

TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL

**PETITION BY PRESBYTERIAN MEDICAL CARE CORPORATION d/b/a
NOVANT HEALTH MATTHEWS MEDICAL CENTER
TO INCLUDE A NEED DETERMINATION FOR ONE UNIT OF FIXED CARDIAC
CATHETERIZATION EQUIPMENT IN MECKLENBURG COUNTY
IN THE 2022 STATE MEDICAL FACILITIES PLAN**

July 28, 2021

Via Email: DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

1. Name, address, email address and phone number of Petitioners:

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Overview

Presbyterian Medical Care Corporation d/b/a Novant Health Matthews Medical Center (“Novant Health Matthews” or “Petitioner”) hereby submits this Petition for an adjusted need determination to include one (1) unit of cardiac catheterization equipment in Mecklenburg County in the 2022 State Medical Facilities Plan (“SMFP”).

Novant Health Matthews first opened its doors in the town of Matthews, a suburb of Charlotte, in August 1994. Although it has undergone many service expansions over time, Novant Health Matthews has steadfastly maintained its commitment to providing remarkable care to all patients in a patient-friendly environment that is easy to access and navigate. As a community hospital, Novant Health Matthews focuses on providing a comfortable, home-like environment. Novant Health Matthews offers emergency department services, radiology, outpatient and inpatient surgery, laboratory service, intensive care and maternity care, among other services. Novant Health Matthews is licensed for 154 acute care beds, yet it only has one fixed unit of cardiac catheterization equipment to serve its many cardiac patients.

One of the most important aspects of Novant Health Matthews’ mission is to improve its community through dedicated outreach, including partnering with multiple agencies and organizations to extend health and wellness services to the community, sponsoring health and wellness-focused events and offering free health fairs and events. Matthews is a rapidly growing

area of Mecklenburg County in a densely populated and growing part of the State. Since 2010, the population of Matthews has grown over 25%.¹

Since 2016, utilization of cardiac catheterization equipment at Novant Health Matthews has been rapidly increasing. In Federal Fiscal Year (“FFY”) 2018, utilization exceeded 1,200 procedures, *i.e.*, 80% of 1,500 diagnostic equivalent procedures used in the SMFP methodology to determine the need for additional equipment in a health planning service area. See Exhibit A, attached hereto, an analysis of historical and projected cardiac catheterization growth at Novant Health Matthews; Proposed 2022 SMFP at pp. 312-13. In both FFY 2019 and 2020, utilization exceeded the State defined capacity of a unit of cardiac catheterization equipment, which is 1,500 weighted procedures per year. See Exhibit A; 10A NCAC 14C.1601(2). As demonstrated below, due to its heavy volume and robust utilization, an additional unit of cardiac catheterization equipment is needed at Novant Health Matthews in order to allow the facility to meet the needs of the patients it serves.

2. Statement of the requested adjustment, citing the provision or need determination within the Proposed SMFP for which the adjustment is proposed.

Novant Health Matthews respectfully requests that an adjusted need determination for one (1) additional unit of fixed cardiac catheterization equipment in Mecklenburg County be included in the 2022 SMFP.

3. Reasons for the proposed change, including:

Even where the projections in a proposed SMFP do not show a need calculated for an additional piece of technology and equipment, summer petitions provide an opportunity for petitioners to seek adjusted need determination:

Summer petitions and Agency proposals. Summer petitions involve requests for adjustments to need determinations in the Proposed SMFP. Petitioners may submit a written petition requesting an adjustment to the need determination in the Proposed SMFP if they believe that special attributes of a service area or institution give rise to resource requirements that differ from those provided by the standard methodologies and policies. The Agency may also seek adjusted need determinations during this time. [REDACTED]

Excerpt from Proposed 2022 SMFP at p. 8. As demonstrated in this Petition, such unique circumstances exist here where Novant Health Matthews’ consistent, robust utilization warrants the addition of a need determination for one additional unit of cardiac catheterization equipment in Mecklenburg County.

¹ <https://worldpopulationreview.com/us-cities/matthews-nc-population>.

Cardiac Catheterization Services

Cardiac catheterization is a vital tool utilized to both diagnose and treat certain cardiovascular conditions, including heart attacks.² Cardiac catheterization has become a critical tool in the emergent treatment of patients experiencing ST-Elevation Myocardial Infarction (“STEMI”) heart attacks, where a patient suffers a complete blockage of the coronary artery. A STEMI heart attack is colloquially referred to as a “widow maker,” *i.e.*, a potentially fatal event.³ For these patients in particular, seconds count and immediate treatment through percutaneous coronary intervention (“PCI”) is necessary to save lives and minimize damage to the heart. See Declaration of Gary Stewart Niess, M.D. (“Dr. Niess Decl.”) at 5, attached hereto as Exhibit B. Novant Health Matthews is the first STEMI program located at a Mecklenburg County facility without on-site cardiovascular surgery. Declaration of Gabriel A. Delgado, M.D. (“Dr. Delgado Decl.”) at 4, attached hereto as Exhibit C.

The cardiac catheterization lab at Novant Health Matthews also serves adult patients experiencing chest pain, myocardial infarction, peripheral vascular disease, congestive heart failure, acute coronary syndrome, pulmonary embolus, pulmonary hypertension, valvular dysfunction, rhythm disturbances, and deep vein thrombosis (“DVT”) diseases, among other conditions. See Declaration of Eileen Ciotti (“Ciotti Decl.”) at 6, attached hereto as Exhibit D.

While many procedures utilizing the cardiac catheterization equipment are diagnostic, approximately half of those weighted procedures are interventional, meaning patients have an urgent condition that must be treated or repaired through this procedure. See Exhibit A.

Growth in Demand for Cardiac Catheterization at Novant Health Matthews

As both population (particularly the age 65 and older population) and other services at Novant Health Matthews have grown over the years, so has the demand for cardiac catheterization services. Novant Health Matthews has also focused on expanding its cardiology services and recruiting cardiologists in the Matthews area of Mecklenburg County, where residents would otherwise have to travel long distances across the county and into or through Charlotte to receive emergent cardiac catheterization services. Thus, this program ensures that the areas outside of Charlotte have immediate access to life-saving cardiac services where time is of the essence. See Dr. Niess Decl. at 8-9.

As demonstrated in the attached Exhibit A, the five-year (FFY 2016-2020) compound annual growth rate (“CAGR”) of diagnostic and interventional cardiac catheterization procedures at Novant Health Matthews is 25.8%. See Exhibit A. Diagnostic procedures alone have grown at a rate of 13.6% during this same period and interventional procedures have grown 50.9%. See

² Cardiac catheterization equipment is also utilized to perform electrophysiology (“EP”) studies to diagnose arrhythmias or abnormal heartbeats. Novant Health Matthews performs hundreds of EP studies annually, however, those studies are not part of the diagnostic or interventional volumes utilized to determine need by either the State or by Novant Health Matthews in this petition. See Exhibit A, a chart reflecting historical and projected Mecklenburg County population growth rates.

³ <https://www.medicalnewstoday.com/articles/327332#treatment>.

Exhibit A. However, with only one unit of cardiac catheterization equipment, Novant Health Matthews is constrained in its ability to serve all the patients who seek care at Novant Health Matthews. See Dr. Niess Decl. at 8.

