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Petition to Change the Assumptions of the Need Methodology in Chapter 9 of the 2024 SMFP

March 1, 2023

North Carolina Division of Health Service Regulation
Healthcare Planning
809 Ruggles Drive
Raleigh, North Carolina 27603
Via email: DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

PETITIONER

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STATEMENT OF REQUESTED CHANGE

Fresenius Medical Care Holdings, Inc., (parent company of the Fresenius Medical Care related entities[1]) d/b/a Bio-Medical Applications, Inc. (BMA) respectfully submits this petition to the State Health Coordinating Council (SHCC) to change the need methodology in Chapter 9 of the 2024 State Medical Facilities Plan (2024 SMFP). The proposed changes are requested to resolve

[1] Bio-Medical Applications of North Carolina, Inc., Bio-Medical Applications of Fayetteville, Inc., Bio-Medical Applications of Clinton, Renal Care Group of the South, Inc., RAI Care Centers of North Carolina II, LLC and several joint venture operations in North Carolina: Carolina Dialysis, LLC, FMS ENA Home, LLC, Fresenius Medical Care of Lillington, LLC, Independent Nephrology Services, Inc., Fresenius Medical Care of Morrisville, LLC, Fresenius Medical Care of Rock Quarry, LLC, and Fresenius Medical Care of White Oak, LLC.

ambiguity that resulted from changes in the 2022 SMFP, and to provide clarity on the development of new dialysis stations at home training facilities, which is not yet addressed in Chapter 9.

The term "home training facility" was first defined in the 2022 SMFP. A home training facility is an ESRD facility dedicated exclusively to the training of hemodialysis or peritoneal dialysis patients to dialyze at home or at a location other than a kidney disease treatment center that provides in-center dialysis, as defined by in G.S. §131E-176(14e). A "home patient" receives hemodialysis or peritoneal dialysis in the patient's home, except for training that is provided in an ESRD facility.

ASSUMPTIONS OF THE METHODOLOGY

Home patients and dialysis stations in home training facilities are excluded from both the county need and facility need methodologies for dialysis stations. Chapter 9 of the 2023 SMFP identifies the assumptions of the methodology for dialysis stations as follows (emphasis added):

1. ***Home patients are not included in the determination of need for new stations****.* *Home patients include those that receive hemodialysis or peritoneal dialysis in their home.*

2. *In-center facilities may have been approved to use at least one dialysis station for dedicated training of home dialysis patients. If so, these stations are included in the planning inventory.*

3. *The county and facility need methodologies assume that 100% utilization is four patients per station per week. The utilization rate is calculated by dividing the number of in-center patients reported in December of each year by the number of certified stations and then dividing the result by four.*

4. *Under the facility need methodology, any facility at 75% utilization or greater as of the current reporting date may apply to add dialysis stations.*

5. *Facilities that are eligible to add stations based on the facility need methodology may add the number of stations calculated by the methodology, up to a maximum of 20 stations in a single calendar year.*

6. *Facilities certified and in operation at least nine but fewer than 21 months do not have a need determination in the SMFP. Rather, they may apply to add stations based on Condition 1 in the Facility Need Methodology.*

7. *Facilities that meet both the definition of "small" under Condition 1.a in the Facility Need Determination Methodology and have been in operation for at least 21 months*

may apply for additional stations either under Condition 1.b. or 2. "Small" facilities may not apply under both Condition 1.b and Condition 2 in the same year.

8. *When a CON application has been received to relocate stations to a home training facility, the stations to be relocated are included in both the county and facility need determination calculations.* ***When the home training stations are certified, then they are excluded from both the county and facility need determination calculations.***

9. *The methodology uses patient origin data aggregated to the county level. . ."*

As described above, county and facility need determinations are based on the number of in-center patients divided by the number of certified stations. Home patients and home training stations are not included in the county and facility need determination calculations at all.

Because home patients and stations at home training facilities are not included in the need determination calculations, **the patient population reflected in a county need determination is, by definition, in-center patients only. A need determination does not reflect the need or lack of need for stations in home training facilities**. There is no need methodology or need determination in the SMFP for dialysis stations in home training facilities.

Options for Developing Dialysis Stations in Home Training Facilities

In general, dialysis stations can be developed in a facility one of two ways: (1) existing or approved stations can be relocated from one facility to another pursuant to Policy ESRD-2, or (2) new stations can be developed. The SMFP currently recognizes that Policy ESRD-2 can be used to relocate stations to a home training facility (see **Assumption 8**, above), in which case those stations are excluded from the county inventory. However, Chapter 9 does not address the development of new dialysis stations in home training facilities or the effect on the planning inventory.

As discussed below, Policy ESRD-2 alone does not allow providers to meet the need for stations in home training facilities. There is no health planning purpose in requiring a need determination for stations in home training facilities, or for including such stations in the planning inventory. Providers should be allowed to develop new stations in home training facilities without a need determination in the SMFP, and without affecting the planning inventory.

REASONS FOR THE PROPOSED ADJUSTMENT/CHANGE

Relocation of Existing Stations Pursuant to Policy ESRD-2

Dialysis providers can apply to relocate existing stations to a home training facility from existing in-center facilities **within the same county** or in a **contiguous county**. Policy ESRD-2: Relocation of Dialysis Stations states the following:

"Relocations of existing dialysis stations to contiguous counties are allowed. Certificate of need application proposing to relocate dialysis stations to a contiguous county shall:

1. *demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*

2. *demonstrate that the proposal shall not result in a deficit or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan; and*

3. *demonstrate that the proposal shall not result in a surplus or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan."*

While being able to relocate stations within the same county or from a contiguous county is sometimes an option, the ability to develop stations in a home training facility under Policy ESRD-2 is very limited, because a dialysis provider wishing to develop a station in a home training facility may not have an existing in-center facility in the same county or a contiguous county from which stations can be relocated. As a result, Policy ESRD-2 can only be used in limited circumstances where a provider already has in-center facilities nearby.

