



EASTERN NEPHROLOGY ASSOCIATES

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August 1, 2018

Eastern Nephrology Associates Physician Support Letter
State Health Coordinating Counsel, Christopher Ulrich, M. D., Chairman
Care of Health Care Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Petition for adjusted need determination for additional operating rooms in Pitt/Greene/Hyde/Tyrell and Craven/Jones/Pamlico operating room service areas by Eastern Nephrology Associates, PLLC and Fresenius Vascular Care, Inc. also known as Azura Vascular Care.

Dear Dr. Ulrich,

I am a practicing nephrologist and partner at Eastern Nephrology Associates, PLLC (ENA), which provides eastern North Carolina's most comprehensive nephrology care. Our practice delivers state of the art medical management and intervention to patients with end-stage renal disease, chronic kidney disease, kidney transplants and performs vascular access procedures for patients with these diseases. I am writing to support the above-referenced petition for adjusted need determination for one additional operating room in the Pitt/Greene/Hyde/Tyrrell operating room service area as well as one additional operating room in the Craven/Jones/Pamlico operating room service area.

Eastern Nephrology Associates currently takes care of 1,300 patients on dialysis. As you, I am sure are aware, the most critical and important piece of a dialysis patient's health care is having a functional dialysis access. Over 300,000 people are on dialysis in our country and nearly 12,000 in North Carolina alone. These dialysis accesses require routine maintenance as well as semi-urgent interventions to allow patients not to miss routine dialysis treatments.

As part of the comprehensive care my practice provides to kidney patients, we provide vascular access care and maintenance at offices at both Greenville in Pitt County and New Bern in Craven County. These vascular access centers are highly specialized and dedicated to making sure that dialysis patients get timely declot of clotted accesses when necessary and are able to coordinate their dialysis on an expedited manner. Additionally, for routine maintenance of these accesses, these vascular access staffs are highly coordinated and work with the dialysis centers to make sure that patients do not miss dialysis treatments. It is well documented that missing dialysis treatments is associated with increased hospitalizations and increased risk of mortality.

Eastern Nephrology Associates is actively participating with Center for Medicare Services on a national project as an ESCO (which is end-stage renal disease seamless care organizations). The goal of this pilot is to improve the quality of care delivered to end-stage renal disease patients while simultaneously reducing costs to the system at large, which is CMS. We believe that fine tuning the outpatient management of dialysis patients' access through a dedicated ASC in the above-mentioned areas would greatly improve quality and decrease costs.

Since 2017, unfortunately the cost of performing dialysis access procedures in the office setting has increased substantially. This is primarily due to Medicare reimbursement cuts. As a result Eastern Nephrology Associates cannot sustain the continued revenue differential indefinitely. Unfortunately, despite the large volume of surgical procedures needed by our patients, Eastern Nephrology would not be able to apply for a CON for an ambulatory surgical facility under proposed 2019 state medical facilities plan as currently drafted because the OR methodology does not show a need for any new operating rooms in Pitt or Craven County or any other nearby counties.

Unless our existing vascular access centers can be licensed as ASCs, these procedures will ultimately have to be referred to local hospitals which would inundate and swamp these hospital's ability to take care of the complex and specialized care required for care of dialysis patient access care. The quality of care provided to the patient in this situation would be much more expensive and outcomes would almost certainly be less optimal. Furthermore hospitals are reimbursed at much higher rates than either physical offices or ASCs, thus the overall cost of doing these procedures would rise incrementally.

The requested adjusted need determination would reduce the cost of care for dialysis patients by helping to insure timely interventions and preventing

unnecessary hospitalizations by allow dialysis access procedures to be done. This would be accomplished through allowing dialysis access procedures to be performed in a less expensive ASC setting. It will also improve coordination of care between patients and dialysis center and result in better outcomes for dialysis patients compared to providing this care in hospitals. In addition, because most dialysis access procedures have been provided in unlicensed physician offices in the past, allowing requested need determination will not adversely affect hospitals or any existing ASCs.

In conclusion, I reiterate the unique characteristics of dialysis patients and maintaining these dialysis accesses or shunts justifies an adjusted need determination for an additional OR in the Pitt/Greene/Hyde/Tyrell OR service area as well as in the Craven/Jones/Pamlico OR service area for the purpose of providing vascular access procedures in a licensed regulated ASC.

If you have any questions or concerns regarding these instructions, please don't hesitate to contact me.