In the most recent federal fiscal year (FFY), Novant Health Matthews performed 1,833 weighted procedures, 333 more procedures (or 122% capacity) than the State defined annual capacity for a single unit of cardiac catheterization equipment.⁴ See Exhibit A; Proposed 2022 SMFP at p. 319; Dr. Niess Decl. at 7. As both the 2021 SMFP and Proposed 2022 SMFP reflect, Novant Health Matthews needs more than one cardiac catheterization unit to serve the needs of its patients. See Proposed 2022 SMFP at p. 319; 2021 SMFP at p. 320.

Growth in Population

Patients receiving cardiac catheterization services at Novant Health Matthews are overwhelmingly in the 65 and older age cohort. See Dr. Niess Decl. at 9; Dr. Delgado Decl. at 8. This age cohort is the fastest growing in Mecklenburg County, with a compound annual growth rate (“CAGR”) of 4.8% in Mecklenburg County from 2015-2020, compared to only 1.6% in overall Mecklenburg County population. See Exhibit A chart reflecting historical and projected Mecklenburg County population growth rates.

The high growth rate of the age 65 and older population will only continue to increase the demand for cardiac catheterization services in the Novant Health Matthews service area.

Projecting Forward

As demonstrated, utilization has been steadily increasing at Novant Health Matthews—this is not a one-time occurrence. The trend in increasing utilization and demand of Novant Health Matthews cardiac catheterization equipment shows no signs of waning. As population, particularly in the age 65 and older cohort continues to grow, cardiac catheterization utilization will also continue to increase. This is most clearly shown by applying growth rates for cardiac catheterization procedures at Novant Health Matthews (based on its own experience).

Importantly, the Proposed 2022 SMFP shows a need for 1.53 units of fixed cardiac catheterization at Novant Health Matthews and the 2021 SMFP showed a need for 1.61 units at Novant Health Matthews. See Proposed 2022 SMFP at 319; 2021 SMFP at 320.

As Exhibit A shows, applying the 5-year CAGR (FFY 2016 – 2020) growth rate for diagnostic procedures (13.6%) calculated based on utilization at Novant Health Matthews leads to projections of 1,193 diagnostic procedures by FFY 2022. Applying the 5-year CAGR from that same time period for interventional procedures (50.9%) calculated based on utilization at Novant Health Matthews, results in a projection of 2,069 weighted procedures by FFY 2022, for a total

⁴ Novant Health Matthews also performed 285 EP procedures during this time period. See Exhibit A.

of 3,262 procedures annually. Utilizing the SMFP methodology to determine need⁵ equates to a need for 2.72 units of cardiac catheterization equipment at Novant Health Matthews in FFY 2022. There is no practical way that Novant Health Matthews, with all other factors held constant, can operate at this level of utilization with only one unit of cardiac catheterization. See Exhibit A.

Moreover, by FFY 2024, Novant Health Matthews projects 6,253 procedures annually, and a need for 5.21 units of cardiac catheterization equipment. See Exhibit A.

It is clear based on historical and projected utilization that there is a sustained and immediate need for a second unit of fixed cardiac catheterization at Novant Health Matthews.

a. A statement of the adverse effects on the population of the affected area that are likely to ensue if the change is not made.

If the requested change is not made, the population of patients in the affected area will be harmed by the lack of sufficient cardiac catheterization services at their hospital of choice—Novant Health Matthews. It is quite simply a health and safety issue for these patients. The robust cardiac program at Novant Health Matthews has led to that facility having the most highly utilized cardiac catheterization services in Mecklenburg County for years. See Proposed 2022 SMFP at p. 319. It consistently operates over capacity, exceeding the State defined capacity of 1,500 weighted procedures in both FFY 2019 and 2020. See 2021 SMFP at p. 320; Proposed 2022 SMFP at p. 319. Novant Health Matthews' one unit of cardiac catheterization equipment performed many more procedures than equivalent units at competing facilities. See Proposed 2022 SMFP at p. 319. However, excess capacity at other providers and locations in Mecklenburg County does not alleviate the need for an additional unit at Novant Health Matthews.

Patient Preference & Convenience

As described by Eileen Ciotti, Nurse Manager of the cardiac catheterization lab at Novant Health Matthews, and Dr. Gabriel Delgado, Director of the Novant Health Matthews Vascular and Cardiac Catheterization Laboratory, patients are intentionally choosing to receive care at Novant Health Matthews and do not want to travel to other locations to receive their care. See Ciotti Decl. at 15; Dr. Delgado Decl. at 8. These patients want to receive care from their chosen physicians and prefer the physical location of the Novant Health Matthews facility, which is both convenient in its location away from center city Charlotte and provides an easy-to-navigate physical layout. These patients may be unable to travel physically or arrange for assistance to travel outside of their home service area for care due to physical limitations, reliance upon others, co-morbidities that make care and transport too complicated, or other mobility challenges. See Ciotti Decl. at 15; Dr. Delgado Decl. at 8.

⁵ This is calculated by dividing the utilization by 1,200 or 80% of the State-defined capacity of 1,500 procedures per piece of equipment, as reflected in Step 4 of the SMFP methodology. Proposed 2022 SMFP at pp. 312-313.

Novant Health Huntersville Medical Center (“Novant Health Huntersville”) is located north of Charlotte, on the other side of Mecklenburg County, some 25 miles away (and at least 30 minutes without traffic delays) from Novant Health Matthews. Dr. Niess Decl. at 11. See Exhibit E attached hereto, Google maps reflecting distances and travel time (without accounting for traffic) between Novant Health Matthews, Novant Health Huntersville and Novant Health Presbyterian. It is not reasonable or appropriate to expect patients to travel so far for their care, particularly given the age and co-morbidities from which many of these patients suffer.

Novant Health Presbyterian Medical Center (“Novant Health Presbyterian”) is in the heart of the busy City of Charlotte. For patients residing in and around Matthews, travelling to center city Charlotte for care is time consuming and inconvenient. For patients experiencing a STEMI event, travelling to Charlotte could be life-threatening. See Ciotti Decl. at 15; Dr. Delgado Decl. at 8-9.⁶ Moreover, Novant Health Presbyterian is a large, tertiary-care medical center with over 500 acute care beds and a large physical footprint that some patients and caregivers, particularly in the age 65 and older cohort and those experiencing acute issues like cardiac episodes and issues, may find very difficult and inconvenient to navigate. See Ciotti Decl. at 15; Dr. Niess Decl. at 11; Dr. Delgado Decl. at 8.

The location of Novant Health Matthews, on the other hand, is ideal for its cardiac catheterization patients, particularly those aged 65 and older, the majority of patients receiving this service. That age group particularly desires to receive care near their home and support system and in a smaller environment. Those patients and their families/caregivers are unable and/or unwilling to travel long distances for these services and often have mobility or co-morbidity issues that make such travel both inconvenient and burdensome. See Ciotti Decl. at 14-15; Dr. Delgado Decl. at 8.