Development of New Dialysis Stations at Home Training Facilities

Although there is a need methodology for new dialysis stations in the SMFP, it is unclear whether the resulting need determinations limit the development of new dialysis stations in home training facilities. As explained below, Chapter 9 of the SMFP should be revised to clarify that need determinations are specific to **in-center** facilities, and providers can be approved for new stations in home training facilities without a need determination and without affecting the county inventory of dialysis stations.

Under N.C. Gen. Stat. § 131E-183(a)(1), a need determination in the SMFP is a determinative limitation on health service facilities that may be approved for a CON. Chapter 9 of the SMFP contains a need methodology based on in-center patients and in-center stations only, which results in need determinations without which new in-center dialysis stations cannot be approved. However, because the dialysis station need methodology **excludes** home patients and stations in home training facilities, it **does not** reflect the home dialysis patient population; and a need determination, or deficit or surplus in the service area, does not determine the need or lack of need for stations in home training facilities.

Also, under the county need methodology, a deficit of at least 10 stations is necessary to trigger a county need determination for additional stations. Such deficits are rare, especially in rural counties where many years often pass without a county need determination. Consequently,

applying the need determinations to stations in home training facilities would effectively prevent the development of home hemodialysis training stations throughout most of the state based on a methodology that does not even consider that patient population.[2] Therefore, it serves no valid health planning purpose to require a need determination before new stations can be developed in home training facilities. Similarly, it would serve no valid health planning purpose to include **new stations** in home training facilities in the planning inventory while stations **relocated** to home training facilities are excluded. Accordingly, any such new stations should be excluded from the planning inventory, consistent with the current treatment of stations relocated to home training facilities.

Also, the requirement for a 10-station deficit is based on Basic Principle 1, which requires new facilities to project a need for at least 10 stations to be cost effective and to assure quality of care. This basic principle was adopted before home training became common and before home training facilities were incorporated in the SMFP. The SMFP already recognizes that new **home training** facilities do not require 10 or more stations, as demonstrated by SMFP Table 9E.[3]

2022 CON Applications

Two recent CON reviews illustrate the need for the changes requested in this petition. On September 15, 2022, FMS ENA Home, LLC (ENA Home), a subsidiary of BMA filed two CON Applications, Chowan Home Dialysis and Wilson Home Dialysis, each of which proposed to develop one dialysis station at an existing/approved home training facility to be used exclusively for home hemodialysis training and support services. BMA was not proposing to offer in-center dialysis services in either CON application.

To BMA's knowledge, the Chowan and Wilson Home Dialysis applications were the first applications to develop new dialysis stations in a home training facility in a service area without a need determination since the 2022 SMFP changes regarding home training facilities. Accordingly, both applications explained BMA's belief that a need determination in the SMFP was unnecessary.

The Agency concluded that ENA Home demonstrated the need for the services proposed and was conforming to §131E-183(a)(3) which states,

> *"The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed…."*

The Agency also determined that ENA Home conformed to §131E-183(a)(5), which requires the demonstration of the immediate and long-term financial feasibility of the proposal.

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[2] Furthermore, if there were a need determination in the SMFP and an applicant were to apply to develop these stations at a home training facility for the purpose of offering home hemodialysis, the application could be denied because the population it proposes to serve (home training patients) would not be the same population that generated the county need determination (in-center patients) and therefore, would not adequately address the need identified in the SMFP.

[3] None of the 17 home training facilities shown in the 2023 SMFP has more than 7 dialysis stations.

Nevertheless, both applications were denied, for the sole reason that the 2022 SMFP contained no need determination for dialysis stations in the service area. The Agency Findings for both applications stated,

> *"An alternative method or policy for developing new dialysis stations that would be used exclusively for home hemodialysis training, and that would not require a need determination in the SMFP would need to be developed and approved by the State Health Coordinating Council."*

Accordingly, BMA submits this petition to the SHCC requesting clarification of Chapter 9, limiting the need determination to in-center dialysis stations.

Numerous Health Services are Not Subject to Need Determinations

The Petitioner notes that the absence of a specific need methodology does not preclude a CON applicant from filing an application to develop a new institutional health service. There are a number of health services regulated by the CON Law and in the SMFP that have no specific need methodology and for which CON applications have been filed and a certificate of need issued. The following chapters and services in the SMFP do not have a specific need methodology:

- Chapter 14: Psychiatric Inpatient Services
- Chapter 15: Substance Use Disorder Inpatient and Residential Services
- Chapter 16: Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)
- Chapter 17: Technology and Equipment for Gamma Knives

Advancing American Kidney Health Initiative

In 2019, the Federal government launched the Advancing American Kidney Health Initiative, which was designed to advance American kidney health. As part of the Initiative, the President signed Executive Order 13879, which directed the U.S. Department of Health & Human Services (HHS) to take bold action to transform how kidney disease is prevented, diagnosed, and treated within the next decade. The Executive Order identified the following goals, stated in part:

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

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* **[emphasis added]**

As a result, BMA and other dialysis providers are seeing significant growth in our home therapy programs. Our physician partners are referring more patients for home hemodialysis when suitable and more dialysis patients are choosing home hemodialysis as their modality of choice. Our ability to offer these services at our home training facilities would help us carry out this initiative.

ESRD Treatment Choices (ETC) Model

In 2021, the Centers for Medicare and Medicaid Services (CMS) revised their guidelines to encourage greater use of home dialysis. The home dialysis modalities have support among health care providers and patients as preferable alternatives to in-center hemodialysis. The model began on January 1, 2021. In fall 2021, it became one of the first CMS Innovation Center models to directly address health equity, as social factors of health have a significant impact on chronic kidney disease and ESRD.

North Carolina Home Patient Growth

The following information is extracted from Chapter 9: Dialysis Data by County of Patient Origin reports for the 2021-2023 SMFP:

	SMFP	2023	2022	2021
	Current as of:	12/31/2021	12/31/2020	12/31/2019
1.	ESRD Census	19,302	19,547	19,288
2.	PD Census	2,156	2,104	2,001
3.	HH Census	654	605	562
4.	Total Home Patients	2,810	2,709	2,563
Home Patients Residing in Another State, but treating through a NC dialysis facility:				
5.	GA	1	0	1
6.	SC	25	27	22
7.	TN	2	2	0
8.	VA	16	15	16
9.	Other States	2	5	8
10.	Total Out of State Home Patients	46	49	47
11.	**North Carolina Home Patients**	**2,764**	**2,660**	**2,516**

The information in the above table shows that the total North Carolina home dialysis patient population across our state increased by 247 patients from 2,563 to 2,810 between December 31, 2019 and December 31, 2021, an increase of 9.64%, or at a compound annual growth rate (CAGR) of 4.71%. In the same period, the home **hemodialysis** patient population (the population that would use home training stations) increased by 92 patients, an increase of 16.4%, or a CAGR of 7.87%, almost twice the growth rate of the overall home dialysis population.