Sincerely,



Maxwell E. Fisher, M. D.
Partner Eastern Nephrology Associates
Greenville, North Carolina
MEF/gc

cc: Carney Taylor, M. D.
Original copy to Martha

Date Dictated: 08/01/2018

Date Transcribed: 08/01/2018



EASTERN NEPHROLOGY ASSOCIATES

ENA Physician Support Letter

July 24, 2018

State Health Coordinating Council
Christopher Ullrich, MD, Chairman
c/o Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Petition for Adjusted Need Determination for Additional Operating Rooms in Pitt/Greene/Hyde/Tyrell and Craven/Jones/Pamlico Operating Room Service Areas by Eastern Nephrology Associates, PLLC and Fresenius Vascular Care, Inc. d/b/a Azura Vascula Care

Dear Dr. Ullrich,

I am a practicing nephrologist and the managing partner of Eastern Nephrology Associates, PLLC (ENA), which provides eastern North Carolina's most comprehensive nephrology care.

Our nephrologists and advanced care practitioners deliver state-of-the-art medical management and intervention to patients with End Stage Kidney Disease, chronic kidney disease, kidney transplants and vascular access. I am writing to support the above-referenced petition for an adjusted need determination for one additional operating room in the Pitt/Greene/Hyde/Tyrell Operating Room Service Area and one additional operating room in the Craven/Jones/Pamlico OR Service Area.

ENA currently has 1300 ESRD patients who must have a functioning dialysis access receive hemodialysis to replace their lost kidney function. We support the petition for an adjusted need determination to allow for the development of a licensed ambulatory surgery center with a special purpose OR for vascular access procedures. Dialysis patients have unique and complex needs and benefit greatly from the coordinated care that only a dedicated vascular access center provides, and hospital surgical departments and traditional ASCs are not well suited to this population.

As part of the comprehensive care we provide to kidney patients, ENA provides vascular access maintenance and repair procedures at its offices in Greenville and New Bern. By providing these procedures in a dedicated setting with specialized staff, we have been able to provide very timely interventions, which benefit our patients by reducing their morbidity and mortality. ENA is also actively participating with CMS (Center for Medicare Services) in a national pilot project called an ESCO (End Stage Renal Disease Seamless Care Organization) whereby the goal is to improve the quality of care delivered to the patient while simultaneously reducing the cost of that care to the payer (CMS and the American tax payer). ENA is held personally accountable for both the quality and cost of the care we deliver. Based on our experience, we must be able to perform these procedures in an outpatient setting to achieve the quality outcomes and cost control that our citizens deserve.

However, since 2017 the cost of performing dialysis access procedures in the office setting has increased and is now greater than Medicare reimbursement for those procedures. ENA

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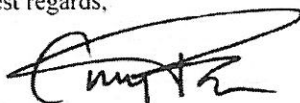
cannot sustain the loss from providing these procedures indefinitely. Unfortunately, despite the large volume of surgical procedures needed by ENA's patients, ENA would not be eligible to apply for a CON for an ambulatory surgical facility under the Proposed 2019 State Medical Facilities Plan as currently drafted because the OR methodology does not show a need for any new ORs in Pitt County, Craven County or any other nearby counties.

Unless our existing vascular access centers can be licensed as ASCs, these procedures will ultimately have to be referred to local hospitals, but local hospitals are not equipped to accommodate the urgent and specialized nature of these vascular cases. The quality of care provided to the patient would likely decline and the need for hospitalization would rise. Furthermore, hospitals are reimbursed at much higher rates than either physician offices or ASCs. For these reasons, the overall cost of caring for these patients would undoubtedly rise.

The requested adjusted need determination would reduce the cost of care for dialysis patients by helping to ensure timely interventions and preventing unnecessary hospitalizations and by allowing dialysis access procedures to be done in a less expensive ASC setting. It would also improve coordination of care and result in better patient outcomes for dialysis patients compared with providing this care in hospitals. In addition, because most dialysis access procedures have been provided in unlicensed physician offices in the past, allowing the requested adjusted need determination will not adversely affect hospitals or any existing ASCs.

In conclusion, I reiterate the unique characteristics of dialysis patients justify an adjusted need determination for an additional OR in the Pitt/Greene/Hyde/Tyrell OR service area and the Craven/Jones/Pamlico OR service area for the purpose of providing vascular access procedures in a licensed, regulated ASC.

