
March 18, 2019

Ms. Elizabeth Brown, Planner
Dr. Amy Craddock, Assistant Chief
Ms. Martha Frisone, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Wake Forest Baptist Health – ESRD Petition for a Home Hemodialysis
Methodology

Ms. Brown, Dr. Craddock and Ms. Frisone:

The following comments are submitted on behalf of the Fresenius Medical Care related dialysis facilities in North Carolina.

The suggested methodology is overly restrictive and fails to recognize the “new normal” for dialysis patients. More and more, patients are choosing home dialysis and especially home hemodialysis. This is in line with President Trump’s Executive Order on Advancing American Kidney Health¹.

The Petition is internally inconsistent. The Petitioner’s methodology seems to suggest that a single dedicated station could provide training for 12 patients per year (Condition 2 b. iv.). However, the petitioner goes on to say in the table on page 4 of the petition, “3 Days Per Week Per Patient for 8.3 Weeks). This infers that the station could only provide training for eight patients on an annual basis. Thus, the petitioner has recommended an inconsistent methodology which does not allow the DHSR Staff an opportunity to conduct an accurate analysis of the petition.

Further, the proposed methodology assumes the same number of training days for all patients. Home hemodialysis patient training can continue for up to 25 patient training days. However, in our corporate experience most patients do not train for five consecutive days, over a five week period. Our training model generally plans for the patient to train four days per week, which therefore would extend training to at least six weeks, plus one day into the seventh week. Our experience across North Carolina is therefore limited to a training capacity of approximately eight patients per year. We believe that 300 training days in the year is not an appropriate number.

¹ Attachment 1.

Fresenius Medical Care has filed CON applications seeking to develop additional dialysis stations which would be utilized for home hemodialysis training and support. In fact, this has been the only way in which stations for home hemodialysis have been developed. The in-center facility applies for additional stations as it can demonstrate the need, and then the in-center facility utilizes these stations for home hemodialysis training and support services. This has long been the successful practice by North Carolina dialysis facilities offering home hemodialysis.

The petitioner’s logic is faulty. Within its discussion of a recommended new performance standard for home hemodialysis stations, the petitioner says in paragraph (g), “**Only those new patients**” should be included in utilization projections. The petitioner fails to account for patients who may begin training but not complete the training. These patients utilize the dialysis stations much the same as those patients who complete the training and go home to dialysis.

Fresenius CON applications have documented that not every patient who begins training will complete the training and return home for dialysis. Training and support for home hemodialysis involves more than just the patient population which completes the training. There are also a significant number of patients who begin the journey for home hemodialysis and ultimately determine that another modality (PD, or in-center) is more appropriate, or, leave home hemodialysis for other reasons such as transplant or death.

This has been documented this in several Fresenius related CON applications:

CON Project ID #	Facility
F-11637-19	INS Charlotte
F-11638-19	INS Huntersville
E-11648-19	FMC Hickory Home Program
L-11838-20	Edgecombe Home Dialysis*
P-11840-20	FMC Sea Spray*

*Still under review

Each of these applications documents that not every patient who begins the journey to home hemodialysis will be able complete the home training. The Agency must consider **all** utilization of a dialysis station before concluding that only new patients should be considered.

The Petitioner offers comment with regard to adverse effects if change are not made. Paragraph a. ii. addresses Quality, Safety and Access. The petition suggests that the Agency cannot measure the quality, safety and access specific to the service requested. This is absurd. Every CON applicant must address quality, safety and access to care within the CON application. These aspects are already considered within each CON application review.

In paragraph a.iii. the Petitioner suggests that the overall cost of providing care is passed on to the patient. This may be true of the Wake Forest Baptist Health CON projects, but this is not true in the case of Fresenius related CON applications.

Within the discussion of alternatives, the petitioner indicates in paragraph b.i. that *maintaining the status quo would result in an unfair advantage for providers proposing home hemodialysis in home-training-only facilities*. The 2020 SMFP Table 9B reports 255 operational or CON approved dialysis facilities in North Carolina. A review of this table reveals that it does not include the free standing home dialysis facilities. There are six existing home training facilities, as indicated in the table below:

County	Home Training Facility
Buncombe	Biltmore Home Training
Catawba	FMC Hickory Home Program
Edgecombe	Edgecombe Home Dialysis
Iredell	INS Statesville
Mecklenburg	INS Charlotte
Mecklenburg	INS Huntersville

Of the above noted facilities, only three currently are certified for home hemodialysis training and support services. In addition, the Edgecombe Home Dialysis facility also has filed a CON application to relocate one dialysis station to the facility to be used for home hemodialysis training and support services.