While the total ESRD patient population in North Carolina decreased by 1.25% or 245 patients between December 31, 2020 and December 31, 2021, the number of North Carolina home dialysis patients increased by 3.73% during this same time period, or roughly 101 patients. It is clear that more patients across the state are choosing home training as their modality of treatment.

Staffing shortages

The COVID-19 pandemic has further exasperated staffing shortages, particularly in the dialysis industry. Being able to train more patients to dialyze at home would significantly help to reduce

the number of in-center patients and staff in our facilities and redirect staff to areas that exclusively offer in-center dialysis services.

Adjusted Need Determination for Outpatient Dialysis Stations

In both the Spring and Summer of 2022, Liberty Healthcare filed a petition for an adjusted need determination in the 2023 SMFP requesting the addition of a special need determination for outpatient dialysis stations at a nursing facility. While the spring petition was denied, the result of the summer petition was an adjusted need determination for six outpatient dialysis stations located at a nursing home facility in Mecklenburg County in the 2023 SMFP.

Table 9C: Dialysis Station Need Determination County Need Determination Methodology states:

> *"dialysis stations developed pursuant to this need determination are excluded from the planning inventory in the SMFP and excluded from the county and facility need methodologies"*

The Petitioner suggests that developing stations at home training facilities without a county need determination or policy should also be excluded from the planning inventory and county and facility need methodologies because these stations would otherwise be excluded from the inventory and methodologies if they were relocated pursuant to Policy ESRD-2.

PROPOSED LANGUAGE FOR THE ASSUMPTIONS OF THE METHODOLOGY

The Petitioner proposes the following underlined definition to be added to Chapter 9 of the 2024 SMFP:

An ***in-center facility*** is a kidney disease treatment center as defined in G.S. § 131E-176(14e), that provides in-center dialysis.

The Petitioner proposes the following underlined language to be added to the first basic principle in Chapter 9 of the 2024 SMFP:

1. New in-center facilities must have a projected need for at least 10 stations to be cost effective and to assure quality of care.

The Petitioner proposes the following underlined language to be added to the assumptions of the methodology in Chapter 9 of the 2024 SMFP:

8. When a CON application has been received to relocate stations to a home training facility, the stations to be relocated are included in both the county and facility need determination calculations. When the home training stations are certified, then they are excluded from both the county and facility need determination calculations. New dialysis stations developed in a home training facility are excluded from both county and facility need determination calculations.

10. The county need methodology and county need determinations in the plan are specific to in-center dialysis stations, and do not apply to development of new

dialysis stations in home training facilities. Any person may apply to develop one or more new dialysis stations in a home training facility at any time.

The Petitioner believes that inclusion of the language above in Chapter 9 will be helpful in that it will provide clarity in future CON reviews that involve developing stations at home training facilities.

EVIDENCE THE PROPOSED CHANGES WOULD NOT RESULT IN UNNECESSARY DUPLICATION

The Petitioner believes the following language in the existing methodology supports the development of stations at home training facilities without a county need determination or policy:

1. Home patients who receive hemodialysis or peritoneal dialysis in their home are not included in the determination of need for new stations; thus, developing a station used exclusively to train home patients should also not be included in the determination of need for new stations;
2. Dialysis stations at in-center facilities certified for home dialysis are included in the planning inventory; and
3. Certified stations relocated from in-center facilities to home training facilities are excluded from both the county and facility need determination calculations.

Because home patients and stations in home training facilities are not currently part of the inventory or the planning process, the current inventory and any resulting surpluses do not reflect the current capacity to meet home dialysis patients' needs. As a result, the Chapter 9 need methodology has no bearing on whether new stations in home training facilities unnecessarily duplicates existing facilities or services. Unnecessary duplication can instead be avoided through G.S. §131E-183(a)(6), which applies to all CON applications. It states:

> *"The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities."*

Therefore, the applicant has the burden to demonstrate that proposed new stations in a home training facility will not duplicate existing or approved facilities or services. For example, stations used for home training in a county that does not currently offer those services would not result in an unnecessary duplication of existing or approved health service capabilities or facilities but will instead increase access of those services in the county. The requirement of a need determination before a new station may be developed at a home training facility is the result of ambiguity in Chapter 9, as described above, and does not serve any health planning purpose. Instead it only serves to unnecessarily prevent the development of home training capacity that would improve access for home hemodialysis patients. This is especially true for rural counties like Chowan County where home hemodialysis services are not currently being offered but a need for the services has been identified by BMA, the physicians of Eastern Nephrology Associates and the Agency.

EVIDENCE THE PROPOSED CHANGES ARE CONSISTENT WITH THE THREE BASIC PRINCIPLES: SAFETY AND QUALITY, ACCESS AND VALUE

The changes proposed in this petition are intended to increase access to home dialysis training and support services for an especially vulnerable population. CON applicants are required by law to address safety and quality, access and value in every CON application submitted for review and quality and safety requirements are set forth in CMS regulations that would continue to apply to existing and new providers of these services. Patient satisfaction is also a huge component of quality care and offering home training services closer to a patient's home would be more convenient as it would reduce travel and transportation burdens to the patient.

Adequate access to home dialysis training is a critical part of the Advancing American Kidney Health Initiative, so creating additional flexibility for providers to meet these needs would expand access to care. It is important to note that peritoneal dialysis patients will eventually require a transplant or require hemodialysis as the peritoneal dialysis modality has an expiration date with use of a natural membrane. Thus, it is reasonable to assume that a home peritoneal dialysis patient would choose to convert to home hemodialysis at some point during the course of their treatment, otherwise they would have to return to in-center treatment for hemodialysis. If home hemodialysis training services are not offered, a patient would have to transfer to another facility which can be disruptive to the patient's continuity of care.