Patient Safety

Moreover, the urgency associated with many cardiac catheterization procedures does not allow for extended travel due to the health risks associated with delayed care. See Dr. Delgado Decl. at 9. Time is of the essence and minutes can be the difference between a successful outcome or permanent damage or even death. Dr. Delgado Decl. at 9. While many diagnostic procedures are scheduled tests, some also require intervention during the procedure. It is unknown at the time of testing whether that will be the case. Diagnostic patients are scheduled because there was some issue or problem that created a need for the patient to be seen for

⁶ Moreover, Atrium Health Pineville, which has three units of cardiac catheterization equipment, is located south of Charlotte, some 15 miles away from Novant Health Matthews. Atrium Health Carolinas Medical Center, a very large, quaternary care hospital with nine units of cardiac catheterization equipment, is located over twelve miles from the Novant Health Matthews’ facility, in the heart of the City of Charlotte. See Exhibit F, attached hereto, Google Maps of the distance between Novant Health Matthews and Atrium Health Pineville and Atrium Health Carolinas Medical Center, respectively. Novant Health and Atrium each have their own network of physicians who tend to practice at either Novant Health or Atrium hospitals, but not both. It is unreasonable and unrealistic to assume that patients will forego their chosen physician to seek care at a different facility.

testing in the first place; delay could seriously impact the ability to catch and intervene in problems in a timely manner. *See Ciotti Decl. at 14.* For a heart attack such as a STEMI, also known as a “widow-maker,” there is simply no time for treatment at a facility further away from the patient’s original location. *See Dr. Delgado Decl. at 4.*

Patients are typically scheduled for diagnostic procedures at Novant Health Matthews’ cardiac catheterization lab throughout the day, during its normal operating hours of 8:00 am – 4:30 pm. However, because of the high utilization at Novant Health Matthews, the facility is regularly operating well beyond its normal hours. This is because when other, non-scheduled patients arrive in acute distress, scheduled patients’ procedures are often delayed in order to accommodate urgent interventional procedures on emergency department or inpatient admissions. *See Ciotti Decl. at 8; Dr. Delgado Decl. at 7.* On average, this situation occurs a few times each week. *See Ciotti Decl. at 8.*

With only one available unit of cardiac catheterization equipment, when urgent patients arrive, there is no choice but to delay procedures on scheduled patients. Novant Health Matthews strives to treat these scheduled patients later in the same day; however, at times, that is simply not possible. Scheduled patients may be required to remain overnight as observation patients in order to receive their diagnostic procedure the following day. This happens several times each month. In some circumstances, patients are able to have their procedure in the same day; however, because the procedure happened so late in the day, those patients must remain in the hospital overnight in order to complete their post-op care and recovery, thus converting what should have been an outpatient procedure into an overnight observation episode. *See Ciotti Decl. at 8-9, 12.* This happens multiple times each month. *See Ciotti Decl. at 12.* As addressed in greater detail below, this increases costs to patients, payors and to the hospital. In addition to the inconvenience, stress and concern this causes cardiac patients and their caregivers, it also ties up hospital resources that may be needed for other patients. *See Ciotti Decl. at 11.*

One example of this situation occurred on July 27, 2021 in the Novant Health Matthews cardiac catheterization lab. Five outpatient procedures were initially scheduled. Two additional outpatients were placed on the schedule by physician offices because patients had abnormal test results or some other concerning issue. In addition, seven hospital inpatients required procedures and had to be added to the schedule due to symptoms and/or test results they had received. Another STEMI patient arrived needing emergency treatment and late in the say, another emergent patient required a procedure upon admission from the emergency department. That was a total of 16 patients for one unit of cardiac catheterization equipment in a single day. While staff worked to continuously reschedule and adjust patients, two patients had to be rescheduled for their procedures for the following day. *See Ciotti Decl. at 9.* This is not the type of remarkable, patient-centered care that is Novant Health Matthews’ mission to provide.

This is also a health and safety concern because even scheduled diagnostic patients may, at times, require an interventional procedure during the scheduled diagnostic procedure once a

physician is in the process of evaluating the patient's condition. If these procedures are delayed, it further risks harm to the patient who was only at the facility for a diagnostic procedure because there was some risk factor or problem identified requiring further analysis. See Ciotti Decl. at 13.

There are also times when an emergent STEMI patient arrives while a diagnostic patient is in the process of receiving their procedure or intervention. Because of the critically urgent nature of the STEMI patient, the diagnostic patient must be taken off the table to allow treatment to be administered to the STEMI patient, and then later returned to the table once the STEMI procedure is completed. This presents a potential health and safety risk to patients. The only reason this scenario occurs is because there is only one unit of cardiac catheterization equipment available to treat patients, leaving no open room available for use by non-scheduled, emergent patients and STEMI procedures. See Ciotti Decl. at 10.

Delays such as these occur multiple times each week at Novant Health Matthews. See Ciotti Decl. at 8. Although the facility operates its cardiac catheterization lab well beyond its normal operating hours and makes every effort to avoid delay for any patient, the reality is that with only one unit of cardiac catheterization equipment, there will always be delays and backups at a facility this highly utilized unless and until it can acquire a second unit of cardiac catheterization equipment.

Precedent

Under circumstances similar to those experienced by Novant Health Matthews, the SHCC has, in the past, approved a petition to include additional cardiac catheterization equipment in the SMFP.

In 2016, Rex Healthcare ("Rex") petitioned for an adjusted need determination for one unit of cardiac catheterization equipment in Wake County. Rex argued that although there was a surplus of equipment county-wide, there was a deficit of equipment at Rex specifically. While the surplus in Wake County had remained consistent, Rex consistently demonstrated a deficit that was increasing. See the Agency Report on the Rex Petition for Special Need Adjustment for Fixed Cardiac Catheterization Equipment in the 2017 SMFP, attached hereto as Exhibit G. The State Health Coordinating Council agreed with Rex and ultimately approved the petition, with the Agency Report noting that "Rex's utilization has increased from 84% two years ago to 116% in the most current year of data, which exceeds the need for one additional machine." See Agency Report at p. 4.

Like the Wake County example, utilization at other facilities and in particular, at other health systems in Mecklenburg County, has not consistently reached the levels experienced at Novant Health Matthews described herein. Thus, the unique need at Novant Health Matthews that cannot be met at other facilities as described herein, warrants the need determination requested here. However, in the case of Novant Health Matthews, historical utilization is even higher. Like Rex, Novant Health Matthews has consistently exceeded the 80% utilization threshold for determining need in a health service area. See Exhibit G. In FFY 2018, Novant Health Matthews' equipment operated at 85% utilization of its total capacity of 1,500 procedures

annually. In FFY 2019, utilization was at 129% and in FFY 2020, even with closures and other complications created in the healthcare industry by the COVID-19 pandemic, utilization was at 122%.⁷ See Exhibit A. This was even higher growth than the utilization reported by Rex. While certain other facilities in Mecklenburg County may have a surplus of equipment, for the reasons stated in this Petition, Matthews cannot reduce its capacity constraints by shifting patients to other Novant Health or non-Novant Health facilities. Patients should not be deprived of their choice of facility or physicians simply because of equipment capacity constraints.

Moreover, the Proposed 2022 SMFP already shows a need for 1.53 units of fixed cardiac catheterization at Novant Health Matthews and the 2021 SMFP showed a need for 1.61 units at Novant Health Matthews. See Proposed 2022 SMFP at 319; 2021 SMFP at 320.

Thus, Novant Health Matthews' experience demonstrates that the unique attributes of this institution cannot be addressed by the standard need methodology in the SMFP and therefore a need determination should be approved as requested.

b. A statement of alternatives to the proposed adjustment that were considered and found not feasible.

Maintain the Status Quo

Novant Health Matthews considered maintaining the status quo and not filing a petition for an adjusted need determination to add an additional unit of cardiac catheterization equipment in Mecklenburg County. However, for the reasons detailed above, mainly patient safety and health, and due to the tremendous and sustained historical and projected growth of this service, doing nothing to alleviate the serious capacity constraints was not a viable option. Novant Health Matthews carefully reviewed historical and projected growth and conservatively determined that adding one additional unit of equipment would alleviate the capacity constraints described in this Petition.

