Testimony of Suzanne Watnick, MD
on Behalf of the American Society of Nephrology

before the House Committee on Ways and Means Subcommittee on Health Hearing on
"Improving Kidney Health through Better Prevention and Innovative Treatment"

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Chairman Smith, Chairman Buchanan, Ranking Member Doggett, and distinguished members of the Health Subcommittee of the House Committee on Ways and Means, thank you for the opportunity to testify today on "improving kidney health through better prevention and innovative treatment."

My name is Dr. Suzanne Watnick. I am a Professor of Medicine at the University of Washington, practicing at the Seattle VA, with the profound honor of caring for America's Veterans living with kidney diseases for over 30 years, and serving as the health policy scholar at the American Society of Nephrology.

In July 2019, President Trump said, "The state of care for patients with chronic kidney disease and end-stage renal disease is unacceptable." As a kidney doctor, I agree. For example, one of my patients, a Veteran who served this country, recently started dialysis again after a transplant he received in the 1990s failed. He was shocked that the dialysis facility had not changed.

Dialysis care should have accessible choices, from in-center to home therapies, transplant, or no dialysis at all. Kidney care should occur earlier through better detection, slowing, even curing kidney diseases. This vision aligns with the Advancing American Kidney Health (AAKH) initiative that the first Trump Administration initiated and the Biden Administration continued.

Unfortunately, dialysis care has seen few changes or improvements during the past 50 years. The federal government made a remarkable commitment to the American people in 1972: expanding the Medicare program to guarantee access to dialysis and kidney transplant for every American regardless of age, income, or disability. Today, the Medicare End-Stage Renal Disease (ESRD) Program costs the federal government $50 billion annually as a mandatory expenditure.

Dialysis is life-extending but not life-transforming, and innovation in dialysis is stagnant. When the commitment to Americans living with kidney failure was made, the federal government also declared "War on Cancer," committing millions of dollars in federal funding to cancer research. Cancer care and kidney care have gone in very different directions since then.

While public investment in advancement lags, private investment in dialysis innovation also faces economic disincentives; and a fixed, fully bundled reimbursement with inadequate mechanisms to incorporate new products inhibits innovation. Programs intended to spur innovation, including the Transitional Drug Add-on Payment Adjustment (TDAPA) and Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) have not succeeded.

The conditions for reimbursement in dialysis care, the “conditions for coverage,” have not been updated in decades, further inhibiting novel technologies and practice patterns. This situation is ripe for reform.

As a result, outcomes are grim for Americans on dialysis. More than one-half of the people who start dialysis are no longer alive five years later, a worse survival rate than many advanced cancers. Even in the best cases, dialysis results in extensive side effects and a poor quality of life.

Even though dialysis should be a bridge to transplant for most people with ESRD, that connection is broken. In fact, during this hearing, on average, one American will die on the kidney transplant waitlist.

Medicare reimbursement and incentives have failed to spur improvements in value-based kidney care. To address “broken incentives” in the traditional fee-for-service environment, the Centers for Medicare & Medicaid Services (CMS) innovation center introduced value-based care (VBC) to kidney care. These VBC models aim to accomplish the twin goals of improving care for Americans living with kidney failure and saving the federal government money. Additionally, the AAKH initiative in 2019 promoted VBC models to incent home dialysis and transplant, improve quality of life, increase survival, and decrease costs.

The mandatory ESRD Treatment Choices (ETC) Model was a laudable endeavor to align incentives to foster better patient care and value. However, multiple factors led to an inability to achieve the desired outcomes, such as increasing home dialysis and transplantation. Dialysis organizations operated across the “experimental” and “control” arms, diluting differences that could occur from initiatives. The model was initiated during the COVID-19 pandemic, when the dialysis industry was most concerned, appropriately, about keeping patients, nephrologists, nurses, and other health professionals safe while also navigating severe staffing shortages. Made possible for the first time by the 21st Century Cures Act in 2021, Medicare Advantage (MA) also removed patients from this model, lessening any effects.

Even though the mandatory model included adjustments for dialysis facilities that served a patient population experiencing challenges to achieving the best outcomes, such as a lack of transportation between their homes and the facility, these challenges were not fully addressed. It is rare for people who start in-center dialysis to switch to home dialysis, and this model was unable to overcome that trend. Key gaps remain in promoting home dialysis, which can improve quality of life and has equally good survival to in-center treatment. This includes poor availability of desired home treatments in non-home settings, such skilled nursing facilities, resulting in an involuntary switch to hemodialysis from home peritoneal dialysis. Policies are needed to start more people on home dialysis and maintain these patients on their chosen home therapy.

The voluntary Kidney Care Choices (KCC) model addressed siloed care by also including Americans living with kidney diseases who are not on dialysis. The voluntary model was successful in increasing home dialysis and transplant from living kidney donors. However, this success was determined to have higher costs, rather than savings.