The changes proposed herein are also consistent with the value basic principle. They would not increase the cost of care, while simultaneously increasing access and saving patients money by lowering travel and transportation burdens.

For all of these reasons, Fresenius Medical Holdings, Inc. believes the proposed changes will have beneficial effects of facilitating access to these critical services consistent with the principles of the CON law.

CONCLUSION

The intent of this petition is to ensure adequate access to home training for hemodialysis. Absence of a county need determination or policy should not be the factor limiting development of these services as there are a number of health services identified in the SMFP for which there is no specific need determination. The Petitioner has been on the leading edge of offering hemodialysis at home training facilities and we believe that this petition is the next step in the right direction to improving access to home dialysis care in North Carolina.

You can contact me at 984-268-8421 or by email at Fatimah.wilson@freseniusmedicalcare.com if you have any questions or need more information.

Sincerely,

Fatimah Wilson
Director, Certificate of Need

Attachments:

1. CMS Medicare Guidelines
2. Advancing American Kidney Health Initiative
3. Findings for CON Project ID# R-12268-22

An official website of the United States government Here's how you know

Attachment #1

Search

Centers for Medicare & Medicaid Services

ESRD Treatment Choices (ETC) Model

CMS has released the final rule for the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model to encourage greater use of home dialysis and kidney transplants for Medicare beneficiaries with ESRD, while reducing Medicare expenditures and preserving or enhancing the quality of care furnished to beneficiaries with ESRD. Both of these modalities have support among health care providers and patients as preferable alternatives to in-center hemodialysis, but utilization has been less than in other developed nations. The Model will begin on January 1, 2021.

Background

Studies have shown that for patients who require dialysis, dialyzing at home is often preferred by patients and physicians. The benefits include increased independence and quality of life. The rate of home dialysis in the U.S. – about 12% in 2016 – falls far below that of other developed nations.

Transplantation is widely viewed as the optimal treatment for most patients with ESRD, generally increasing survival and quality of life while reducing medical expenditures. However, in 2016 only 29.6% of prevalent ESRD patients in the US had a functioning transplant and only 2.8% of incident patients received a preemptive transplant. These rates are below those of other developed nations. The U.S. was ranked 39th of 61 countries reporting to the USRDS in 2016.

Model Details

One of the goals of the ETC model is to give ESRD beneficiaries the freedom and choice of ESRD treatment that best works with their lifestyles. For example, if a beneficiary chooses home dialysis, they would have greater flexibility to adjust the hours and frequency of their treatment. Under the ETC Model, CMS will make certain payment adjustments that will encourage participating ESRD facilities and Managing Clinicians to ensure that ESRD beneficiaries have access to and receive education about their kidney disease treatment options. Specifically, CMS will positively adjust certain Medicare payments to participating ESRD facilities and Managing Clinicians for the first three years of the model for home dialysis and dialysis-related services.

The model will require the Medicare payment adjustments for the selected ESRD facilities and Managing Clinicians. For the model, a Managing Clinician is a Medicare-enrolled physician or non-physician practitioner who furnishes and bills the monthly capitation payment (MCP) for managing one or more adult ESRD beneficiary. Payment to ESRD facilities and Managing Clinicians not selected to participate in the model would not be affected.

To implement a model test that would require participation on the part of certain health care providers, CMS is required to issue a Notice of Proposed Rulemaking (NPRM). Accordingly, CMS's proposals for the ETC Model are included in the proposed rule for Specialty Care Models to Improve Quality of Care and Reduce Expenditures. This NPRM was issued on July 10, 2019 CMS reviewed public comments and published the final rule for the model on September 18, 2020.

In July 2021, CMS proposed changes to the ETC Model to address health and socioeconomic disparities, which are a major contributor to chronic kidney disease and ESRD. These proposed changes were part of the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Notice of Proposed Rulemaking. The proposed changes include incentives for participating ESRD facilities and Managing Clinicians to address health equity among their patients. They also include incentives that would reduce the disparities in which ESRD patients of lower socioeconomic status are able to access alternatives to in-center dialysis, specifically home dialysis and transplantation.

If these changes are finalized, the ETC Model would be the agency's first CMS Innovation Center model to directly address health equity.

CMS is requiring participation in order to minimize the potential for selection effect. Selection effect occurs when only the potential participants who would benefit financially from a model choose to participate. Selection effect may reduce the amount of savings that a model can generate. Requiring participation for certain models helps CMS understand the impact on a variety of provider types so that the resulting data would be more broadly representative.

Methodologies

CMS will select ESRD facilities and Managing Clinicians to participate in the model according to their location in randomly selected geographic areas so as to account for approximately 30 percent of the ESRD facilities and Managing Clinicians in the 50 States and District of Columbia. A specific element of the selection will be that ESRD facilities and Managing Clinicians in Maryland would generally be included in the model's interventions, so as to be consistent with the Total Cost of Care Model being tested in that State. Across the U.S., certain facilities and clinicians will be excluded from certain portions of the model's interventions on account of serving low volumes of adult ESRD beneficiaries.

Beneficiaries will be attributed on a month-by-month basis. A beneficiary will be attributed to the ESRD facility accounting for the most dialysis claims during the month, and the Managing Clinician billing the first MCP for the month.

Two types of payment adjustments will apply. The first will be a uniformly positive adjustment on Medicare claims for home dialysis during the initial three years of the model, providing an additional payment to selected facilities and clinicians for supporting beneficiaries dialyzing at home. The second adjustment will apply to both home and in-center dialysis and related claims, and could be either positive or negative. These adjustments, either upward or downward, would be made to the per treatment payment for dialysis based on the rate of home dialysis and transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate . Greater positive and negative adjustments for model participants would be phased in over the performance period of the model.

Timeline

The proposed ESRD Treatment Choices Model is included in the Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures Notice of Proposed Rule Making. The public comment period for the Notice of Proposed Rule Making closed on September 16, 2019. CMS reviewed comments and published a final rule on September 18, 2020.