Extended Hours

Novant Health Matthews considered further extending its operational hours; however, doing so will not solve the near daily issue caused by delayed procedures nor will it address the need to have a second laboratory available for emergent and STEMI procedures. Novant Health Matthews has been operating extended hours for some time and as demonstrated above and in the Declarations of Dr. Niess, Dr. Delgado and Ms. Ciotti, extended hours have not provided the desired or needed relief. Moreover, extended hours will further tax the one existing unit of equipment, which is not designed to operate at such extreme levels indefinitely without potential damage or issues arising.

Additionally, as Ms. Ciotti testifies in her Declaration, the sustained, extended hours have placed an enormous stress on staff, making it practically impossible to further extend (and

⁷ The slight, one-time decline in FFY 2020 is easily attributable to the COVID-19 pandemic, which caused the delay or cancellation of many non-urgent diagnostic procedures.

difficult to even maintain) the current schedule. This makes recruiting and retaining qualified staff very challenging. See Ciotti Decl. at 7, 16; Dr. Delgado Decl. at 7. In addition, when procedures are performed in later in the day, this often leads to overnight observation stays. This increases costs and creates stress and inconvenience for patients and caregivers.

Use of Mobile Equipment or Transfers

Novant Health Matthews has also explored the option of utilizing mobile equipment to alleviate capacity constraints; however, this is not a feasible option. See Dr. Niess Decl. at 10; Dr. Delgado Decl. at 10. In the opinion of these physicians, mobile units are not appropriate for interventional procedures. If a patient scheduled for a diagnostic procedure is deemed to require intervention, that patient's procedure would not be able to be completed in the mobile unit. Should a patient crash during a diagnostic procedure, special equipment would have to be quickly brought into the mobile unit, which could cost lifesaving time. See Dr. Niess Decl. at 12; Dr. Delgado Decl. at 10. Moreover, the costs of contracting for a mobile unit are much more expensive than owning the equipment.

As addressed above in detail, transferring patients, particularly those in cardiac distress, is not a safe or viable option, even for diagnostic procedures where intervention may be required. Reducing travel time for patients after their procedures is also an important part of providing the best and safest care. See Ciotti Decl. at 15; Dr. Delgado Decl. at 7-9; Dr. Niess Decl. at 11. Moreover, Novant Health Matthews' patients have made clear their desire to receive care at that facility—not at other locations either within or outside of the Novant Health network in Mecklenburg County.

4. Evidence that health service development permitted by the proposed adjustment would not result in unnecessary duplication of health resources in the area.

Approval of this Petition will not result in the unnecessary duplication of healthcare resources in the area. As demonstrated above, cardiac catheterization volume at Novant Health Matthews continues to increase and as the population continues to age and grow, that demand is not expected to wane. Because of its location and the fact that there are no other practical options for emergent procedures like those that need to be done on cardiac catheterization equipment, Novant Health Matthews presents the only viable option for the vast majority of patients in its service area requiring diagnostic and/or interventional cardiac catheterization procedures. These patients cannot be easily or safely transferred to other facilities or locations.

As recognized in the 2021 SMFP and Proposed 2022 SMFP, the total number of machines required to meet the demand at Novant Health Matthews is 1.61 and 1.53, respectively (see 2021 SMFP at p. 320; Proposed 2022 SMFP at p. 319). The need for an additional unit of cardiac catheterization equipment at Novant Health Matthews is based on its utilization and that need cannot be met elsewhere in the county or the Novant Health system. Moreover, that need is based upon demand from Novant Health Matthews' patients and not based upon in-migration of cardiac catheterization patients from other facilities in Mecklenburg County or other counties. In other words, the need for additional capacity is based on serving those patients already

choosing Novant Health Matthews; it is not based on pulling patients from other facilities. Therefore, an additional unit of equipment will not impact utilization at other existing facilities.

5. Evidence that the requested adjustment is consistent with the three Basic Principles governing the development of the SMFP: safety and quality, access, and value.

Safety and Quality

Safety and quality are of utmost importance to Novant Health Matthews. Demand currently exceeds the capacity of the one existing unit of cardiac catheterization equipment at Novant Health Matthews nearly daily, resulting in delays that potentially jeopardize patient care and certainly patient comfort.

It is critical that cardiac catheterization patients be afforded timely access for diagnostic and interventional procedures. In addition to emergent patients such as those suffering from STEMI, diagnostic procedures may also require a simultaneous intervention. As detailed above, Novant Health Matthews must be able to treat all these patients without unnecessary and potentially harmful delay. See Ciotti Dec. at 13, 15; Dr. Delgado Decl. at 9.

Access

Novant Health Matthews is a part of the Novant Health, Inc. (“Novant Health”) hospital network. As with all Novant Health facilities, Novant Health Matthews provides services to all persons, regardless of their ability to pay. In addition to its Uninsured Discount Policy, Novant Health has implemented a robust charity care policy that allows a patient with a household income up to 300% of the Federal Poverty Level to easily seek charity care for needed medical services. Based upon the 2021 Federal Poverty Level, this means that an uninsured family of four with an annual income of \$79,500 or less will receive a write-off of all charges from services received in the Novant Health system, including Novant Health Matthews.

Novant Health Matthews also ensures that its services are available to all patients, regardless of their age, race, sex or any other characteristic. Novant Health Matthews is committed to ensuring that all patients who choose to seek services at its facilities, especially cardiac catheterization services, can do so. A second unit of fixed cardiac catheterization equipment at Novant Health Matthews will increase access for all patients in the service area, regardless of their ability to pay.

Value

As described in detail above and in the Declarations of Dr. Niess, Dr. Delgado and Ms. Ciotti, the high utilization of Novant Health Matthews’ existing cardiac catheterization equipment at more than 120% of its annual capacity, often results in delays in treating patients who were otherwise intended to be only outpatients, including overnight stays in the hospital utilizing acute care beds. These overnight stays are not only inconvenient for the patient, but they tie up limited acute care bed resources unnecessarily, and result in far more expensive care. Increasing cardiac catheterization equipment capacity will alleviate this problem and ensure that hospital resources

are utilized appropriately and cost effectively. This helps lower costs to patients, payors and Novant Health Matthews.

Novant Health Matthews will continue its commitment to serve all patients and to equitably provide that treatment to patients. Because of the current and projected high demand for this service, an additional unit of cardiac catheterization equipment also will be highly utilized and will increase choice for patients.

Conclusion

For the reasons addressed here, under the unique circumstances of this market and specifically at Novant Health Matthews, Novant Health Matthews respectfully requests that the SHCC include a need determination for an additional unit of fixed cardiac catheterization equipment for Mecklenburg County in the 2022 SMFP.