Best regards,



Carney Taylor MD
Managing Partner
Eastern Nephrology Associates



EASTERN NEPHROLOGY ASSOCIATES

August 6, 2018

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State Health Coordinating Council
Christopher Ullrich, MD, Chairman
c/o Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Petition for Adjusted Need Determination for Additional Operating Rooms in Pitt/Greene/Hyde/Tyrell and Craven/Jones/Pamlico Operating Room Service Areas by Eastern Nephrology Associates, PLLC and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care

Dear Dr. Ullrich,

I am a nephrologist, and partner, practicing with Eastern Nephrology Associates, PLLC (ENA), which provides eastern North Carolina's most comprehensive nephrology care. I am Medical Director of Craven County Dialysis Incenter and also the Home Therapies Program which includes the Home Therapies Department at Sea Spray Dialysis. Our nephrologists and advanced care practitioners deliver state-of-the-art medical management and intervention to patients with End Stage Kidney Disease, chronic kidney disease, kidney transplants and vascular access. I am writing to support the above-referenced petition for an adjusted need determination for one additional operating room in the Pitt/Greene/Hyde/Tyrell Operating Room Service Area and one additional operating room in the Craven/Jones/Pamlico OR Service Area.

ENA currently has 1300 ESRD patients who must have a functioning dialysis access receive hemodialysis to replace their lost kidney function. We support the petition for an adjusted need determination to allow for the development of a licensed ambulatory surgery center with a special purpose OR for vascular access procedures. Dialysis patients have unique and complex needs and benefit greatly from the coordinated care that only a dedicated vascular access center provides, and hospital surgical departments and traditional ASCs are not well suited to this population.

As part of the comprehensive care we provide to kidney patients, ENA provides vascular access maintenance and repair procedures at its offices in Greenville, New Bern and Kinston. By providing these procedures in a dedicated setting with specialized staff, we have been able to provide very timely interventions, achieve positive outcomes and reduce rates of

State Health Coordinating Council
Christopher Ullrich, MD, Chairman
c/o Healthcare Planning and Certificate of Need Section
August 6, 2018
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Re: Petition for Adjusted Need Determination for Additional Operating Rooms in Pitt/Greene/Hyde/Tyrell and Craven/Jones/Pamlico Operating Room Service Areas by Eastern Nephrology Associates, PLLC and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care

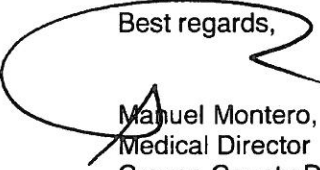
complications. However, since 2017 the cost of performing dialysis access procedures in the office setting is now greater than Medicare reimbursement for those procedures, and ENA cannot sustain the loss from these procedures indefinitely. Unfortunately, despite the large volume of surgical procedures needed by ENA's patients, ENA would not be eligible to apply for a CON for an ambulatory surgical facility under the Proposed 2019 State Medical Facilities Plan as currently drafted because the OR methodology does not show a need for any new ORs in Pitt County, Craven County or any other nearby counties.

Unless our existing vascular access centers can be licensed as ASCs, these procedures will ultimately be referred to as hospitals, which are reimbursed at much higher rates than either physician offices or ASCs. Also, hospitals do not specialize in dialysis access care and usually cannot accommodate urgent cases as quickly as a specialized dialysis access facility, which compromises patient outcomes and increases the chances of hospitalization.

As a result, the requested adjusted need determination would reduce the cost of care for dialysis patients by helping to ensure timely interventions and preventing unnecessary hospitalizations and by allowing dialysis access procedures to be done in a less expensive ASC setting. It would also improve coordination of care and result in better patient outcomes for dialysis patients compared with providing this care in hospitals. In addition, because most dialysis access procedures have been provided in unlicensed physician offices in the past, allowing the requested adjusted need determination will not adversely affect hospitals or any existing ASCs.

In conclusion, I reiterate the unique characteristics of dialysis patients justify an adjusted need determination for an additional OR in the Pitt/Greene/Hyde/Tyrell OR service area and the Craven/Jones/Pamlico OR service area for the purpose of providing vascular access procedures in a licensed, regulated ASC.

Best regards,


Manuel Montero, MD
Medical Director
Craven County Dialysis and
Craven County Home Therapies Program

MM:dwr



EASTERN NEPHROLOGY ASSOCIATES

August 1, 2018

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ENA currently has 1300 ESRD patients who must have a functioning dialysis access to receive hemodialysis to replace their lost kidney function. We support the petition for an adjusted need determination to allow for the development of a licensed ambulatory surgery center with a special purpose OR for vascular access procedures. Dialysis patients have unique and complex needs and benefit greatly from the coordinated care that only a dedicated vascular access center provides, and hospital surgical departments and traditional ASCs are not well suited to this population.