The model went into effect January 1, 2021.

In July 2021, ETC Model proposed changes were part of the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Notice of Proposed Rulemaking. Public comments are due August 31, 2021.

For any questions, please email the ETC Model team atETC-CMMI@cms.hhs.gov.

Click here to subscribe to receive ETC Model emails.

Events

ESRD Treatment Choices Introductory Webinar - Wednesday, 12/9/2020 from 1:00 - 2:00 pm - Transcript (PDF) | Slides (PDF) | Recording (MP4)

Additional Information

ETC Model Achievement Benchmarks for Measurement Year 1 (January 1, 2021 – December 31, 2021: Updated May 27, 2021) (PDF)
ETC Model Achievement Benchmarks for Measurement Year 2 (July 1, 2021 – June 30, 2022) (PDF)
ETC Model Fact Sheet (September 2020)
ETC Model Press Release (September 2020)
ETC Model Fact Sheet (July 2021)
ETC Model Press Release (July 2021)
ETC List of Selected Geographic Areas: PDF | XLS
Specialty Care Models Final Rule
ETC Model Beneficiary Notification Form and Guidance - English (PDF)
ETC Model Beneficiary Notification Form and Guidance - Spanish (PDF)
Advancing American Kidney Health
ETC Model Archived Materials

Related Items

Episode-based Payment Initiatives

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Last updated on: 07/28/2021

Attachment #2

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.

REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date: January 25, 2023
Findings Date: January 25, 2023

Project Analyst: Ena Lightbourne
Co-Signer: Gloria C. Hale

Project ID #: R-12268-22
Facility: Chowan Home Dialysis
FID #: 200027
County: Chowan
Applicant(s): FMS ENA Home, LLC
Project: Develop one dialysis station to be used exclusively for home hemodialysis training and support services

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NC

FMS ENA Home, LLC (hereinafter referred to as "the applicant" or "ENA Home"), proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to home hemodialysis (HH). Chowan Home Dialysis is a dialysis home training facility that currently serves peritoneal patients only. Upon project completion, Chowan Home Dialysis will be certified for both HH and Peritoneal Dialysis (PD) training and support services.

<u>Conclusion</u>

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Information publicly available during the review and used by the Agency

Bases on that review, the Agency concludes that the application is not conforming to this criterion because there is no county need determination in the 2022 State Medical Facilities Plan (SMFP) for any additional dialysis stations. Table 9B on page 135 of the 2022 SMFP shows there is a surplus of four dialysis stations in Chowan County. Adding an additional dialysis station would increase the surplus of dialysis stations. Home hemodialysis stations are certified dialysis stations and are included in the ESRD planning inventory.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, … persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

Patient Origin

On page 115, the 2022 SMFP defines the service area for dialysis stations as *"the service area is the county in which the dialysis station is located."* Thus, the service area for this facility consists of Chowan County. Facilities may also serve residents of counties not included in their service area.

On page 25, the applicant states that Chowan Home Dialysis began offering services for PD patients on April 21, 2022. The applicant provides the historical patient origin for the period beginning April 21, 2022, through August 1, 2022.

Chowan Home Dialysis Historical Patient Origin		
	04/21/2022 to 08/01/2022	
	# of PD Patients	% of Total
Chowan	4.0	36.4%
Martin	1.0	9.1%
Perquimans	2.0	18.2%
Tyrell	2.0	18.2%
Washington	2.0	18.2%
Total	**11.0**	**100.0%**

Source: Section C, page 25

The following table illustrates projected patient origin for the second full fiscal year.

Chowan Home Dialysis Projected Patient Origin 2nd Full FY, CY 2025				
County	HH		PD	
	# of Patients	% of Total	# of Patients	% of Total
Chowan	6.0	75.0%	7.1	50.3%
Bertie	1.0	12.5%	0.0	0.0%
Martin	0.0	0.0%	1.0	7.1%
Pasquotank	1.0	12.5%	0.0	0.0%
Perquimans	0.0	0.0%	2.0	14.2%
Tyrell	0.0	0.0%	2.0	14.2%
Washington	0.0	0.0%	2.0	14.2%
Total	**8.0**	**100.0%**	**14.1**	**100.0%**

Source: Section C, page 26

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In Section C, pages 26-34 and Section Q, pages 94-101, the applicant provides the assumptions and methodology used to project its patient origin.

Home Hemodialysis

- Chowan Home Dialysis was approved as a freestanding peritoneal dialysis facility. BMA, co-parent of the applicant, and Eastern Nephrology Associates (ENA), are committed to increasing the home therapy penetration rate in Chowan County. Physicians from ENA serve chronic kidney disease patients and serve as a referral source for dialysis facilities. BMA facilities currently serve some dialysis patients in Chowan County.
- Chowan Home Dialysis was certified April 2022 (Project ID# R-11834-20) and has served 11 PD patients in the first four months of operation which will exceed 12.6 PD

patients by the end of the first operating year as projected in the original application. The applicant states that this demonstrates the commitment to increase home therapy penetration in the service area.

- The applicant identified patients in other counties that ENA serves from eastern North Carolina who could potentially choose home therapy services at Chowan Home Dialysis. However, the applicant assumes that patients prefer to be served in their home county. The applicant does not project growth for patients served in another county since home therapy patients do not have to travel to a center three times a week after training.
- The applicant cites data from the CMS Dialysis Compare website to illustrate the number of facilities in Chowan County offering home therapy. According to the data, Edenton Dialysis is the only dialysis facility operating in Chowan County and does not offer home therapy. The applicant states that Chowan Home Dialysis was not reflected on the website because the facility was certified in April 2022. The next closest facility that offers home therapy is 15.2 miles from Edenton Dialysis. The applicant assumes that the proposal will bring services closer to patients' residences, thus, enhancing access to care for patients in the service area.
- The applicant identified three HH patients who reside in Chowan County that receive services at FMC Pamlico in Beaufort County. The facility also served two PD patients residing in Chowan County who are interested in converting to HH. The applicant assumes that one of these PD patients will be required to change to HH in the near future. Additionally, the applicant identified two HH patients who reside in Bertie County and receive services at the Greenville Dialysis facility in Pitt County. The applicant assumes that at least one of these patients will transfer to Chowan Home Dialysis, as the facility would be closer to the patient's residence.
- The applicant identified three HH patients who reside in Pasquotank County receiving services at the FMC Pamlico facility in Beaufort County. The applicant assumes that at least one of these patients will transfer to Chowan Home Dialysis, as the facility would be closer to the patient's residence.
- The applicant received patient support letters from four home dialysis patients expressing interest in transferring their care to Chowan Home Dialysis.
- Based on the Executive Order to advance kidney health nationally, the applicant assumes that more patients will be referred for home dialysis.
- ENA Home has a history of achieving a home penetration greater that 45% and assumes that ENA Home can achieve a home penetration of at least 25% based on the number of counties across the state historically achieving a home penetration that exceeds 25%. The applicant identified the home penetration in a county similar to Chowan County. The applicant compares the following counties based on a similar ESRD patient population.