Cath Cases - Not Weighted

Pulled from LRAs

Facility	Cath Type	FFY 2016	FFY 2017	FFY 2018	FFY 2019	FFY 2020	FFY 16-20 CAGR
NHMMC	Dx	556	698	983	996	925	13.6%
	Interv.	100	129	169	537	519	50.9%
	EP	238	209	275	291	285	4.6%

Cath Cases - Weighted - Using 2016-2021 CAGR

Pulled from LRAs - Weighted: 1.75x Interventional Caths

Facility	Cath Type	FFY 2016	FFY 2017	FFY 2018	FFY 2019	FFY 2020	FFY 16-20 CAGR
NHMMC	Dx	556	698	983	996	925	13.6%
	Interv.	175	226	296	940	908	50.9%
	Total cath	731	924	1,279	1,936	1,833	25.8%

Projection using NHMMC 4 yr CAGR

FFY 2021	FFY 2022	FFY 2023	FFY 2024
1,051	1,193	1,355	1,539
1,371	2,069	3,123	4,714
2,421	3,262	4,478	6,253

Source: NC OSBM Data

Mecklenburg Population by Age Group, 2015-2020							
Age Group	2015	2016	2017	2018	2019	2020	CAGR
0 to 17	251,429	255,458	258,498	259,914	260,996	262,456	0.9%
18 to 24	91,895	91,912	92,061	92,127	92,882	94,858	0.6%
25 to 44	331,732	335,601	339,395	340,598	342,203	346,510	0.9%
45 to 64	251,086	258,797	265,341	270,619	275,310	280,310	2.2%
65 Plus	106,487	111,778	117,234	122,641	128,454	134,641	4.8%
Total	1,032,629	1,053,546	1,072,529	1,085,899	1,099,845	1,118,775	1.6%

TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL

**DECLARATION OF GARY STEWART NIESS, M.D. IN SUPPORT OF PETITION BY
NOVANT HEALTH, INC. AND NOVANT HEALTH MATTHEWS MEDICAL CENTER
TO INCLUDE A NEED DETERMINATION FOR ONE (1) UNIT OF ADDITIONAL
FIXED CARDIAC CATHETERIZATION EQUIPMENT IN MECKLENBURG COUNTY
IN THE 2022 STATE MEDICAL FACILITIES PLAN**

July 28, 2021

Pursuant to 28 U.S.C. § 1746, Gary Stewart Niess, M.D. declares as follows:

1. My name is Gary Stewart Niess, M.D. I am a resident of the State of North Carolina. The facts stated in this Declaration are true of my own personal knowledge, and if called to testify, I would so testify. I am over the age of eighteen and do not suffer from any disability that impacts this Declaration or my ability to testify truthfully.

2. I am an Interventional Cardiologist practicing at Novant Health Heart & Vascular Institute- Elizabeth (Cardiology). (“NHHVI”). I previously served as the Director of the Cardiac Catheterization (“cardiac catheterization”) Laboratory for the Novant Health Heart & Vascular Institute (“NHHVI”) from 2003 – 2019.

3. I attended Dartmouth College where I obtained my Bachelor of Arts degree in Psychology. I earned my Doctor of Medicine degree from the University of North Carolina Chapel Hill School of Medicine in 1973. I completed my residency and fellowship in Internal Medicine and Cardiology in 1978. I am board certified in cardiology and interventional cardiology, which is an achievement that requires extensive, rigorous training and assessment in my specific specialty as well as the passing of an examination for each medical specialty.

4. In my roles and experience as an Interventional Cardiologist with the NHHVI, I am personally familiar with the various cardiac catheterization labs operated throughout the NHHVI, including at Novant Health Huntersville Medical Center (“Novant Health Huntersville”), Novant Health Presbyterian Medical Center (“Novant Health Presbyterian”) and Novant Health Matthews Medical Center (“Novant Health Matthews”). There are two (2) units of cardiac catheterization equipment at Novant Health Presbyterian, one (1) unit of cardiac catheterization equipment at Novant Health Huntersville and one (1) unit of cardiac catheterization equipment at Novant Health Matthews, all of which are heavily utilized.

5. Cardiac catheterization equipment is a vital tool in the diagnosis and treatment of certain cardiovascular conditions. It provides physicians with reliable information on how well a patient’s heart works and is considered to be very safe with few risks. Time is of the essence when it comes to providing lifesaving cardiac treatment and care. In particular, ST-Elevation

Myocardial Infarction (“STEMI”) heart attacks some of the most serious and profoundly dangerous types of heart attacks where there is a total blockage of the coronary artery, which can cause extensive damage to a large area of the heart. STEMI’s require immediate treatment typically through percutaneous coronary intervention (“PCI”), a cardiac catheterization procedure.

6. Novant Health Matthews’ cardiac catheterization lab has only one (1) unit of cardiac catheterization equipment. That equipment is heavily utilized. As recognized in both the 2021 SMFP and recent draft planning assessments from the Technology and Equipment Committee, Novant Health Matthews’ utilization is high enough to establish a need for one (1) additional unit of cardiac catheterization equipment at that facility. See 2021 SMFP, Table 17A-3 at p. 320; Proposed 2022 SMFP at p. 319.

7. The existing cardiac catheterization unit at Novant Health Matthews is already operating at 1,833 annual procedures, well above 100% of the State defined capacity of 1,500 procedures. See Proposed 2022 SMFP at p. 319.

8. The cardiac catheterization program at Novant Health Matthews has grown dramatically over the last several years. The five-year compound annual growth rate (“CAGR”) for diagnostic and interventional catheterization procedures (FFY 2016 – 2020) at Novant Health Matthews is 25.8% as shown in Exhibit A to the Novant Health Matthews Petition. During that time, a focus on recruiting, including our recruitment and retention of additional interventional cardiologists, and sustained growth in providers has contributed to the high utilization levels we experience.

9. We have also seen growth in our patient population, particularly our elderly population, leading to an increased demand for these services.

10. In response to the increased demand at Novant Health Matthews, we have extended hours, and have considered other potential options to help meet this need, including transferring certain patients to Novant Health Presbyterian and the use of mobile equipment. However, these options are not viable.

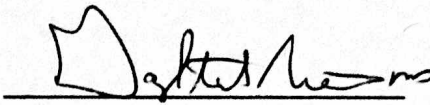
11. Transferring patients to Novant Health Presbyterian for cardiac catheterization procedures is generally not a feasible option due to the health and safety risks to those patients. These procedures are critically time sensitive—seconds count, and it is not in the interests of those patients to risk their health with transfer times. Transfer is also not in the interest of patients or their families where transfer puts the patients at locations further from their family and care network. Novant Health Huntersville is located 25 miles away from Novant Health Matthews. At best that is a nearly 30-minute drive not counting Charlotte traffic. Novant Health Presbyterian is approximately 11 miles from Novant Health Matthews and would require our largely elderly patients to travel into Charlotte and navigate a large hospital system in order to utilize this service.

12. The use of mobile cardiac catheterization equipment also is not a sustainable option due to the limited availability of such equipment and the high cost of obtaining such services. In particular, the practicalities of performing delicate cardiac catheterization procedures in a small, mobile space is not the ideal care we strive to provide our patients.

13. In order to continue meeting the needs of its patients, it is critical that Novant Health Matthews be permitted to expand its cardiac catheterization program. We have done everything we can with the resources available to us to expand care and ensure access but have met that capacity and are at a critical juncture where additional resources are needed and in fact, required by our patients. An additional unit of equipment will save lives, improve the hours worked by staff and physicians, aid in the recruiting of high-quality providers and improve the efficiency of our services. I strongly urge the approval of this petition for one additional unit of cardiac catheterization equipment.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 26 July, 2021.



Gary Stewart Niess, M.D.

TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL**DECLARATION OF GABRIEL A. DELGADO, M.D. IN SUPPORT OF PETITION BY
NOVANT HEALTH, INC. AND NOVANT HEALTH MATTHEWS MEDICAL CENTER
TO INCLUDE A NEED DETERMINATION FOR ONE (1) UNIT OF ADDITIONAL
FIXED CARDIAC CATHETERIZATION EQUIPMENT IN MECKLENBURG COUNTY
IN THE 2022 STATE MEDICAL FACILITIES PLAN****July 28, 2021**

Pursuant to 28 U.S.C. § 1746, Gabriel A. Delgado, M.D., FACC, FSCAI, FSVM, declares as follows:

1. My name is Gabriel A. Delgado, M.D., FACC, FSCAI, FSVM. I am a resident of the State of North Carolina. The facts stated in this Declaration are true of my own personal knowledge, and if called to testify, I would so testify. I am over the age of eighteen and do not suffer from any disability that impacts this Declaration or my ability to testify truthfully.

2. I am an Interventional Cardiologist practicing at Novant Health Heart & Vascular Institute- Matthews. I also serve as the Director of the Novant Health Matthews Medical Center Vascular and Cardiac Catheterization (“cardiac catheterization”) Laboratory, a position that I have held since June 2020.

3. I am Board Certified in Interventional Cardiology and Cardiovascular Disease. My practice areas focus on Coronary Balloon Angioplasty, Coronary Stent Placement, Endovascular Surgery, Heart Disease and Vascular Disease. I earned my Doctor of Medicine degree from the Universidad Del Norte School of Medicine in 1998 and completed an Internal Medicine Internship at St. Elizabeth’s Medical Center of Boston 2001. I completed my Residency in Internal Medicine in 2003 at Massachusetts General Hospital. In 2012 I completed a Fellowship in Interventional Cardiology and in 2013 I completed a Fellowship in Vascular and Endovascular Medicine, both at the Brown University School of Medicine.

4. Novant Health Matthews has one unit of cardiac catheterization equipment. Cardiac catheterization procedures are used to diagnose (diagnostic) and treat (interventional) certain cardiac conditions. A STEMI, or “widow-maker” heart attack, is a ST-Segment Elevation Myocardial Infarction, the most severe type of heart attack. In a STEMI, a blood clot suddenly and completely blocks an artery supplying blood to the heart. Immediate treatment with cardiac catheterization is critical in treating STEMIs. Novant Health Matthews is the first STEMI program in Mecklenburg County at a facility without on-site cardiovascular surgery.

5. The single unit of cardiac catheterization equipment at Novant Health Matthews is performing at well more than its capacity in procedures annually, which is defined by the State

to be 1,500 procedures per year. Utilization of this equipment for both diagnostic and interventional procedures has been increasing substantially over the last several years, including throughout the COVID-19 pandemic.

6. In addition to population growth in the Matthews area, growth in the cardiac catheterization program at Novant Health Matthews has contributed to this increase in utilization. Novant Health has focused on recruiting interventional cardiologists in order to meet patient demand and as a result, utilization has also increased.

7. Though our published operational hours for the cardiac catheterization lab at Novant Health Matthews are from 8:00 am – 4:30 pm, due to demand, we must operate much longer hours. We routinely have situations where patients who are scheduled for diagnostic procedures have their procedures delayed due to emergent, acute inpatient or emergency department admissions experiencing cardiac episodes that require immediate interventional treatment (such as STEMIs). As a result, scheduled diagnostic procedures often must be rescheduled for later in the day. Sometimes, patients must stay overnight and have their procedures performed the following day due to capacity constraints. This increases costs, causes patients and families additional anxiety and inconvenience, and is simply unacceptable patient service.

8. We have explored various options in addition to extended hours in order to meet the demand for cardiac catheterization services, such as whether certain patients can be transferred to other facilities for their care. However, such other options are truly not feasible. The majority of our patients at Novant Health Matthews requiring diagnostic or interventional cardiac catheterization procedures are age 65 or older. This is the fastest growing population by age cohort and I have found that these patients do not want (or, in many cases, are unable) to travel to locations that are further from their homes for these procedures, such as Novant Health Presbyterian Medical Center in Charlotte. They also value the smaller setting that our facility offers, which is substantially easier to navigate. Our patients also do not want to travel through Charlotte to the Novant Health Huntersville Medical Center, a drive that could take up to an hour with traffic. Our patients want and deserve to be treated by their trusted physician at their facility of choice, close to their home and family support network.

9. Moreover, in many cardiac cases, time is of the essence. Mere minutes can mean the difference between life and death in some circumstances. There is often not time to spend on the road and in traffic traveling to a facility for treatment. Travel following recovery from a procedure should also be minimized for the comfort of the patient. Our need for additional cardiac catheterization capacity is quite simply a patient safety issue.

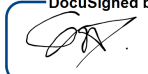
10. We have also considered using mobile cardiac catheterization equipment in order to relieve capacity constraints. This is not practical in most situations. If there were an episode where a patient crashed during a procedure, special equipment would have to be brought in, taking valuable time. Moreover, mobile units are not appropriate for interventional procedures.

Thus, if a patient undergoing a diagnostic procedure in a mobile unit needed intervention, that procedure could not be completed at the same time as it will typically be done in a fixed lab. I also understand that contracting for mobile service is much more expensive than a facility owning its cardiac catheterization equipment.

11. Therefore, because of the high utilization and consistent growth of cardiac catheterization procedures at Novant Health Matthews, we respectfully request that the State Health Coordinating Council include a need determination for cardiac catheterization equipment in Mecklenburg County in the 2022 State Medical Facilities Plan. Having a second available room with cardiac catheterization equipment available to handle additional cases at Novant Health Matthews, including STEMIs and other urgent procedures, is of utmost importance to ensuring the availability of lifesaving resources for this community.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on July, 2021.
 7/27/2021

DocuSigned by:

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Gabriel A. Delgado, M.D., FACC, FSCAI, FSVM

TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL**DECLARATION OF EILEEN CIOTTI IN SUPPORT OF PETITION BY
NOVANT HEALTH, INC. AND NOVANT HEALTH MATTHEWS MEDICAL CENTER
TO INCLUDE A NEED DETERMINATION FOR ONE (1) UNIT OF ADDITIONAL
FIXED CARDIAC CATHETERIZATION EQUIPMENT IN MECKLENBURG COUNTY
IN THE 2022 STATE MEDICAL FACILITIES PLAN****July 28, 2021**

Pursuant to 28 U.S.C. § 1746, Eileen Ciotti declares as follows:

1. My name is Eileen Ciotti. I am a resident of the State of North Carolina. The facts stated in this Declaration are true of my own personal knowledge, and if called to testify, I would so testify. I am over the age of eighteen and do not suffer from any disability that impacts this Declaration or my ability to testify truthfully.

2. I am the Nurse Manager of the Invasive and Non-Invasive Cardiology Departments which include the Cardiac Catheterization Lab ("cardiac catheterization") at Novant Health Matthews Medical Center ("Novant Health Matthews"). I have served in this position for nine years. Prior to working for Novant, I was the Director of Medical Surgical Services at Westside Regional Medical Center and an RN and Charge Nurse at The Reading Hospital and Medical Center

3. I am a Registered Nurse by training. I first received my Associates Degree in Nursing from the Community College of Philadelphia in 1981. I then received my BSN from the University of Phoenix in 2005. In 2010, I received my MBA/MHA in Healthcare from Pfeiffer University.

4. As Manager of the cardiac catheterization lab at Novant Health Matthews, I am responsible for the day-to-day operations of the lab, among many other responsibilities. I am familiar with all aspects of the operations and participate in the decision-making process for the facility. Specifically, I supervise both clinical and support staff and liaise with physicians, community educators and other interdisciplinary team members. I am responsible for staffing and scheduling oversight as well. Ensuring both patient and employee satisfaction are key responsibilities of my position.