As part of the comprehensive care we provide to kidney patients, ENA provides vascular access maintenance and repair procedures

State Health Coordinating Council
Christopher Ullrich, MD, Chairman
August 1, 2018
Page 2 of 3

Re: Petition for Adjusted Need Determination for Additional Operating Rooms in Pitt/Greene/Hyde/Tyrell and Craven/Jones/Pamlico Operating Room Service Areas by Eastern Nephrology Associates, PLLC and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care

at its offices in Greenville, New Bern and Kinston. By providing these procedures in a dedicated setting with specialized staff, we have been able to provide very timely interventions, achieve positive outcomes and reduce rates of complications. However, since 2017 the cost of performing dialysis access procedures in the office setting is now greater than Medicare reimbursement for those procedures, and ENA cannot sustain the loss from these procedures indefinitely. Unfortunately, despite the large volume of surgical procedures needed by ENA's patients, ENA would not be eligible to apply for a CON for an ambulatory surgical facility under the Proposed 2019 State Medical Facilities Plan as currently drafted because the OR methodology does not show a need for any new ORs in Pitt County, Craven County or any other nearby counties.

Unless our existing vascular access centers can be licensed as ASCs, these procedures will ultimately be referred to as hospitals, which are reimbursed at much higher rates than either physician offices or ASCs. Also, hospitals do not specialize in dialysis access care and usually cannot accommodate urgent cases as quickly as a specialized dialysis access facility, which compromises patient outcomes and increases the chances of hospitalization.

As a result, the requested adjusted need determination would reduce the cost of care for dialysis patients by helping to ensure timely interventions and preventing unnecessary hospitalizations and by allowing dialysis access procedures to be done in a less expensive ASC setting. It would also improve coordination of care and result in better patient outcomes for dialysis patients compared with providing this care in hospitals. In addition, because most dialysis access procedures have been provided in unlicensed physician offices in the past, allowing the requested adjusted need determination will not adversely affect hospitals or any existing ASCs.


In conclusion, I reiterate the unique characteristics of dialysis patients justify an adjusted need determination for an additional OR in the Pitt/Greene/Hyde/Tyrell OR service area and the

State Health Coordinating Council
Christopher Ullrich, MD, Chairman
August 1, 2018
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**Re: Petition for Adjusted Need Determination for Additional
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Craven/Jones/Pamlico Operating Room Service Areas by
Eastern Nephrology Associates, PLLC and Fresenius Vascular
Care, Inc. d/b/a Azura Vascular Care**

Craven/Jones/Pamlico OR service area for the purpose of providing
vascular access procedures in a licensed, regulated ASC.

Best regards,


W. Joseph Newman, MD
Medical Director
Crystal Coast Dialysis

WJN:dwr



EASTERN NEPHROLOGY ASSOCIATES

August 6, 2018

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Dear Dr. Ullrich,

I am a nephrologist practicing with Eastern Nephrology Associates, PLLC (ENA), which provides eastern North Carolina's most comprehensive nephrology care. We have somewhere around 20 physicians. I was the third physician in this group, joining in 1978, so I have some perspective on care of patients, with particular reference to trying to provide excellent care and keep them out of the hospital.

I am writing to support the above referenced petition for an adjusted need determination for an additional operating room in the Pitt/Greene/Hyde/Tyrell operating room service area and one additional operating room in the Craven/Jones/Pamlico operating room service area.

When I started doing nephrology in eastern North Carolina there were three of us basically, with another physician in Wilson and another physician in Wilmington. We had 110 patients and we serviced everything to the coast as there were no other nephrologists. Since then, the group I am with has grown to some 20-odd physicians with over 1,000 patients. This does not even include patients with chronic kidney disease approaching dialysis or transplant patients.

One of the major problems that nephrologists had for many years has been that of adequate access for those hemodialysis patients. Obviously, we have many peritoneal dialysis patients, but the great majority of patients in this country still are on hemodialysis.

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Christopher Ullrich, MD, Chairman
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Eastern Nephrology Associates, PLLC and Fresenius Vascular
Care, Inc. d/b/a Azura Vascular Care**

When I started, it wasn't uncommon, even back in 1978, to have 10 patients in the hospital with access problems. This included accesses that were just not functioning adequately, or accesses that clotted and needed to have work done by the surgeons and/or radiologists.

