HEMODIALYSIS IN THE UNITED STATES:

THE ADVANCING AMERICAN KIDNEY HEALTH EXECUTIVE ORDER

HOW THE ADVANCING AMERICAN KIDNEY HEALTH EXECUTIVE ORDER COULD AFFECT DIALYSIS CLINICS, PATIENTS AND KIDNEY CARE PROFESSIONALS

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In the United States, dialysis is a large, profitable and continually growing business. Despite this, patient outcomes in the US fall behind those of other countries. Each year, Medicare spends $114 billion a year on Americans with kidney disease. Nearly **750,000 people in the United States are affected by end-stage renal disease** (ESRD), and that number is expected to increase by 5% each year. In an effort to reduce healthcare costs for ESRD and improve patient outcomes, President Trump signed an executive order revamping kidney care in the U.S. over the next 10 years. This piece will take a deep dive into the order, its proposals and how those proposals could affect clinicians, dialysis clinics and staff and patients.

What's Happening with Kidney Care in the United States

Advancing American Kidney Health

In July 2019, President Donald Trump signed an executive order — Advancing American Kidney Health — designed to "improve the lives of Americans suffering from kidney disease, expand options for American patients, and reduce healthcare costs," according to the **Department of Health and Human Services (HHS).**

The HHS has laid out three goals for improving kidney health in the U.S.:

1. Reduce the number of Americans with end-stage renal disease (ESRD) by 25% by 2025
2. Have 80% of new ESRD patients receiving either home dialysis or kidney transplants by 2025
3. Double the number of kidneys available for transplant by 2030

The Center for Medicare and Medicaid Innovation (CMMI) released four voluntary Comprehensive Kidney Care Contracting (CKCC) payment models and one mandatory payment model at the same time as the executive order. These payment models will provide financial incentives for better management of ESRD patients and improve rates of home dialysis, and kidney or kidney-pancreas transplants. The executive order will use these models to drive the changes it has laid out above.

Medicare-certified Clinics and Home Hemodialysis

According to homedialysis.org, there are 7,564 Medicare-certified dialysis clinics in the U.S. but only 21% are certified to provide home hemodialysis training and support. If selected clinics are not are certified to offer home hemodialysis training and support, an additional time and infrastructure investment might be needed to prepare clinics.

Voluntary CKCC Models

According to CMS, the models will have three distinct accountability frameworks:

CKCC GRADUATED MODEL: This model is based on the existing CEC Model One-Sided Risk Track – allowing certain participants to begin under a lower-reward, one-sided model and incrementally phase in to greater risk and greater potential reward.

CKCC PROFESSIONAL MODEL: This payment arrangement is based on the Professional Population-Based Payment option of the Direct Contracting Model – with an opportunity to earn 50% of shared savings or be liable for 50% of shared losses based on the total cost of care for Part A and B services.

CKCC GLOBAL MODEL: This payment arrangement is based on the Global Population-Based Payment option of the Direct Contracting Model – with risk for 100% of the total cost of care for all Parts A and B services for aligned beneficiaries.

The models are expected to run from January 1, 2020, through December 31, 2023.

Mandatory ESRD Treatment Choices (ETC) Model

The ETC Model notes that managing clinicians and dialysis clinics in certain geographic areas throughout the country that treat 50% of Medicare patients would be randomly selected to participate. Clinics can be excluded if they're in U.S. territories, treat too few patients or treat pediatric patients. Patients can be excluded if they live outside the U.S., are receiving dialysis due to acute kidney injury, have dementia, are under 18 or are in hospice. Patients can't opt out of the ETC Model if they're at a clinic that's been selected, but they can choose whether to receive dialysis from a provider under the model.

The model would extend kidney disease education to nurses, dietitians and social workers. Education would be expanded to Medicare patients with Stage 5 CKD and to Medicare patients who would have received an ESRD diagnosis within the last six months.

How Will Advancing American Kidney Health Affect Patients and Dialysis Clinics?

