

President Trump's Executive Order on Kidney Disease Treatments



In his Health Law column, Francis J. Serbaroli summarizes President Donald Trump's recent Executive Order addressing Medicare payments for kidney disease treatments. This Executive Order, among other things, aims at encouraging significantly more home dialysis as well as the development of wearable or implantable artificial kidneys, and increasing the availability of human kidneys available for transplant. When fully implemented, this Executive Order could result in major improvements in kidney disease treatment outcomes and reduced costs to the Medicare program.

By Francis J. Serbaroli | July 22, 2019 | New York Law Journal

When the Medicare program came into existence in 1965, it covered many medical services and procedures for those over the age of 65. Treatments for chronic renal disease for those under the age of 65 were not covered. It wasn't until 1972 that Congress enacted and President Richard Nixon signed into law the so-called Kidney Disease Entitlement (Public Law 92-603). This law extended Medicare coverage by classifying as "disabled" anyone under the age of 65, enrolled in the Social Security program, or the spouse or

dependent child of the enrollee, “who is medically determined to have chronic renal disease and who requires hemodialysis or renal transplantation.” The law created a three-month waiting period before Medicare would pay for dialysis treatment, and limited payment for dialysis to 12 months after the month in which the patient had a kidney transplant, or dialysis was terminated.

It is generally accepted that Congress and the Nixon administration significantly under-estimated what the Kidney Disease Entitlement would eventually cost. Due to a variety of factors, including the dramatic growth in the incidence of obesity, high blood pressure, and diabetes in the American population, approximately 37 million Americans have chronic kidney disease, and more than 726,000 have end stage renal disease (ESRD), i.e., they need dialysis or a kidney transplant to survive. In 2016, Medicare costs for covered individuals with chronic kidney disease were \$114 billion (20% of total traditional Medicare expenditures), of which \$35 billion was spent to care for ESRD patients and \$79 billion for those with chronic kidney disease without kidney failure.

The clinical statistics are of even more concern. According to the U.S. Department of Health and Human Services (HHS):

- In 2017, kidney disease was the ninth leading cause of death in the United States;
- There are nearly 100,000 people awaiting the availability of a kidney for transplant;
- More than 100,000 people begin dialysis to treat ESRD each year; and
- One in five of people beginning dialysis treatment will die within a year.

Executive Order

On July 10, 2019, President Donald Trump signed an Executive Order intended to improve treatment options and bring down the costs of treating kidney disease. Executive Office of the President, [Executive Order an Advancing American Kidney Health](#), July 10, 2019. The Executive Order begins by reciting the problems with how kidney disease is currently handled:

The state of care for patients with chronic kidney disease and [ESRD] is unacceptable: too many at-risk patients progress to late-stage kidney failure; the mortality rate is too high; current treatment options are expensive and do not produce an acceptable quality of life; and there are not enough kidneys donated to meet the current demand for transplants.

It goes on to declare that it is the policy of the United States to:

- Prevent kidney failure whenever possible through better diagnosis, treatment and initiatives for preventive care;
- Increase patient choice through affordable alternative treatments for ESRD by encouraging higher value care, educating patients on treatment alternatives, and encouraging the development of artificial kidneys; and
- Increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.

The Executive Order directs the HHS Secretary to take specific actions within a fairly aggressive timetable. Within 30 days, the Secretary is directed to “select a payment model to test innovations in compensation

for providers of kidney care services based on kidney patient costs and quality outcomes.” The Order directs that the payment model broaden the range of care and Medicare payment options available with a focus on delaying or preventing the onset of kidney failure and preventing unnecessary hospitalizations, and increasing the rate of kidney transplants. The payment model should create incentives to provide care for Medicare patients who have advanced kidney disease but are not yet on dialysis, and options for flexible advance payments to nephrologists “to better support this management and coordination of care for patients with kidney disease.”

The Order directs the Secretary, within 30 days, to select a payment model to evaluate the effects of creating payment incentives for the greater use of home dialysis and kidney transplants for those already on dialysis. The payment model is to adjust payments based on the percentage of a participating provider’s patients who are on home dialysis or have received a kidney transplant. The payment model should also include a learning system to help participants improve performance with the goal of improving the quality of life and patient care through greater utilization of home dialysis and transplants, and possibly eliminating the need for dialysis for some patients.