The institution of outpatient dialysis access work has revolutionized the care of patients.

Unfortunately, although I esteem my surgical and radiology colleagues, such work is not considered very "sexy". Nevertheless, it is a patient's lifeline, and when an access is having problems, getting to it immediately and performing needed interventions enables that patient to stay out of the hospital and continue their life. There is no question that access is a tremendous expense and by being aggressive we can lower the expense for end stage renal disease and still provide excellent care for these people.

We have an access center and we have utilized it for over five years to the betterment of our patients. Unfortunately, Medicare has seen fit to decrease the reimbursement for these procedures to where it is becoming difficult to sustain doing these procedures in the office setting. That is ridiculous, obviously, since the alternative is doing them in the hospital setting or admitting the patient to the hospital; nevertheless, that is the current situation.

One way for us to continue working with these patients would be to have our facility designated as an ambulatory surgical facility. This would allow us to continue treating these patients in an office setting, providing the same quality of care and outcomes as can be done in a hospital setting at a vastly decreased cost.

I appreciate the opportunity to correspond with you and would appreciate your careful consideration of this request.

Sincerely,



Thomas E. Burkart, MD
TEB:dwr



EASTERN NEPHROLOGY ASSOCIATES

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State Health Coordinating Council
Christopher Ullrich, MD, Chairman
c/o Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Petition for Adjusted Need Determination for Additional Operating Rooms in Pitt/Greene/Hyde/Tyrell and Craven/Jones/Pamlico Operating Room Service Areas by Eastern Nephrology Associates, PLLC and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care

Dear Dr. Ullrich,

I am a partner at Eastern Nephrology Associates (ENA) and Medical Director of our 2 vascular access centers, Azura Vascular Care of Greenville and Azura Vascular Care of New Bern, NC. ENA is a nephrology practice with 16 general nephrologists, 3 interventional nephrologists, and 1 interventional radiologist. ENA provides eastern North Carolina's most comprehensive nephrology care. Our nephrologists and advanced care practitioners deliver state-of-the-art medical management and intervention to patients with End Stage Renal Disease (ESRD), chronic kidney disease, kidney transplants and vascular access. I am writing to support the above-referenced petition for an adjusted need determination for one additional operating room in the Pitt/Greene/Hyde/Tyrell Operating Room Service Area and one additional operating room in the Craven/Jones/Pamlico OR Service Area.

Our two unlicensed, office-based centers allow us to manage the vascular access care of ENA's 1300 ESRD patients as well as several hundred ESRD patients managed by other practices in Eastern NC, from the South Carolina to Virginia border. Because such patients must have a functioning dialysis access to receive hemodialysis to replace their lost kidney function, ESRD patients have unique and complex needs that benefit greatly from the coordinated care that our dedicated access centers provide. In contrast, we believe that hospital surgical departments and traditional ASCs are not well suited to this population. As a result, we support the petition for an adjusted need determination to allow for the development of a licensed ambulatory surgery center with a special purpose OR for vascular access procedures.

With a specialized staff and dedicated and singular focus on ESRD vascular access care, our access centers have been able to provide very timely interventions, achieve positive outcomes, and reduce rates of complications. However, since 2017 the cost of performing dialysis access procedures in the office setting has been greater than Medicare reimbursement for such procedures. ENA cannot sustain the loss from these procedures indefinitely. Unfortunately, despite the large volume of surgical procedures needed by ENA's patients, ENA would not be eligible to apply for a CON for an ambulatory surgical facility under the Proposed 2019 State

Medical Facilities Plan as currently drafted because the OR methodology does not show a need for any new ORs in Pitt County, Craven County or any other nearby counties.

Unless our existing vascular access centers can be licensed as ASCs, these procedures will ultimately be referred to our local hospitals, which are reimbursed at much higher rates than either physician offices or ASCs. Additionally, our hospitals do not specialize in dialysis access care and usually cannot accommodate urgent cases as quickly as a specialized dialysis access facility, compromising patient outcomes and increasing the chances of hospitalization. Ultimately, hospital-based vascular access care would compromise our current participation in the End-Stage Renal Disease Seamless Care Organization (ESCO), in which ENA is responsible for not only improving the quality of ESRD care but also reducing the costs of such care to the Centers for Medicare Services.

