

December 5, 2019

*DHSR received via email 12/5/19*

Ms. Nadine Pfeiffer  
Rule Review Manager

And,

Ms. Martha Frisone, Chief  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
809 Ruggles Drive  
Raleigh, North Carolina 27603

Re: Proposed Change to 10A NCAC 14C .2203 Performance Standards

Dear Ms. Pfeiffer and Ms. Frisone:

The following comments are offered on behalf of all Fresenius Medical Care related dialysis facilities operating in North Carolina.

We strongly oppose this reduction in the required performance standards. In fact, we would recommend an increase to the performance standard from 80% to 85%.

The 80% performance standard has been in use for many years. Providers and the CON Agency have successfully and comfortably relied upon the current 80% utilization standard for many years. Lowering the performance standard will lead to surplus and unnecessary duplication of dialysis stations.

- A review of the proposed 2020 SMFP indicates that 60 of the 100 counties in North Carolina already have a surplus of dialysis stations.
- Look back at the January 2014 SDR. This SDR reports that 50 North Carolina counties had a surplus of dialysis stations.
- Compare this to the January 2004 SDR. At that point the SDR reported only 38 North Carolina Counties with a surplus of stations.
- As you consider these numbers, keep in mind that only 87 of the 100 counties in North Carolina have existing or approved dialysis stations. Thus, 68.97% of our counties have a surplus of stations.

- And this surplus is further compounded when you consider that the Proposed 2020 SMFP indicates 110 dialysis facilities across the state could apply for up to 885 new dialysis stations. Most of these are in counties with surplus inventories already.

On July 10th of this year, President Trump Issued an Executive Order on Advancing American Kidney Health. One part of this Order very clearly favors increasing home dialysis care, and less reliance upon the more traditional model of in-center care.

FMC has already experienced growth in the home patient population; we are seeing more patients admitted to home dialysis, and fewer patients referred for in-center dialysis. The CON Agency will see the first reports confirming this shift in February 2020 as the 2019 year end ESRD Data Collection Forms are submitted.

Obviously I can't speak for other providers, except to say they must deal with the same Executive Order and the must realize the same emphasis by CMS for more patients to dialyze at home.

In our State Health Planning process, home patients are expressly excluded from station need determinations. With more patients doing home dialysis, there is going to be less need for new dialysis stations. Couple this paradigm shift – more patients dialyzing at home – with the station surplus that already exists in 60 counties. There is no compelling reason to reduce the utilization standard from 80% to 70%. Such a reduction will only serve to exacerbate the increasing surplus of dialysis stations.

CON applicants have always had opportunity to prove their station needs. Applicants have only had to demonstrate their methodology was reasonable, and then demonstrate conformity with the performance standards.

In my 15+ years of preparing CON applications for new dialysis stations, less than 1% of our applications have been denied for failure to meet the 80% utilization threshold. That is less than five applications, over a greater than 15 year period. Less than five in 500 applications have been denied for failure to meet the required 80% utilization standard.

And this has been because the 80% number is achievable.

I applaud the CON Agency for reviewing the standards and considering ways in which to enhance access to care for patients in need. But today, we don't have a serious deficit of stations in any county, except of course those 13 counties where a dialysis facility does not currently exist. It is unfortunate, but a facility does not exist in these 13 counties because of the nature of our planning process – not because of the performance standard.

Respectfully, we strongly oppose the lowering of the performance standard.

If you have any questions please contact me at 910-568-3041, or email [jim.swann@fmc-na.com](mailto:jim.swann@fmc-na.com).

Sincerely,

*Jim Swann, via email*

Jim Swann  
Director of Operations, Certificate of Need

Attachment: Copy of Executive Order on Advancing American Kidney Health



## EXECUTIVE ORDERS

# Executive Order on Advancing American Kidney Health

## HEALTHCARE

Issued on: July 10, 2019



By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Purpose. My Administration is dedicated to advancing American kidney health. The state of care for patients with chronic kidney disease and end-stage renal disease (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.

Kidney disease was the ninth-leading cause of death in the United States in 2017. Approximately 37 million Americans have chronic kidney disease and more than 726,000 have ESRD. More than 100,000 Americans begin dialysis each year to treat ESRD. Twenty percent die within a year; fifty percent die within 5 years. Currently, nearly 100,000 Americans are on the waiting list to receive a kidney transplant.

Sec. 2. Policy. It is the policy of the United States to:

(a) prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care;

(b) 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

(c) increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.

Sec. 3. Announcing an Awareness Initiative on Kidney and Related Diseases. Within 120 days of the date of this order, the Secretary of Health and Human Services (Secretary) shall launch an awareness initiative at the Department of Health and Human Services (Department) to aid the Secretary's efforts to educate patients and support programs that promote kidney disease awareness. The initiative shall develop proposals for the Secretary to support research regarding preventing, treating, and slowing progression of kidney disease; to improve kidney transplantation; and to share information with patients and providers to enhance awareness of the causes and consequences of kidney disease.

Sec. 4. Payment Model to Identify and Treat At-Risk Populations Earlier in Disease Development. Within 30 days of the date of this order, the Secretary shall select a payment model to test innovations in compensation for providers of kidney care services based on kidney patient cost and quality outcomes. The model should broaden the range of care and Medicare payment options available to potential participants with a focus on delaying or preventing the onset of kidney failure, preventing unnecessary hospitalizations, and increasing the rate of transplants. It should aim at achieving these outcomes by creating incentives to provide care for Medicare beneficiaries who have advanced stages of kidney disease but who are not yet on dialysis. The selected model shall include options for flexible advance payments for nephrologists to better support their management and coordination of care for patients with kidney disease.

Sec. 5. Payment Model to Increase Home Dialysis and Kidney Transplants. Within 30 days of the date of this order, the Secretary shall select a payment model to evaluate the effects of creating payment incentives for greater use of home dialysis and kidney transplants for Medicare beneficiaries on dialysis. The model should adjust payments based on the percentage of a participating provider's attributed patients who either are on home dialysis or have received a kidney transplant and should include a learning system to help participants improve performance. Greater rates of home dialysis and transplantation will improve quality of life and care for patients who require dialysis and may eliminate the need for dialysis altogether for many patients.

Sec. 6. Encouraging the Development of an Artificial Kidney. Within 120 days of the date of this order, in order to increase breakthrough technologies to provide patients suffering from kidney disease with better options for care than those that are currently available, the Secretary shall:

(a) announce that the Department will consider requests for premarket approval of wearable or implantable artificial kidneys in order to encourage their development and to enhance cooperation between developers and the Food and Drug Administration; and

(b) produce a strategy for encouraging innovation in new therapies through the Kidney Innovation Accelerator (KidneyX), a public-private partnership between the Department and the American Society of Nephrology.

Sec. 7. Increasing Utilization of Available

Organs. (a) Within 90 days of the date of this order, the Secretary shall propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO's performance.

(b) Within 180 days of the date of this order, the Secretary shall streamline and expedite the process of kidney matching and delivery to reduce the discard rate. 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.

Sec. 8. Supporting Living Organ Donors. Within 90 days of the date of this order, the Secretary shall propose a regulation to remove financial barriers to living organ donation. The regulation should expand the definition of allowable costs that can be reimbursed under the Reimbursement of Travel and Subsistence Expenses Incurred Toward Living Organ Donation program, raise the limit on the income of donors eligible for reimbursement under the program, allow reimbursement for lost-wage expenses, and provide for reimbursement of child-care and elder-care expenses.

Sec. 9. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP

THE WHITE HOUSE,  
July 10, 2019.