In the interest of total transparency, Fresenius related entities have also recently filed CON applications to develop four additional free standing home PD facilities:

County	Peritoneal Dialysis Training Facility
Chowan	Chowan Home Dialysis
Cleveland	INS Cleveland County
Hertford	Hertford Home Dialysis
Wilson	Wilson Home Dialysis

Thus, there are 265 dialysis facilities, as summarized in the following table:

Summary of NC Dialysis Facilities	
Identified in the SMFP Table 9B	255
Free standing PD only facilities	3
Free standing with PD and home hemodialysis	3
PD only facilities pending CON review	4
Total	265

The petitioner suggests that three facilities of 265 facilities would have an unfair advantage. This is an unrealistic characterization. Any of the above facilities must pass the CON application review, and demonstrate conformity with each of the CON review criteria. There is absolutely no unfair advantage afforded to any provider.

Further, nothing has stopped Wake Forest Baptist Health from filing a CON application to develop a free standing home training dialysis facility. The Petitioner has the exact same opportunities as other providers in North Carolina. The choices of the Petitioner should not be used to dictate the way in which other providers seek to provide dialysis care.

We absolutely disagree with the Petitioners comments on page 5, in response to 5. a. Safety and Quality. The petitioner suggests the “limitation of services to only those needed also prevents the rapid rise in services that may be unsafe or of lesser quality.”

We are not familiar with the manner in which the Petitioner might provide home training. However, despite the suggestion by the Petitioner, quality of care and patient safety are not negotiable within Fresenius related facilities. Care of the patient is always the first consideration.

We must assume that the Wake Forest Baptist Health facilities are providing care at the minimum levels as established by CMS. Otherwise, these facilities could not pass survey. The CMS survey is the tool used to measure dialysis facility performance with regard to quality of care.

The reality today is that there is a national emphasis on improving access to home dialysis. Limiting home dialysis in a manner as prescribed by the Petitioner is absolutely the wrong direction for the SHCC and CON Agency to move.

We have briefly touched on the President’s Executive Order on Advancing American Kidney Health. A new day has dawned for dialysis patients and patients suffering with chronic kidney disease. The paradigm for dialysis treatment is being turned upside down. More and more patients are being referred for home dialysis versus the traditional in-center model for dialysis patient treatment.

The President’s Executive Order mandated that Secretary of Health and Human Services shall launch an awareness initiative at the Department of Health and Human Services to aid the Secretary’s efforts to educate patients and support programs that promote kidney disease awareness.

HHS Secretary Azar included the following comment in a statement released in response to the Executive Order²:

“Most Americans who suffer from kidney disease don’t even know it. To raise awareness and provide them with opportunities to improve their health, we look forward to working with nephrologists, other healthcare providers, patients, payors, innovators, and public health professionals inside and outside of government. This is just one step in the President’s kidney initiative, the first major effort by a President to improve kidney health since Medicare began covering end-stage renal disease patients in 1972.”

² Attachment 2: <https://www.hhs.gov/about/news/2019/11/04/hhs-secretary-azar-statement-step-forward-president-trump-s-kidney-health-initiative.html>

On November 4, 2019, the National Kidney Foundation (NKF) and American Society of Nephrology announced a new partnership with the Department of Health and Human Services to collaborate on the Public Awareness initiative outlined in the President's Order. Let me share with you some information from the announcement³:

“One-third, or 33%, of the American public is at risk for developing kidney disease due to factors such as **diabetes, high blood pressure, cardiovascular disease, obesity** and family history of kidney disease.”

“Most Americans who suffer from kidney disease don't even know it.”

“In the United States approximately 37,000,000 adults have **kidney disease** – and most aren't aware of it. One in three American adults are at risk for kidney disease. Risk factors for kidney disease include diabetes, high blood pressure, heart disease, obesity and family history. People of African American, Hispanic, Native American, Asian or Pacific Islander descent are at increased risk for developing the disease. African Americans are three times more likely than whites, and Hispanics are nearly 1.5 times more likely than non-Hispanics, to develop end stage renal disease kidney failure.”