The requested adjusted need determination would reduce the cost of care for dialysis patients by ensuring timely interventions, preventing unnecessary hospitalizations, and allowing dialysis access procedures to be done in a less expensive ASC setting. It would also improve coordination of care and result in better patient outcomes for dialysis patients compared to providing this care in hospitals. Lastly, because most dialysis access procedures have been provided in unlicensed physician offices in the past, allowing the requested adjusted need determination will not adversely affect hospitals or any existing ASCs.

In conclusion, I reiterate the unique characteristics of dialysis patients justify an adjusted need determination for an additional OR in the Pitt/Greene/Hyde/Tyrell OR service area and the Craven/Jones/Pamlico OR service area for the purpose of providing vascular access procedures in a licensed, regulated ASC.

Best regards,

Richard Blair, MD

Richard Blair, MD
Medical Director, Azura Vascular Care of Greenville and New Bern



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ENA Physician Support Letter

August 7, 2018

State Health Coordinating Council

Christopher Ullrich, MD, Chairman

c/o Healthcare Planning and Certificate of Need Section

2704 Mail Service Center

Raleigh, NC 27699-2704

Re: Petition for Adjusted Need Determination for Additional Operating Rooms in Pitt/Greene/Hyde/Tyrell and Craven/Jones/Pamlico Operating Room Service Areas by Eastern Nephrology Associates, PLLC and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care

Dear Dr. Ullrich,

I am a practicing nephrologist and a partner of Eastern Nephrology Associates, PLLC (ENA), which provides eastern North Carolina's most comprehensive nephrology care. Our nephrologists and advanced care practitioners deliver state-of-the-art medical management and intervention to patients with End Stage Kidney Disease, chronic kidney disease, kidney transplants and vascular access. I am writing to support the above-referenced petition for an adjusted need determination for one additional operating room in the Pitt/Greene/Hyde/Tyrell Operating Room Service Area and one additional operating room in the Craven/Jones/Pamlico OR service area.

ENA currently has 1300 ESRD patient who must have a functioning dialysis access to receive hemodialysis to replace their lost kidney function. We support the petition for an adjusted need determination to allow for the development of a licensed

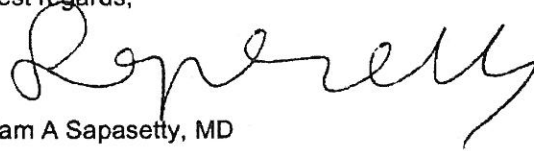
ambulatory surgery center with a special purpose OR for vascular access procedures. Dialysis patients have unique and complex needs and benefit greatly from the coordinated care that only a dedicated vascular access center provides, and hospital surgical departments and traditional ASCs are not well suited to this population.

As part of the comprehensive care we provide to kidney patients, ENA provides vascular access maintenance and repair procedures at its offices in Greenville and New Bern. By providing these procedures in a dedicated setting with specialized staff, we have been able to provide very timely interventions, which benefit our patients by reducing their morbidity and mortality. ENA is also actively participating with CMS (Center for Medicare Services) in a national pilot project called an ESCO (End Stage Renal Disease Seamless Care Organization) whereby the goal is to improve the quality of care delivered to the patient while simultaneously reducing the cost of that care to the payer (CMS and the American tax payer). ENA is held personally accountable for both the quality and cost of the care we deliver. Based on our experience, we must be able to perform these procedures in an outpatient setting to achieve the quality outcomes and cost control that our citizens deserve. However, since 2017, the cost of performing dialysis access procedures in the office setting has increased and is now greater than Medicare reimbursement for those procedures. Also, hospitals do not specialize in dialysis access care and usually cannot accommodate urgent cases quickly as a specialized dialysis access facility can., This compromises patient outcomes and increases the chances of hospitalization. Especially in rural areas like Kinston and Snow Hill, the ESRD patients have serious problems with transportation and a delay of the vascular procedures leads to missed dialysis treatments, increase risk of complications related to ESRD. The proximity and availability of these procedures are very crucial.

As a result, the requested adjusted need determination would reduce the cost of care for dialysis patients by helping to ensure timely interventions and preventing unnecessary hospitalizations and by allowing dialysis access procedures to be done in a less expensive ASC setting. It would also improve coordination of care and result in better patient outcomes for dialysis patients compared with providing this care in hospitals. In addition, because most dialysis access procedures have been provided in unlicensed physician offices in the past, allowing the requested adjusted need determination will not adversely affect hospital or any existing ASCs.

In conclusion, I reiterate the unique characteristics of dialysis patients justify an adjusted need determination for an additional OR in the Pitt/Greene, Hyde, Tyrell OR service area and the Craven/Jones/Pamlico OR service area for the purpose of providing vascular access procedures in a licensed, regulated ASC.