The Trump administration's executive order has the potential to fundamentally alter the treatment of ESRD patients in the United States. According to Kaiser Health News, 726,000 patients have ESRD in the United States. Of these, about 88% receive treatment in dialysis clinics with the other 12% receiving home dialysis.

The Potential Impact of Home Dialysis

Home hemodialysis has several benefits: It's more convenient, recovery times are faster, treatments can be individualized and the patient's quality of life is better. However, it's not right for everyone, particularly older adults with bad eyesight, poor fine-motor coordination, depression or cognitive impairment. Adults over age 65 make up half of the 125,000 people newly diagnosed with kidney failure each year.

Despite the benefits of home hemodialysis, patient retention remains an issue. The modality often sees discontinuation rates of between 20% to 25% within the first year. This can have a damaging effect on both the dialysis facilities and patients due to the large upfront costs that come with home hemodialysis.

A study in the *American Journal of Kidney Disease* wanted to define the factors associated with the discontinuation of home hemodialysis. Study authors followed 2,840 patients over a three-year period. At the end of the study, 729 patients had discontinued treatment. Researchers found patients who discontinued home hemodialysis were more likely to:

- Have diabetes
- Use tobacco, alcohol or recreational drugs
- Be less likely to be listed for kidney transplantation
- Live in a rural area

Strategies for Patient Retention

Eric Weinhandl, Ph.D., MS; Marienne Sanders, MS; Michael Kraus, MD; Michelle Carver, BSN, RN, CNN, outline these four patient retention strategies found in the most successful home hemodialysis programs.

TRAIN PATIENTS CONSISTENTLY AND WELL: Weinhandl, et al observed: "The risk for technique failure was more than 15% lower in programs training more than two patients per quarter versus in those who seldom or sporadically train." They also found care team members proactively met with the patients and/or partners and clearly outlined the home dialysis process.

GET THE PRESCRIPTION RIGHT FOR EACH PATIENT: Some patients who discontinued therapy did so because their prescription was not adjusted to their needs, or when they do not understand its rationale. As a result, Weinhandl, et al note: "The physician must be transparent in setting expectations for the patient and be responsive and attentive during training."

How are ESRD Patients Treated?

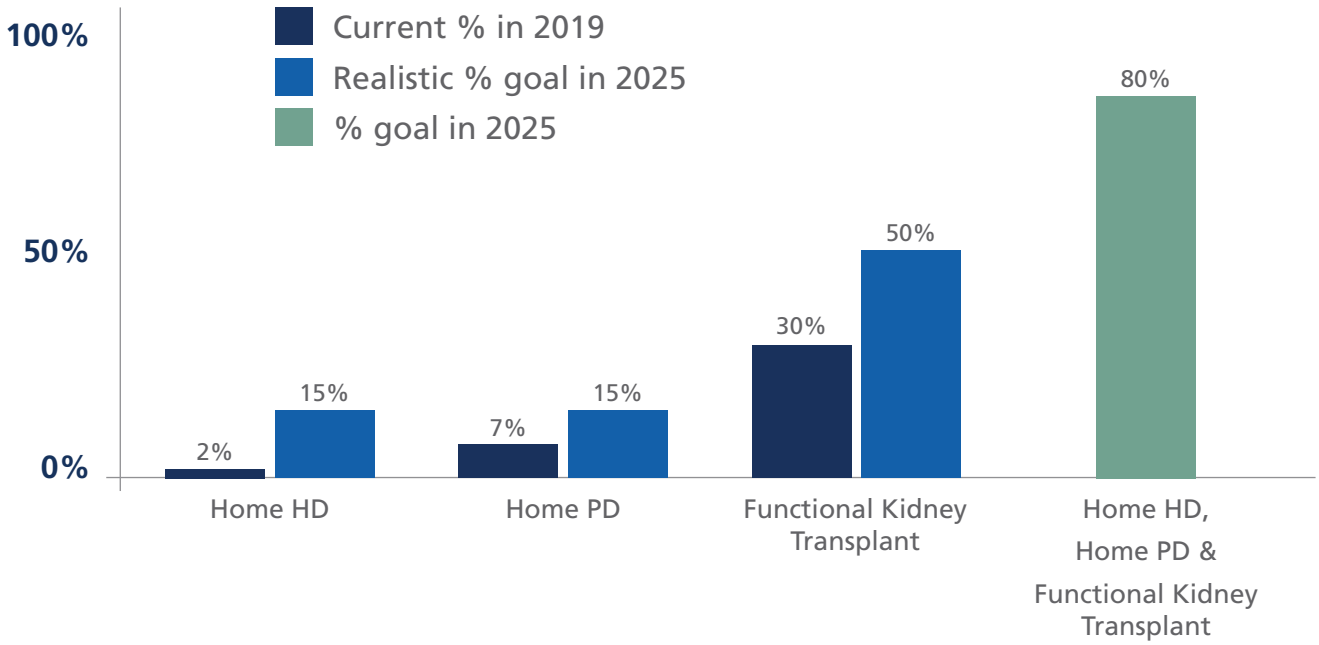
As of December 31, 2016, 63.1% of all prevalent ESRD patients were receiving hemodialysis therapy, 7% were treated with peritoneal dialysis (PD), and 29.6% had a functioning kidney transplant. Among hemodialysis cases, 98% used in-center hemodialysis, and 2% used home hemodialysis.