County	Home Penetration	ESRD Census
Swain	27.5%	51
Chowan	14.5%	55

Source: Section C, page 32

- Despite having an ESRD patient population 7.8% smaller than Chowan County, Swain County home penetration is 89.7% larger than Chowan County. The applicant states that this suggests that more Chowan County patients can dialyze at home.
- A physician at ENA supports the proposal and intends to refer patients for home therapies to the facility.
- The applicant relied on information from Edgecombe Home Dialysis ("Edgecombe") to project future patient population at Chowan Home Dialysis, based on the following factors:

  - Edgecombe offers HH and PD training and support services. Chowan Home Dialysis is proposing to offer the same services.
  - Edgecombe relies on nephrology physicians of ENA for patient referrals and admissions as Chowan Home Dialysis is proposed to do.
  - Chowan Home Dialysis is proposed to have a medical director from the same practice.
  - Edgecombe is located approximately 69 miles away from the proposed Chowan Home Dialysis.

The applicant cites data from the 2020 through the proposed 2023 SMFPs, to illustrate Edgecombe County patient population growth, particularly among HH patients. The applicant states that Edgecombe County has been instrumental in creating changes within the ESRD patient population by referring patients for home therapies. The applicant assumes that Chowan Home Dialysis will have similar results.

Edgecombe County ESRD Census					
SMFP	**2020**	**2021**	**2022**	**Proposed 2023**	**CAGR**
Date of Data	**12/31/2018**	**12/31/2019**	**12/31/2020**	**12/31/2021**	
ESRD	247	247	264	279	4.14%

Source: Section C, page 32

Edgecombe County Home Hemodialysis Census					
Data Source	**2020 SMFP**	**2021 SMFP**	**2022 SMFP**	**Proposed 2023 SMFP**	**CAGR**
Data Period	**12/31/2018**	**12/31/2019**	**12/31/2020**	**12/31/2021**	
# Home Hemodialysis Patients	3	4	4	8	38.67%
% Increase		33.3%		100.0%	

Source: Section C, page 33

The following table illustrates the percentage of growth specific to Chowan County home therapy patients. The applicant states that this largely due the ENA's commitment to increase home therapy penetration in Chowan County.

Chowan County				
SMFP	**2021 SMFP**	**2022 SMFP**	**Proposed 2023 SMFP**	**2-Year CAGR for Home Therapy Patients**
Date of Data	**12/31/2019**	**12/31/2020**	**12/31/2021**	47.2%
Home Patients	6	8	13	
ESRD Patients	48	55	51	
Home %	0.1250	0.1455	0.2549	

Source: Section C, page 33

- The applicant projects growth using the Five-Year Average Annual Change Rate (AACR) of 9.3% for Chowan County, as published in the 2022 SMFP.
- The project is projected to be certified as of December 31, 2023. The applicant projects the first operating year of the project will be January 1, 2024 - December 31, 2024, and the second operating year will be January 1, 2025 - December 31, 2025.

Home Peritoneal Dialysis

- The applicant projects growth using a rate higher than the Five-Year AACR for Chowan County. The applicant states that using a growth rate of 18.6% is reasonable based on the following factors:
    - The facility has exceeded the PD patient population for the first operating year within the first four months of operations.
    - The facility experienced a growth of at least two patients per month since the facility began operations.
    - The facility experienced more than a 100% increase in PD patients since April 2022.
- The project is projected to be certified as of December 31, 2023. The applicant projects the first operating year of the project will be January 1, 2024 - December 31, 2024, and the second operating year will be January 1, 2025 - December 31, 2025.

The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant adequately demonstrates the growth of HH and PD patients in Chowan County and at other facilities serving home therapy patients.
- The applicant reasonably projects growth based on the actual growth in PD patients experienced at Chowan Home Dialysis.
- The applicant's proposal supports the Executive Order to improve kidney health.

Analysis of Need

In Section C, pages 37-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Developing an additional dialysis station dedicated to HH will enhance access to care as the need for home therapy grows.
- The proposed project will focus exclusively on HH and PD which will allow residents of Chowan County and surrounding areas access to HH training and support services.
- Failure to receive dialysis care will lead to the patient's demise.

The information is reasonable and adequately supported based on the following:

- Actual growth in home patients exceeding the applicant's original projections demonstrated in Project ID# R-11834-20.
- The applicant's proposal will enhance access to HH services for Chowan County residents.

<u>Projected Utilization</u>

In Section C, page 35, and Section Q, page 102, the applicant provides projected utilization, as illustrated in the following table.