Initiated less than one year ago, the Increasing Organ Transplant Access (IOTA) model is highly promising. This model addresses gaps in the status quo by incentivizing greater access to transplant; emphasizing transparency for patients, which is a major limitation in the current system; and focusing regulatory attention on a crucial determinant of survival and quality of life for patients that has historically been overlooked because transplant regulation is split between CMS and the Health Resources and Services Administration (HRSA) and should be coordinated through an Office of Kidney Health under the HHS Secretary.

To build on the successes and learn from the shortcomings of these three models to deliver better value for Americans living with kidney diseases and the Medicare program, future models should prioritize intervening earlier to slow or prevent progression to kidney failure and de-siloing dialysis care and transplant care by aligning incentives and commanding greater cooperation. Additionally, future models should emphasize patient choice and individualized care while assessing value in the long-term: savings from home dialysis, transplant, and use of innovative new therapies do not materialize on a quarterly or even annual basis.

Fortunately, potential solutions exist for improving prevention and treatment under Medicare for Americans living with kidney diseases. This is the time to shift the focus from high-cost late-stage crisis management to kidney health through early detection and prevention, patient-centered care, expanding patients' options (such as home dialysis), and maximizing access to transplant.

Accomplishing this ambitious goal requires several immediate steps, including:

1. Calling on the HHS Secretary to establish an Officer of Kidney Health and Transplantation. This individual would coordinate kidney care, research, education, value, and quality across the myriad HHS agencies with a role in kidney health, aligning incentives, reducing duplicative or misaligned efforts, and ensuring a shared strategy for kidney health in the United States.
2. Promoting appropriate screening in populations at risk for kidney diseases and on track for kidney failure.
3. Ensuring patient access to new therapies to manage cardiovascular-kidney-metabolic syndrome.

4. Supporting efforts like the Kidney Health Initiative (KHI). A partnership among the Food and Drug Administration, ASN, and stakeholders in the kidney community, KHI reduces regulatory barriers to innovative therapies at a pre-competitive level. As a result of a KHI project, five drugs have been approved to treat IgA since 2019, transforming care for this rare disease.
5. Recognizing that while KHI helps reduce barriers to approving transformative kidney therapies at FDA, work is needed to ensure that Medicare provides people with kidney diseases access to them.

The current system will remain for the foreseeable future, so bolder interventions are also needed, such as:

1. Modernizing the Medicare ESRD program's bundled payment system to incentivize research, add transformative medications and therapies, increase patient options, and eliminate silos of care.
2. Guaranteeing MA patients have access to, and the ability to maintain, the same continuity of care as Americans in traditional Medicare. MA, including dialysis patients, account for more than one-half of the Medicare population.
3. Ensuring that Americans have access to every possible therapy from in-center dialysis to home dialysis to transplant as early as possible.
4. Improving the environment for in-center dialysis. The Centers for Disease Control and Prevention (CDC) and ASN partnered to establish Nephrologists Transforming Dialysis Safety (NTDS), which has reduced preventable infections in dialysis facilities, used human factors engineering to improve safety, and empowered more effective nursing-physician partnerships.
5. Learning from the kidney care VBC models to improve patient quality and access to their preferred treatment.

Finally, federal research agencies should dramatically increase their investment in kidney research. Last year, ASN and the kidney community produced "Transforming Kidney Health Research." This report makes the case that the federal investment in kidney research should increase from approximately $700 million to $1.8 billion annually. From cancer research in the 1970s, to HIV/AIDS research in the 1980s, to diabetes research in the 1990s, to Alzheimer's research in the 2000s, the federal government has successfully targeted discovery to transform care for Americans with chronic conditions.

By comparison, the federal government has not made a similar investment in kidney research, where only $19 per patient is dedicated to kidney research at the National Institutes of Health (NIH), compared to $423 for cancer research and $2,745 for HIV/AIDS research. Even at $1.8 billion annually, the federal government would be spending less than $50 per patient on kidney research.

On behalf of ASN and the millions of Americans living with kidney diseases, thank you for holding this hearing. Together, we must innovate so that the dialysis facility in five years is unrecognizable because the technology and processes have advanced so far.

Better yet, we must innovate so future patients never have to walk through those doors at all.

In 1972, we took a giant leap for kidney patients. I love that my patients, our Veterans, people with kidney diseases have certain guaranteed treatments, but I want them to have the best care possible. The millions of Americans with kidney diseases are waiting for progress. Let's do our best to provide it to them.

Again, thank you, and I look forward to any questions you may have.

Suzanne Watnick

Suzanne Watnick, MD, FASN
Professor of Medicine, University of Washington
Health Policy Scholar, American Society of Nephrology

Email: swatnick@uw.edu
Cell: 503-329-9820