5. Novant Health Matthews is designated as a Chest Pain Center v7 with Primary PCI (percutaneous coronary intervention) accreditation from the Society of Cardiovascular Patient Care. Chest Pain Center accredited hospitals have achieved a higher level of expertise when dealing with patients who have arrived with symptoms of a heart attack. Accreditation improves processes leading to more efficient and effective evaluation, rapid treatment of urgent patients, helps lower the length of stay, decrease readmissions and sustain continuous process improvement among other benefits.

6. The cardiac catheterization lab includes the laboratory, peripheral/vascular procedure room and all aspects of pre- and post-procedure recovery. We serve adult patients experiencing chest pain, myocardial infarction, peripheral vascular disease, congestive heart failure, acute coronary syndrome, pulmonary embolus, pulmonary hypertension, valvular dysfunction, rhythm disturbances, stable and unstable patients and DVT diseases. We interface with other hospital disciplines as necessary.

7. Novant Health Matthews currently operates one fixed cardiac catheterization lab. Our facility is extremely busy, exceeding 100% capacity. Although our normal hours are from 8:00 am – 4:30 pm, we operate much longer on a daily basis. We also staff a 24/7 call team for STEMI case coverage. STEMI, or ST-Segment Elevation Myocardial Infarction, cases are the most severe type of heart attack. For a patient experiencing a STEMI, a blood clot suddenly and completely blocks an artery supplying blood to the heart. Immediate diagnosis and treatment are absolutely critical in these circumstances. Novant Health Matthews is the first STEMI program in Mecklenburg County at a facility without on-site cardiovascular surgery.

8. Despite our published hours, on many days, the lab opens as early as 7:00 am and is open past 7:00 pm, and at times until 10:00 pm to accommodate the influx of patients. On a typical day, the lab will have approximately 5 outpatients scheduled for interventional procedures. Those patients arrive at the hospital early in the morning, having fasted since the night before. The patients are registered and go through their pre-op procedure, which takes approximately one hour. Unfortunately, as it often the case, instead of going directly into the lab for their scheduled procedure at their scheduled appointment time, these patients will be bumped off the schedule and their procedures delayed until a later time due to an urgent, acute need from an emergency department admission (such as a STEMI) or an inpatient experiencing chest pain symptoms. This situation occurs a few times each week, on average.

9. This exact situation occurred recently when five scheduled cardiac catheterization patients were delayed (and some to the next day) because of emergency inpatients and a STEMI patient who arrived for priority treatment. Just today, we had 5 outpatients scheduled for procedures when 2 additional outpatients were added to the schedule from physician offices due to concerning test results or other issues they were experiencing. In addition to those 7 outpatients, 7 hospital inpatients needed to be added to the schedule due to concerning cardiac symptoms/abnormal tests and a STEMI patient arrived needing emergency treatment. Late in the day, another emergent patient was added from the emergency department for an emergent procedure. Thus, Novant Health Matthews ended the day with 16 cardiac catheterization patients needing care. We had to quickly and repeatedly adjust the schedule in order to accommodate these patients using our one unit of cardiac catheterization equipment. Despite our best efforts, two of those scheduled patients had to be moved to the following day for their procedure. Unfortunately, this is an all too common occurrence that is only getting worse. These situations put an enormous stress and strain on our patients, staff and hospital resources.

10. We have also had situations arise where a procedure was taking place and an emergent STEMI patient arrived for treatment. Because treatment of the STEMI cannot be delayed, the current patient must be taken off the table and if their procedure has not been completed, they must be brought back as soon as the STEMI procedure is complete. This is caused solely because we are only approved and licensed for one unit of cardiac catheterization equipment and therefore can only perform one cardiac catheterization at a time, thus leaving no open room available for non-scheduled, emergent patients and STEMI procedures. Delays in scheduled procedures and interruptions of procedures already in process causes stress and anxiety for patients and decreases patient satisfaction.

11. While we make every effort to keep our patients on schedule, with only one lab to utilize, we are quite regularly unable to do so and end up delaying many patients' scheduled procedures until later in the day. This is expensive, stressful and inconvenient for patients and families and ties up hospital resources.

12. There are also multiple times each month where we are forced to admit patients as observation patients overnight because their scheduled procedure was delayed too late to accommodate it that same day. Those patients are then accommodated first thing the next morning, so long as no other emergent patients have been admitted through the emergency department during the night. Thus, what should be a same day outpatient procedure regularly becomes a multi-day inpatient experience for many patients at Novant Health Matthews which adds to the stress and strain on the patient, their family, support staff and hospital resources.

13. This circumstance also presents a health and safety concern. Even patients who are scheduled for diagnostic cardiac catheterization procedures often require an intervention during the same procedure. In fact, it is assumed that patients scheduled to receive a diagnostic procedure will ultimately need an intervention based upon the physicians' findings during the diagnostic. Such delay on the diagnostic and/or interventional procedure increases the risk of further cardiovascular harm to the patient.

14. The delays our patients routinely face are especially difficult given the demographics of the population we primarily serve in the cardiac catheterization lab—individuals age 65 or older. This population often has comorbidities making their care and treatment more complicated. Many of these patients rely upon caregivers or loved ones for transportation and assistance and may be otherwise mobility-compromised. All of these factors make it even more difficult for them to manage the complications caused by delay.

15. Our facility is in high demand for the population we serve. Our patients have told me and my staff members that they want to have their cardiac catheterization procedures done at Novant Health Matthews and are unwilling or unable to travel to other facilities. They choose their physicians carefully and they choose to have their procedures at Novant Health Matthews. These patients cannot or will not travel across the county to Novant Health Huntersville Medical Center or to Charlotte to Novant Health Presbyterian Medical Center because of the distance and

time it takes. They desire to stay in our smaller, more easily accessible facility rather than navigate the traffic, distance and even the larger facility at Novant Health Presbyterian Medical Center. It is also not ideal for these patients to travel long distances before or after their procedures, especially if they do not have a strong network of caregivers to assist them.

16. Having only one cardiac catheterization lab puts an enormous strain on our staff. It is practically impossible for Novant Health Matthews to add more hours to its existing cardiac catheterization lab and that makes recruiting and retaining staff and the scheduling for this service very challenging. The only way to alleviate these capacity constraints and improve care is for Novant Health Matthews to add an additional unit of cardiac catheterization equipment to its inventory. I respectfully urge the SHCC to approve this Petition. An additional unit of cardiac catheterization equipment will help save lives, decrease cost and improve patient and employee satisfaction.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 27 July, 2021.

DocuSigned by:
Eileen Ciotti
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Eileen Ciotti, RN

Novant Health Huntersville Medical...