Chowan Home Dialysis	HH Patients
Begin with three Chowan County HH patients and two Chowan County PD patients expected convert to HH.	5.0
Add the two patients from other counties. This is the projected ending census for Interim Year One, December 31, 2023.	5.0 + 2.0 = 7.0
Project the Chowan County patient census forward for 12 months to December 31, 2024, increasing it by applying the Five-Year Chowan County AACR of 9.3%	5.0 x 1.093 = 5.5
Add the two patients from other counties. This is the projected ending census for Operating Year One.	5.5 + 2.0 =7.5
Project the Chowan County patient census forward for 12 months to December 31, 2025, applying the Five-Year AACR for Chowan County.	5.5 x 1.093 = 6.0
Add the two patients from other counties. This is the projected ending census for Operating Year Two.	6.0 + 2.0 = 8.0

Chowan Home Dialysis	PD
Begin with the four existing Chowan County PD patients that the facility was serving as of August 1, 2022.	4.0
Project the Chowan County patient census forward for four months to December 31, 2022, using an 18.6% growth rate.	4.0 x (1.186/12 x 4) + 4 = 4.2
Add the seven patients from other counties. This is the projected census for Interim Year One.	4.2 + 7.0 = 11.2
Project the Chowan County patient census forward for 12 months to December 31, 2023, using an 18.6% growth rate.	4.2 x 1.186 = 5.0
Add the seven patients from other counties. This is the projected census for Interim Year Two.	5.0 + 7.0 = 12.0
Project the Chowan County patient census forward for 12 months to December 31, 2024, using an 18.6% growth rate.	5.0 x 1.186 = 6.0
Add the seven patients from other counties. This is the projected census for Operating Year One.	6.0 + 7.0 = 13.0
Project the Chowan County patient census forward for 12 months to December 31, 2025, using an 18.6% growth rate.	6.0 x 1.186 = 7.1
Add the seven patients from other counties. This is the projected census for Operating Year Two.	7.1 + 7.0 = 14.1

In Section C, page 35 and Section Q, page 102, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins with three Chowan County HH patients and two Chowan County PD patients expected to convert to HH.
- The applicant begins with the four PD patients that the facility was serving as of August 1, 2022.
- The applicant assumes that two HH patients and seven PD patients residing in other counties will transfer their care to Chowan Home Dialysis.
- The applicant projects growth of the Chowan County HH patient census using the Chowan County Five-Year AACR of 9.3%, as published in the 2022 SMFP.
- The applicant projects growth of the Chowan County PD patient census using a growth rate of 18.6%.
- The project is projected to be certified as of December 31, 2023. The first operating year of the project will be January 1, 2024 - December 31, 2024, and the second operating year will be January 1, 2025 - December 31, 2025.

The applicant projects to serve the following number of patients upon project completion.

	Operating Year 1	Operating Year 2
Home Hemodialysis	7.5	8.0
Peritoneal Dialysis	13.0	14.1

Source: Section C. page 36

Projected utilization is reasonable and adequately supported based on the following:

- The applicant projects utilization based on the growth of home therapy in Chowan County and surrounding counties.
- Actual growth in home patients exceeds the applicant's original projections demonstrated in Project ID# R-11834-20.

Access to Medically Underserved Groups

In Section C. page 41, the applicant states:

> *"Fresenius Medical Care operates more than 100 dialysis facilities across North Carolina. Each of the facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons."*

The applicant provides the estimated percentage for each medically underserved group during the 2nd full fiscal year, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	20.59%
Racial and ethnic minorities	91.18%
Women	44.12%
Persons with Disabilities	8.82%
Persons 65 and older	32.35%
Medicare beneficiaries	26.47%
Medicaid recipients	20.59%

Source: Section C, page 41

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant relied on the Edgecombe Home Dialysis facility as a model for its patient population projections, based on the facility's similarity in services offered, referral and admission source, and its location to the proposed Chowan Home Dialysis.
- The applicant is an established provider of dialysis services across North Carolina currently providing services to underserved groups.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, … persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

NA

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

In Section E, page 51, the applicant states that there were no other alternatives considered and any other alternative would not support the former President's Executive Order on Advancing American Kidney Health. On page 51, the applicant states:

> *"At the present time, there are only two dialysis facilities operating in Chowan County, Edenton Dialysis and Chowan Home Dialysis. The applicant believes that offering home hemodialysis services to patients of Chowan County and surrounding counties would bring those services closer to the patient's residence, would be more convenient and would enhance access to care for the patients of the area."*

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need because the application is not conforming to all other statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reason stated above. Therefore, the application is denied.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

Capital and Working Capital Costs

In Section Q, page 105, the applicant projects the total capital cost of the project, as shown in the table below.

Projected Capital Cost

Non-Medical Equipment	$750
Furniture	$3,000
Total	**$3,750**

In Section Q, page 105, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on what is needed to operate the facility, such as patient chairs and the water treatment system.

Availability of Funds

In Section F, page 52, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	FMS ENA Home, LLC	Total
Loans	$0	$0
Accumulated reserves or OE *	$3,750	$3,750
Bonds	$0	$0
Other	$0	$0
Total Financing	$3,750	$3,750

* OE = Owner's Equity

On page 54, the applicant states that there will be no start-up costs or initial operating costs for the existing facility.

Exhibit F-2 contains a letter dated September 15, 2022, from the Senior Vice-President and Treasurer of Fresenius Medical Holdings, Inc., majority owner of FMS ENA Home, LLC, stating their commitment to fund the capital needs of the project through accumulated reserves. The letter states the Fresenius Medical Holdings' 2021 consolidated balance sheet reflected $939 million in cash and over $27.2 billion in total assets to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information provided in Section F and Exhibit F-2 of the application.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the second full fiscal year following completion of the project, as shown in the table below.

Chowan Home Dialysis	1st Full FY	2nd Full FY
	CY2024	CY 2025
Total Treatments	2,921	3,145
Total Gross Revenues (Charges)	$18,378,513	$19,785,230
Total Net Revenue	$1,152,554	$1,240,994
Average Net Revenue per Treatment	$395	$395
Total Operating Expenses (Costs)	$1,161,926	$1,220,291
Average Operating Expense per Treatment	$398	$388
Net Income	($9,372)	$36,004 [$20,703]

Project Analyst calculation in brackets.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 109. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Forms F.2, F.3 and F.4.

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

On page 115, the 2022 SMFP defines the service area for dialysis stations as *"the service area is the county in which the dialysis station is located."* Thus, the service area for this facility consists of Chowan County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Chowan County as of December 31, 2021, according to 2021 ESRD Data Collection Forms submitted to the Agency. There is one kidney disease treatment center providing dialysis services in Chowan County.