The Order directs the Secretary, within 90 days, to propose a regulation to revise Organ Procurement Organization (OPO) rules and evaluation metrics to establish “more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance” with the objective of enhancing the procurement and use of more transplantable kidneys. Within 90 days, the Secretary is also directed to propose a regulation to remove financial barriers to kidney donations by living donors. This includes expanding the allowable costs that can be reimbursed to living donors, raising the limit on the income of donors eligible for reimbursement for allowable costs, allowing reimbursement for the lost wage expenses of living donors, and providing reimbursement for their child care or elder care expenses.

The Order directs the Secretary, within 120 days, to launch an “awareness initiative” to educate patients and support programs that promote kidney disease awareness. This initiative also is to develop proposals for HHS to support research regarding preventing, treating and slowing the progression of kidney disease, improve the rate of kidney transplantation, and share information to enhance patients’ and providers’ awareness of the causes and consequences of kidney disease.

Artificial Kidney

In order to provide kidney disease patients with better options for care, the Order directs the Secretary, within 120 days, to:

- a) announce that HHS will consider requests for pre-market approval of wearable or implantable artificial kidneys to encourage the development of these devices, and enhance cooperation between their developers and the Food & Drug Administration; and
- b) produce a strategy for encouraging innovation in new therapies through the Kidney Innovation Accelerator (KidneyX), which is a public-private partnership between HHS and the American Society of Nephrology.

Lastly, the Order directs the Secretary, within 180 days, to “streamline and expedite” the process of matching kidney donors to potential recipients, as well as the delivery of donated kidneys in order to reduce the current organ discard rate. The Order explains:

Removing process inefficiencies in matching and delivery that result in delayed acceptance by transplant centers will reduce the detrimental effects on organ quality of prolonged time with reduced or cut-off blood supply.

In a press release issued on the same day as the Executive Order, HHS set forth three goals for improving kidney patients' health:

1. Reducing the number of those developing ESRD by 25% by 2030;
2. Having 80% of new ESRD patients in 2025 either receiving dialysis at home or receiving a transplant; and
3. Doubling the number of kidneys available for transplant by 2030.

HHS also announced that its Center for Medicare and Medicaid Innovation (CMMI) has developed a required payment model known as ESRD Treatment Choices, which will enroll all dialysis providers in approximately half of the nation and provide them with new incentives to encourage home dialysis. CMMI also released a set of four optional payment models that it expects will result in the enrollment of some 200,000 Medicare patients in payment arrangements that will offer providers new incentives for preventing kidney disease and managing kidney patients' health in "a more comprehensive and person-centered way." HHS's press release states that all five of these new payment models will also give providers new incentives to help eligible patients receive kidney transplants. [HHS Launches President Trump's 'Advancing American Kidney Health' Initiative](#), July 10, 2019.

Analysis

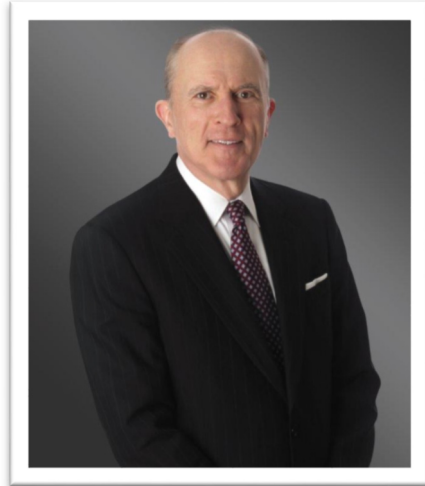
If all of the steps outlined in this Executive Order are implemented, it will result in significant clinical, financial, operational, as well as legal and regulatory changes to the current models of kidney disease treatment. The Order's emphasis on more home dialysis and the potential development of a wearable or implantable kidney is intended not only to improve patient care and outcomes, but to contain and reduce the Medicare program's growing expenditures for long-term dialysis treatment in outpatient dialysis centers.

This Executive Order has the potential to bring about the biggest changes in how kidney disease treatment is provided and paid for since the enactment of the Kidney Disease Entitlement 47 years ago. All stakeholders in this space—including dialysis providers, nephrologists, payors, researchers, device manufacturers, state regulators, and most importantly patients—should closely track developments during its implementation.

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