ENSURE PARTICIPATION OF THE INTERDISCIPLINARY TEAM, PARTICULARLY THE SOCIAL WORKER AND THE PATIENT CARE TECHNICIAN (PCT): In top-performing programs, the home hemodialysis program was not the sole responsibility of the home program nurse, but the responsibility of an integrated care team that included a variety of people including social workers and PCTs. Social workers supported patients throughout their home experience, while PCTs supported the home program nurses.

MONITOR AND GET ACTIVELY INVOLVED WHEN THE PREDICTORS OF PATIENT DISCONTINUATION – HOSPITALIZATION AND MISSED TREATMENTS – PRESENT THEMSELVES: Closely monitoring patients after they go home provides an opportunity to find and address those who are planning to discontinue therapy. Successful programs implemented timely interventions and offered respite care when patients displayed discontinuation triggers.

The administration's goal is for 80% of new ESRD patients to receive home dialysis or kidney transplant by 2025. Here's how much growth would have to occur in home hemodialysis, home PD and functional kidney transplant to make that a reality:

CURRENT % OF HOME HD, HOME PD AND SUCCESSFUL KIDNEY TRANSPLANTS NEED TO DOUBLE IN FIVE YEARS. HOWEVER, MORE REALISTIC GOALS MIGHT BE:



What Could Happen to the Dialysis Clinics?

At the end of 2016, there were 6,871 dialysis facilities in the U.S. treating 493,550 patients, according to the Centers for Disease Control. With Trump's executive order requiring 80% of new ESRD patients to receive either home dialysis or a transplant, it makes sense to wonder what will happen to existing dialysis facilities. As the order takes effect, clinics and staff may experience the following:

- There could be a reduction of new patients for in-center patient stations and staff for coverage.
- There could be a reduction of current patients and census could shift from in-center to home therapies.
- Home hemodialysis therapies training times could cause a bottleneck for new patient training – forcing patients to dialyze in-center until a home training slot opens.
- Teams may be swayed to convince patients to select home PD over home hemodialysis because PD training is quicker, which could increase training capacity.
- The need for respite care may increase and require stations in-center, which could require staff to learn various dialysis systems that the patient can use for their therapy.
- Vascular access care is a critical part of home hemodialysis. As a result, patients could be trained at the in-center stations as they await or decide to go fully into home hemodialysis training including access monitoring and cannulation.

How Could This Order Affect Dialysis Clinic Staff?