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021	Patients Per Station Per Week
Edenton Dialysis	20	51	63.75%	2.55
Total	20	51		

Source: 2021 ESRD Data Collection Forms

In Section G, page 60, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Chowan County. The applicant states:

> *"While the applicant is proposing to develop one dialysis station, the station would be used exclusively for home hemodialysis and should be excluded from the dialysis station inventory in Chowan County. At the time this application was prepared and submitted, Chowan Home Dialysis was the only dialysis facility offering home therapy services in Chowan County. The facility does not currently offer home hemodialysis; thus, the proposed project to develop one station to be exclusively used for home hemodialysis would not result in a duplication of the same existing or approved health services in Chowan County."*

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the proposal would result in an additional dialysis station for which there is no county need determination. Thus, the addition of a dialysis station in Chowan County would increase an existing surplus of dialysis stations in Chowan County. An alternative method or policy for developing new dialysis stations that would be used exclusively for home hemodialysis training, and that would not require a need determination in the SMFP would need to be developed and approved by the State Health Coordinating Council.

<u>Conclusion</u>

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

In Section Q, pages 117-118, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff	
	Current	Projected
	As of 08/01/2022	2nd Full FY CY 2025
Administrator (FMC Clinic Manager)	0.50	0.50
Home Training Nurse	1.00	2.00
Technicians (PCT)	0.00	1.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Maintenance	0.50	0.50
Administrative/Business Office	0.50	0.50
Other: FMC Director of Operations	0.33	0.33
Other: Chief Technician	0.10	0.10
Other: FMC In-Service	0.10	0.10
TOTAL	**4.03**	**6.03**

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, pages 62-63, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant is proposing to offer a wide range of personnel benefits and competitive salaries to attract qualified staff.
- In response to the pandemic's impact on staffing, parent company Fresenius Medical Care, has implemented initiatives such as, sign-on and retention bonuses, increased starting salaries and intensified recruiting efforts.
- New employees are required to complete a 10-week training program that includes safety precautions in addition to clinical training.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

Ancillary and Support Services

In Section I, page 64, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 64-69, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 69, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on following:

- The applicant's established relationships with other physicians and hospitals in the area, which include Eastern Nephrology Associates Access Center, where ESRD patients may receive care.
- The applicant has agreements for lab services, hospital affiliation and transplant.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and … persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

NA

In Section L, page 76, the applicant states that Chowan Home Dialysis began operations on April 21, 2022, therefore, there is no historical payor mix to report for the previous full fiscal year.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 79, the applicant states:

> *"The facility is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities."*

In Section L, page 79, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 79, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Chowan Home Dialysis Projected Payor Mix 2nd Full FY, CY 2025				
Payor Source	HH		PD	
	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0.0	0.00%	0.0	0.00%
Insurance*	1.6	20.67%	3.2	22.62%
Medicare*	6.3	79.33%	9.1	64.74%
Medicaid*	0.0	0.00%	0.6	4.08%
Other Misc. including VA	0.0	0.00%	1.2	8.56%
Total	**8.0**	**100.00%**	**14.1**	**100.00%**

*Including any managed care plans.
Totals may not foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 79.33% of total services will be provided to HH Medicare patients and 64.74% to PD Medicare patients, and 4.08% to PD Medicaid patients.

On pages 79-80, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant calculated payor mix based upon treatment volumes as opposed to the number of patients. The applicant considered the possible change in payor source during the fiscal year.
- Payor mix projections are based on Edgecombe Home Dialysis' historical facility performance which provides similar services.
- The applicant states that Medicaid HH patients will have access to the facility as evidenced by its Medicaid certification letter provided in Exhibit O-2.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 81, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

In Section M, page 83, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- Fresenius Medical Care facilities have a history of allowing health-related education and training programs visit the facility to observe the operation of the unit while patients receive treatment.

- The applicant provides a copy of a letter sent to the College of the Albemarle, encouraging the school to include Chowan Home Dialysis facility in their clinical rotations for nursing students.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

NC

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Chowan County as of December 31, 2021, according to 2022 ESRD Data Collection Forms submitted to the Agency. There is one kidney disease treatment center providing dialysis services in Chowan County.

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021	Patients Per Station Per Week
Edenton Dialysis	20	51	63.75%	2.55
Total	20	51		

Source: 2022 ESRD Data Collection Forms

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 84, the applicant states:

> *"The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the facility begins with patients who are currently being served at the facility and at other facilities owned or operated by Fresenius Medical Care and is grown by reasonable growth rates as discussed in Section C of this application.*
>
> *…*
>
> *This facility also has added value stemming from the strength of our relationship with nephrology physicians of Eastern Nephrology Associates. These nephrologists have been practicing in Chowan County and surrounding counties, serving the ESRD patients of the area for many years. The practice brings together the collaborative efforts of a team of very qualified nephrologists to provide care for the patients choosing to dialyze at Chowan Home Dialysis."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 85, the applicant states:

> *"Approval of this application will ensure continued access to care for the patients; this proposal will ensure continued convenient, affordable access to care for the growing number of home dialysis patients."*

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 85, the applicant states:

> *"Quality of care is always in the forefront at Fresenius Medical Care related facilities. Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment."*

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 85, the applicant states:

> *"All Fresenius related facilities in North Carolina have a history of providing dialysis services to the underserved population of North Carolina. The Form O identifies all Fresenius related operational and/or CON approved facilities across North Carolina. Each of those facilities has a patient population which includes low-income persons, racial or ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons."*

See also Section L of the application and any exhibits.

However, the applicant does not adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrate the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant does not adequately demonstrate that:

1) The proposal is cost effective because the applicant did not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing and approved health services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the reason described above.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, pages 120-124, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 125 of this type of facility located in North Carolina.

In Section O, page 90, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents resulting in immediate jeopardy had not occurred in any of these facilities. After reviewing and considering information provided by the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any

facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to develop one dialysis station dedicated to providing home training and support services for home hemodialysis patients. The Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, are not applicable to this review due to a declaratory ruling issued by the Agency on October 10, 2018, which exempts the Criteria and Standards from applying to proposals to develop or expand facilities exclusively serving home hemodialysis and peritoneal dialysis patients.