“More than 726,000 Americans have **irreversible kidney failure** and need dialysis or a kidney transplant to survive. More than 100,000 Americans begin dialysis each year. Approximately one in five Americans who start dialysis will die within one year, and more than one-half within five years. Nearly 100,000 Americans are on the waitlist for a kidney transplant right now. Depending on where a patient lives, the average wait time for a kidney transplant can be three to seven years. In 2016, Medicare spent approximately \$114 billion to cover people with kidney disease, representing more than one in five dollars spent by the traditional Medicare program.”

Dialysis patients are already facing a multitude of issues. Dialysis patients who do not dialyze at home must necessarily travel to a dialysis facility for three weekly dialysis treatments. Approval of the Petition by Wake Forest Baptist Health will not do anything to relieve the dialysis patient burden associated with dialysis treatment. Rather, it would create barriers to access for home dialysis.

- Home dialysis relieves the patient of the burden of travel to and from dialysis.
- Home dialysis allows the patient to schedule their treatment at times which are most convenient for the patient.

³ Attachment 3: <https://www.kidney.org/news/aakh-announced-public-private-partnership-nkf-asn>

- Home dialysis enhances the patient quality of life by allowing the patient more control over the dialysis treatment.

Approval of this petition is inconsistent with the President's Executive Order. It will impede access to home dialysis training. It perpetuates a system which is focused on the patient continuing to travel to the facility for dialysis treatment.

We strongly recommend denial of this petition.

Respectfully,



Jim Swann
Director, Certificate of Need

3 Attachments:

- 1) President Trump's Executive Order on Advancing American Kidney Health
- 2) HHS Secretary Azar Statement
- 3) NKF, Public Awareness Initiative Announcement

Attachment 1



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.

Attachment 2

Visit [CDC.gov](https://www.cdc.gov) for Coronavirus Disease 2019 (COVID-19) Updates

HHS.gov

U.S. Department of Health & Human Services

FOR IMMEDIATE RELEASE

November 4, 2019

Contact: HHS Press Office

202-690-6343

media@hhs.gov

HHS Secretary Azar Statement on Step Forward in President Trump's Kidney Health Initiative

This week, the Department of Health and Human Services, the American Society of Nephrology, and the National Kidney Foundation signed a memorandum of understanding to create an education, awareness, and prevention campaign regarding kidney disease, as called for in President Trump's [Executive Order on Advancing American Kidney Health](#). The campaign will aim to improve health and prevent worsening outcomes for the more than 30 million Americans with chronic kidney disease.

HHS Secretary Azar released the following statement:

"Most Americans who suffer from kidney disease don't even know it. To raise awareness and provide them with opportunities to improve their health, we look forward to working with nephrologists, other healthcare providers, patients, payors, innovators, and public health professionals inside and outside of government. This is just one step in the President's kidney initiative, the first major effort by a President to improve kidney health since Medicare began covering end-stage renal disease patients in 1972.

Alongside this important public health work, HHS will reform payments and regulations so that fewer Americans suffer kidney failure, more options are available for dialysis patients, and more organs are available for transplant. Together, these efforts will transform how we care for kidney disease in America—and improve the lives of millions of Americans suffering from it."

For more about the Advancing American Kidney Health initiative, see: <https://aspe.hhs.gov/pdf-report/advancing-american-kidney-health>

To read the announcement from the National Kidney Foundation, see: <https://www.kidney.org/news/aakh-announced-public-private-partnership-nkf-asn>

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Note: All HHS press releases, fact sheets and other news materials are available at <https://www.hhs.gov/news>.

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Last revised: November 4, 2019

Attachment 3

Public Awareness Initiative for AAKH Announced as a Public-Private Partnership with NKF and ASN



Goals are to enhance awareness of kidney disease, educate clinical professionals and spur innovation by entities serving the kidney disease community.

Washington, D.C. – November 4, 2019 – Today the National Kidney Foundation (NKF) and American Society of Nephrology (ASN) announced a new partnership with the U.S.

