safety and heading off adverse events.

Notably, the VAA recently made a substantial investment in telehealth technology via its Specialty Care Access Network-Extension for Community (SCAN-ECHO) project, which provides care and collects data in many rural areas a new program to increase access to specialty care for Veterans in rural and medically underserved areas. As data from the success of this program become available, Medicare policymakers should review and consider implementing changes based on these findings.

Telehealth pilot programs in kidney disease

ASN Alliance encourages the Committee to include the creation of pilots and / or demonstration programs to explore the economic and patient outcome benefits of telehealth for patients with kidney disease at every stage. As previously described, patients with severe CKD, are on dialysis—particularly who dialyze at home—and transplant recipients and donors alike, may experience improved outcomes as a result of expanded telehealth interactions as well as generate fewer healthcare costs to Medicare.

Again, ASN thanks the Committee for its interest in telehealth and for the opportunity to provide input regarding the draft legislation on advancing telehealth opportunities in the Medicare program. ASN hopes that these comments have been helpful and society stands ready to provide additional information or answer any questions the Committee may have. To discuss ASN's comments, please contact ASN Manager of Policy and Government Affairs Rachel Meyer at rmeyer@asn-online.org or at (202) 640-4659.

Sincerely,

John R. Sedor, MD, FASN Chair, Public Policy Board

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