Best regards,

A handwritten signature in black ink, appearing to read "R. Sapasetty". The signature is written in a cursive, flowing style with a large initial "R" and a long, sweeping tail.

Ram A Sapasetty, MD



EASTERN NEPHROLOGY ASSOCIATES

August 8, 2018

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State Health Coordinating Council
Christopher Ullrich, MD, Chairman
c/o Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Petition for Adjusted Need Determination for Additional Operating Rooms in Pitt/Greene/Hyde/Tyrell and Craven/Jones/Pamlico Operating Room Service Areas by Eastern Nephrology Associates, PLLC and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care

Dear Dr. Ullrich,

I am a nephrologist, and partner, practicing with Eastern Nephrology Associates, PLLC (ENA), which provides eastern North Carolina's most comprehensive nephrology care. Also, I am Medical Director of Sea Spray Dialysis Unit. Our nephrologists and advanced care practitioners deliver state-of-the-art medical management and intervention to patients with End Stage Kidney Disease, chronic kidney disease, kidney transplants and vascular access. I am writing to support the above-referenced petition for an adjusted need determination for one additional operating room in the Pitt/Greene/Hyde/Tyrell Operating Room Service Area and one additional operating room in the Craven/Jones/Pamlico OR Service Area.

ENA currently has 1300 ESRD patients who must have a functioning dialysis access to receive hemodialysis to replace their lost kidney function. We support the petition for an adjusted need determination to allow for the development of a licensed ambulatory surgery center with a special purpose OR for vascular access procedures. Dialysis patients have unique and complex needs and benefit greatly from the coordinated care that only a dedicated vascular access center provides, and hospital surgical departments and traditional ASCs are not well suited to this population.

As part of the comprehensive care we provide to kidney patients, ENA provides vascular access maintenance and repair procedures at its offices in Greenville, New Bern and Kinston. By providing these procedures in a dedicated setting with specialized staff, we have been able to provide very

State Health Coordinating Council
Christopher Ullrich, MD, Chairman
c/o Healthcare Planning and Certificate of Need Section
August 6, 2018
Page 2 of 2

Re: Petition for Adjusted Need Determination for Additional Operating Rooms in Pitt/Greene/Hyde/Tyrell and Craven/Jones/Pamlico Operating Room Service Areas by Eastern Nephrology Associates, PLLC and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care

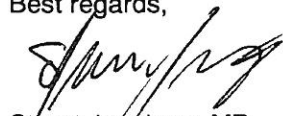
timely interventions, achieve positive outcomes and reduce rates of complications. However, since 2017 the cost of performing dialysis access procedures in the office setting is now greater than Medicare reimbursement for those procedures, and ENA cannot sustain the loss from these procedures indefinitely. Unfortunately, despite the large volume of surgical procedures needed by ENA's patients, ENA would not be eligible to apply for a CON for an ambulatory surgical facility under the Proposed 2019 State Medical Facilities Plan as currently drafted because the OR methodology does not show a need for any new ORs in Pitt County, Craven County or any other nearby counties.

Unless our existing vascular access centers can be licensed as ASCs, these procedures will ultimately be referred to as hospitals, which are reimbursed at much higher rates than either physician offices or ASCs. Also, hospitals do not specialize in dialysis access care and usually cannot accommodate urgent cases as quickly as a specialized dialysis access facility, which compromises patient outcomes and increases the chances of hospitalization.

As a result, the requested adjusted need determination would reduce the cost of care for dialysis patients by helping to ensure timely interventions and preventing unnecessary hospitalizations and by allowing dialysis access procedures to be done in a less expensive ASC setting. It would also improve coordination of care and result in better patient outcomes for dialysis patients compared with providing this care in hospitals. In addition, because most dialysis access procedures have been provided in unlicensed physician offices in the past, allowing the requested adjusted need determination will not adversely affect hospitals or any existing ASCs.

In conclusion, I reiterate the unique characteristics of dialysis patients justify an adjusted need determination for an additional OR in the Pitt/Greene/Hyde/Tyrell OR service area and the Craven/Jones/Pamlico OR service area for the purpose of providing vascular access procedures in a licensed, regulated ASC.