If you're employed at a dialysis clinic, you might be wondering how this executive order could affect your employment. Here are some things to consider:

- **For Nephrology Clinical Technicians and Nephrology Biomedical Technologists:** Learn about your specific state's nurse practice acts to understand the roles that might be available in the home therapy programs. Also, learn more about the role of patient education in the in-center facility provided by the Nephrology Clinical Technicians and Nephrology Biomedical Technologists.

- **For Nephrology Nurses:** Home therapies nurses are required to have three months of experience in the specific modality. Learning about opportunities to get more clinical experience with the home therapies will increase your career opportunities.

Here are some considerations of how these facilities could be used:

SELF-CARE CENTERS

Patients who participate in self-care have better outcomes than those who do not. Currently, self-care is included in the proposed new payment models for treatment in-center. The regulations do allow in-center patients to transition to various levels of self-care.

Self-care would not be counted toward the number of home dialysis patients in the new payment model. If it would be included as a variation of home dialysis, then the utilization of current dialysis facilities could provide a location of hemodialysis to any patient that has housing insecurity to dialyze safely.

Self-care is covered in the ESRD Conditions of Coverage V-Tag 582 which states, "A certified dialysis facility approved for outpatient maintenance dialysis services needs no additional certification or approval to provide in-center self-dialysis or to teach an in-center patient to perform all or part of their dialysis treatment (e.g., self-cannulate, monitor blood pressure)." This allows any CMS-certified dialysis facility to provide self-care to meet the level of care that a patient decides to undertake.

OVERNIGHT PD CENTERS

Dialysis facilities could also be used as an overnight PD center for patients to receive IPD via cyclers. This could address housing restriction issues such as space and lack of proper physical environment (such as water/sewer sources, climate control, electrical supplies).

HOME TRAINING CENTERS

The facilities can be converted to home training centers but would require remodeling to comply with the regulations for a home training area. The standard hemodialysis treatment floor is not set up properly to conduct home training – PD or hemodialysis.

Impact on Nephrologists and Transplant Surgeons

Following Trump's executive order, the Centers for Medicare and Medicaid Services (CMS) proposed five new payment models for providers treating patients with chronic kidney disease.

To encourage greater use of home dialysis and kidney transplantation, **CMS is proposing the End-Stage Renal Disease Treatment Choices Model.** This model would adjust certain Medicare payments to facilities and clinicians randomly selected for participation. Payments would be adjusted upward or downward based on a facility or clinician's home dialysis and transplant rates. The model would also risk adjust the home dialysis and transplant rates used for the performance payment adjustments, which would not penalize those providers with sicker patients. The adjustments would begin on January 1, 2020, and end on June 30, 2026.

These models allow the transplant center, dialysis facilities and nephrologists to collaborate and share profit/risk. As a result, the transplant surgeon and transplant nephrologist will need to closely coordinate with the local referring nephrologist post-transplant, and the patients may return earlier to the community nephrologist for post-transplant follow-up. Currently, these relationships are more referral only and not tied to CMS payments as directly as the proposed new models.

Artificial Kidney Development

There were **19,360 kidney transplants in 2018,** according to UNOS. However, there are around **93,000 people on the kidney transplant waitlist,** and 5% of these patients die each year waiting for a kidney.

Part of the Trump administration's rule is to increase kidney donation, which it plans to do by removing financial disincentives for living organ donation.

KIDNEYX

HHS and the American Society of Nephrology have partnered to accelerate the development of drugs, devices, biologics and other therapies across the spectrum of kidney care.

Phase 1 of the project — which announced winners in April 2019 — focused on the development of artificial kidney devices. Each of **the 15 winners of Phase 1** received $75,000 to create their solutions. **Phase 2 of KidneyX,** "challenges participants to build and test prototype solutions, or components of solutions, that can replicate normal kidney functions or improve dialysis access." Three winners will be awarded $500,000. Submissions are due by January 31, 2020.

Conclusion

Advancing American Kidney Health has the potential to shake up kidney disease treatment in the U.S. By staying on top of the latest developments, you can ensure you have the knowledge you need to provide your patients with the best treatment options while protecting your clinics and staff.