Department of Health and Human Services (HHS) to collaborate on the Public Awareness Initiative outlined in the **Executive Order on Advancing American Kidney Health**, an historic action initiative to transform kidney health. The goals of the Public Awareness Initiative are to enhance awareness of kidney disease, educate clinical professionals and spur innovation by entities serving the kidney community.

This collaborative partnership among HHS, NKF and ASN will provide education about the risks of kidney disease and promote the early detection, treatment and management of kidney disease to improve patient outcomes. This initiative will also share information to enhance awareness of the causes and consequences of kidney disease. NKF is the largest patient organization dedicated to the awareness, prevention and treatment of kidney disease, and ASN is the largest kidney health professional organization leading the fight to prevent, treat, and cure kidney diseases.

“One-third, or 33%, of the American public is at risk for developing kidney disease due to factors such as **diabetes, high blood pressure, cardiovascular disease, obesity and family history of kidney disease**. It is critical to reach the undiagnosed so that, wherever possible, kidney disease can be stopped dead in its tracks before a patient progresses to kidney failure,” said Kevin Longino, CEO of National Kidney Foundation and a kidney transplant patient. “Reaching an estimated 80 million Americans at risk requires a broadscale effort and we are very pleased to partner with HHS and ASN on the Public Awareness Initiative, which will include a nationwide Kidney Risk Campaign™ over the coming months.”

“Aligning the reach and resources of ASN, NKF and HHS is a vital first step to realize the bold vision articulated in this initiative by addressing both awareness and action,” said Mark E. Rosenberg, MD, FASN, ASN President. “I am confident that through our combined efforts, we will raise the profile of kidney disease as a public health crisis, while simultaneously mobilizing the global community of patients, nephrologists, health professionals, innovators, and investors to rapidly advance innovative new approaches to prevent, diagnose, and treat kidney disease.”

“Most Americans who suffer from kidney disease don’t even know it. To raise awareness and provide them with opportunities to improve their health, we look forward to working with nephrologists, other healthcare providers, patients, payors, innovators, and public health professionals inside and outside of government,” said HHS Secretary Alex Azar. “This partnership is an early step in President Trump’s kidney initiative, the first major effort by a President to improve kidney health since Medicare began covering end-stage renal disease patients in 1972. Alongside this important public health work, HHS will reform payments and regulations so that fewer Americans suffer kidney failure, more options are available for dialysis patients, and more organs are available for transplant. Together, these efforts will transform how we care for kidney disease in America—and improve the lives of millions of Americans suffering from it.”

About Kidney Disease

In the United States approximately 37,000,000 adults have **kidney disease** – and most aren’t aware of it. One in three American adults are at risk for kidney disease. Risk factors for kidney disease include diabetes, high blood pressure, heart disease, obesity and family history. People of African American, Hispanic, Native American, Asian or Pacific Islander descent are at increased risk for developing the disease. African Americans are three times more likely than whites, and Hispanics are nearly 1.5 times more likely than non-Hispanics, to develop end stage renal disease kidney failure.

More than 726,000 Americans have **irreversible kidney failure** and need dialysis or a kidney transplant to survive. More than 100,000 Americans begin dialysis each year. Approximately one in five Americans who start dialysis will die within one year, and more than one-half within five years. Nearly 100,000 Americans are on the waitlist for a kidney transplant right now. Depending on where a patient lives, the average wait time for a kidney transplant can be three to seven years. In 2016, Medicare spent approximately \$114 billion to cover people with kidney disease, representing more than one in five dollars spent by the traditional Medicare program. Learn more about kidney disease and how **HHS is advancing kidney health**.

About National Kidney Foundation

The National Kidney Foundation (NKF) is the largest, most comprehensive, and longstanding patient-centric organization dedicated to the awareness, prevention, and treatment of kidney disease in the U.S. For more information about NKF visit: www.kidney.org.

About American Society of Nephrology

Since 1966, **ASN** has been leading the fight to prevent, treat, and cure kidney diseases throughout the world by educating health professionals and scientists, advancing research and innovation, communicating new knowledge, and advocating for the highest quality care for patients. ASN has more than 20,000 members representing 131 countries. For more information, please visit www.asn-online.org or contact the society at 202-640-4660.

Read the HHS release [here](#).

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