Best regards,



Stuart Jennings, MD
Medical Director
Sea Spray Dialysis

SJ:dwr



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August 7, 2018

Eastern Nephrology Associates Physician Support Letter
State Health Coordinating Counsel, Christopher Ulrich, M. D., Chairman
Care of Health Care Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Petition for adjusted need determination for additional operating rooms in Pitt/Greene/Hyde/Tyrell and Craven/Jones/Pamlico operating room service areas by Eastern Nephrology Associates, PLLC and Fresenius Vascular Care, Inc. also known as Azura Vascular Care.

Dear Dr. Ulrich,

I am a practicing nephrologist and partner at Eastern Nephrology Associates, PLLC (ENA), which provides eastern North Carolina's most comprehensive nephrology care. Our practice delivers state of the art medical management and intervention to patients with end-stage renal disease, chronic kidney disease, kidney transplants and performs vascular access procedures for patients with these diseases. I am writing to support the above-referenced petition for adjusted need determination for one additional operating room in the Pitt/Greene/Hyde/Tyrrell operating room service area as well as one additional operating room in the Craven/Jones/Pamlico operating room service area.

Eastern Nephrology Associates currently takes care of 1,300 patients on dialysis. As you, I am sure are aware, the most critical and important piece of a dialysis patient's health care is having a functional dialysis access. Over 300,000 people are on dialysis in our country and nearly 12,000 in North Carolina alone. These dialysis accesses require routine maintenance as well as semi-urgent interventions to allow patients not to miss routine dialysis treatments.

As part of the comprehensive care my practice provides to kidney patients, we provide vascular access care and maintenance at offices at both Greenville in Pitt County and New Bern in Craven County. These vascular access centers are highly specialized and dedicated to making sure that dialysis patients get timely declot of clotted accesses when necessary and are able to coordinate their dialysis on an expedited manner. Additionally, for routine maintenance of these accesses, these vascular access staffs are highly coordinated and work with the dialysis centers to make sure that patients do not miss dialysis treatments. It is well documented that missing dialysis treatments is associated with increased hospitalizations and increased risk of mortality.

Eastern Nephrology Associates is actively participating with Center for Medicare Services on a national project as an ESCO (which is end-stage renal disease seamless care organizations). The goal of this pilot is to improve the quality of care delivered to end-stage renal disease patients while simultaneously reducing costs to the system at large, which is CMS. We believe that fine tuning the outpatient management of dialysis patients' access through a dedicated ASC in the above-mentioned areas would greatly improve quality and decrease costs.

Since 2017, unfortunately the cost of performing dialysis access procedures in the office setting has increased substantially. This is primarily due to Medicare reimbursement cuts. As a result Eastern Nephrology Associates cannot sustain the continued revenue differential indefinitely. Unfortunately, despite the large volume of surgical procedures needed by our patients, Eastern Nephrology would not be able to apply for a CON for an ambulatory surgical facility under proposed 2019 state medical facilities plan as currently drafted because the OR methodology does not show a need for any new operating rooms in Pitt or Craven County or any other nearby counties.

Unless our existing vascular access centers can be licensed as ASCs, these procedures will ultimately have to be referred to local hospitals which would inundate and swamp these hospitals' ability to take care of the complex and specialized care required for care of dialysis patient access care. The quality of care provided to the patient in this situation would be much more expensive and outcomes would almost certainly be less optimal. Furthermore hospitals are reimbursed at much higher rates than either physical offices or ASCs, thus the overall cost of doing these procedures would rise incrementally.

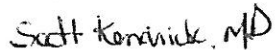
The requested adjusted need determination would reduce the cost of care for dialysis patients by helping to insure timely interventions and preventing

unnecessary hospitalizations by allow dialysis access procedures to be done. This would be accomplished through allowing dialysis access procedures to be performed in a less expensive ASC setting. It will also improve coordination of care between patients and dialysis center and result in better outcomes for dialysis patients compared to providing this care in hospitals. In addition, because most dialysis access procedures have been provided in unlicensed physician offices in the past, allowing requested need determination will not adversely affect hospitals or any existing ASCs.

In conclusion, I reiterate the unique characteristics of dialysis patients and maintaining these dialysis accesses or shunts justifies an adjusted need determination for an additional OR in the Pitt/Greene/Hyde/Tyrell OR service area as well as in the Craven/Jones/Pamlico OR service area for the purpose of providing vascular access procedures in a licensed regulated ASC.

If you have any questions or concerns regarding these instructions, please don't hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Scott Kendrick, MD". The signature is written in a cursive, slightly slanted style.

Scott Kendrick, M. D.
Partner Eastern Nephrology Associates
Greenville, North Carolina

cc: Original copy to Martha