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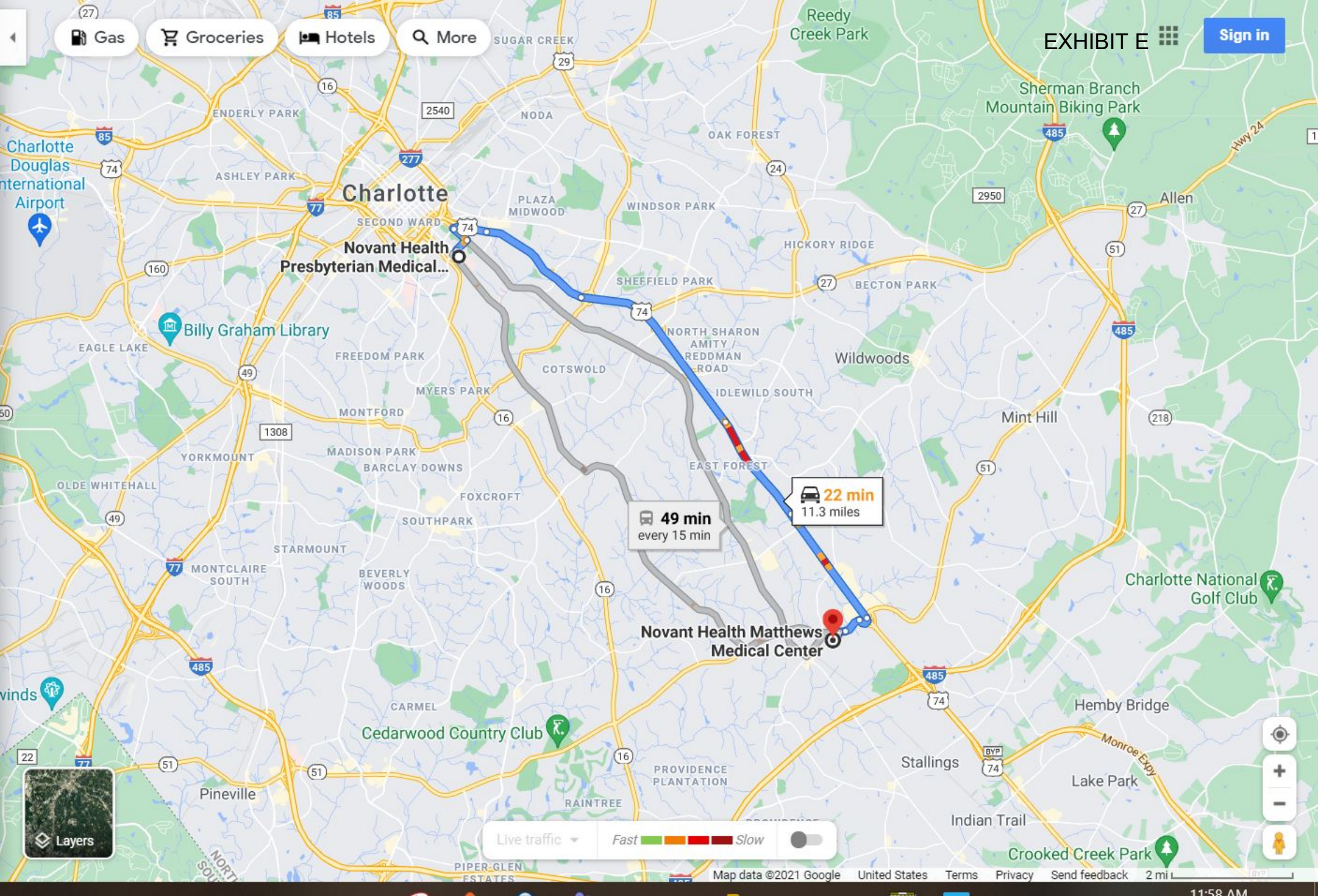
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Novant Health Matthews Medical Center...

Charlotte Douglas International Airport

Carowinds

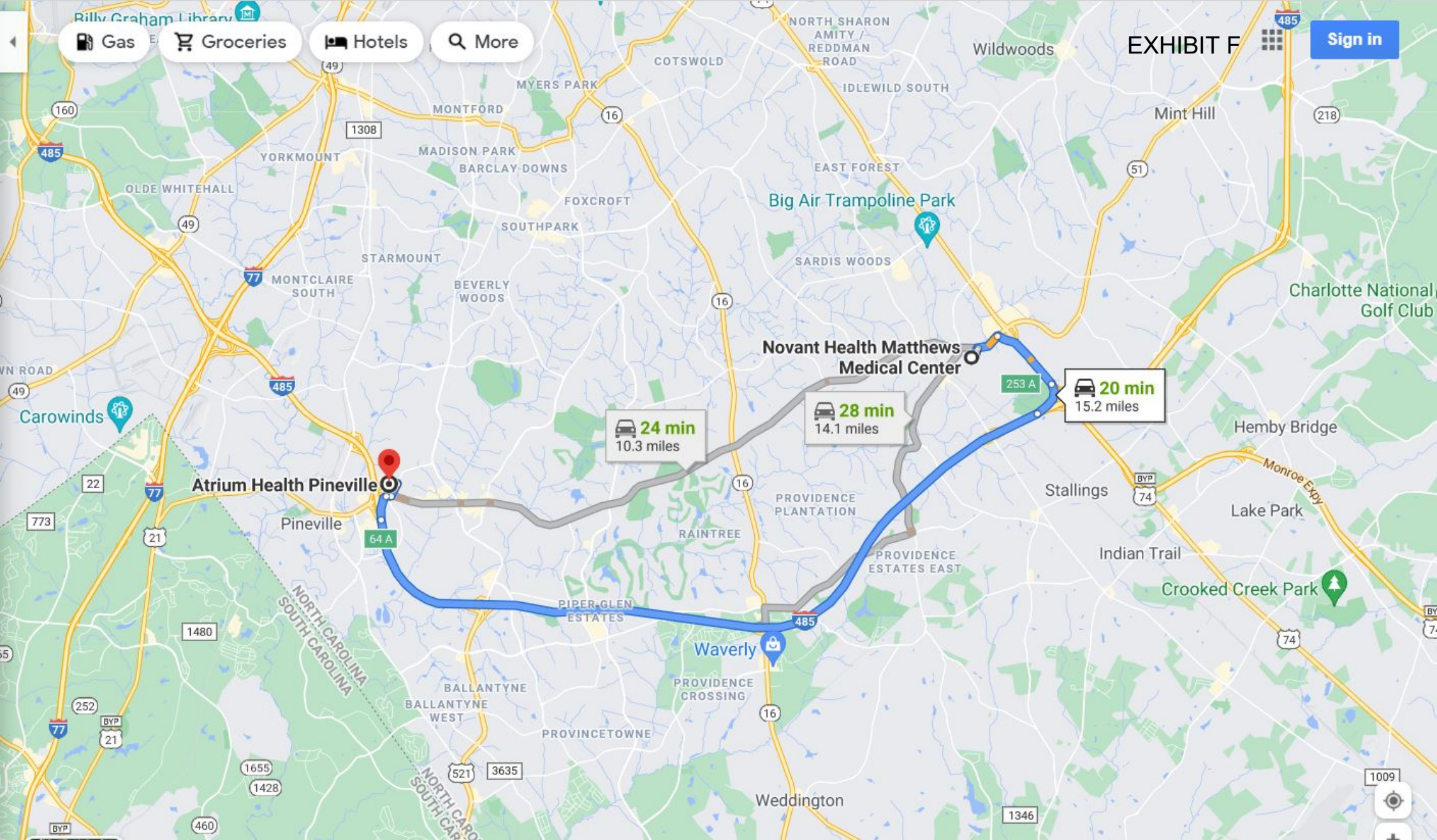




22 min
11.3 miles

49 min
every 15 min

Live traffic Fast Slow



24 min
10.3 miles

28 min
14.1 miles

20 min
15.2 miles

Atrium Health Pineville

Novant Health Matthews Medical Center

Big Air Trampoline Park

EXHIBIT F

Carowinds

Charlotte National Golf Club

Hemby Bridge

Pineville

Waverly

Stallings

Lake Park

Indian Trail

Crooked Creek Park

Weddington

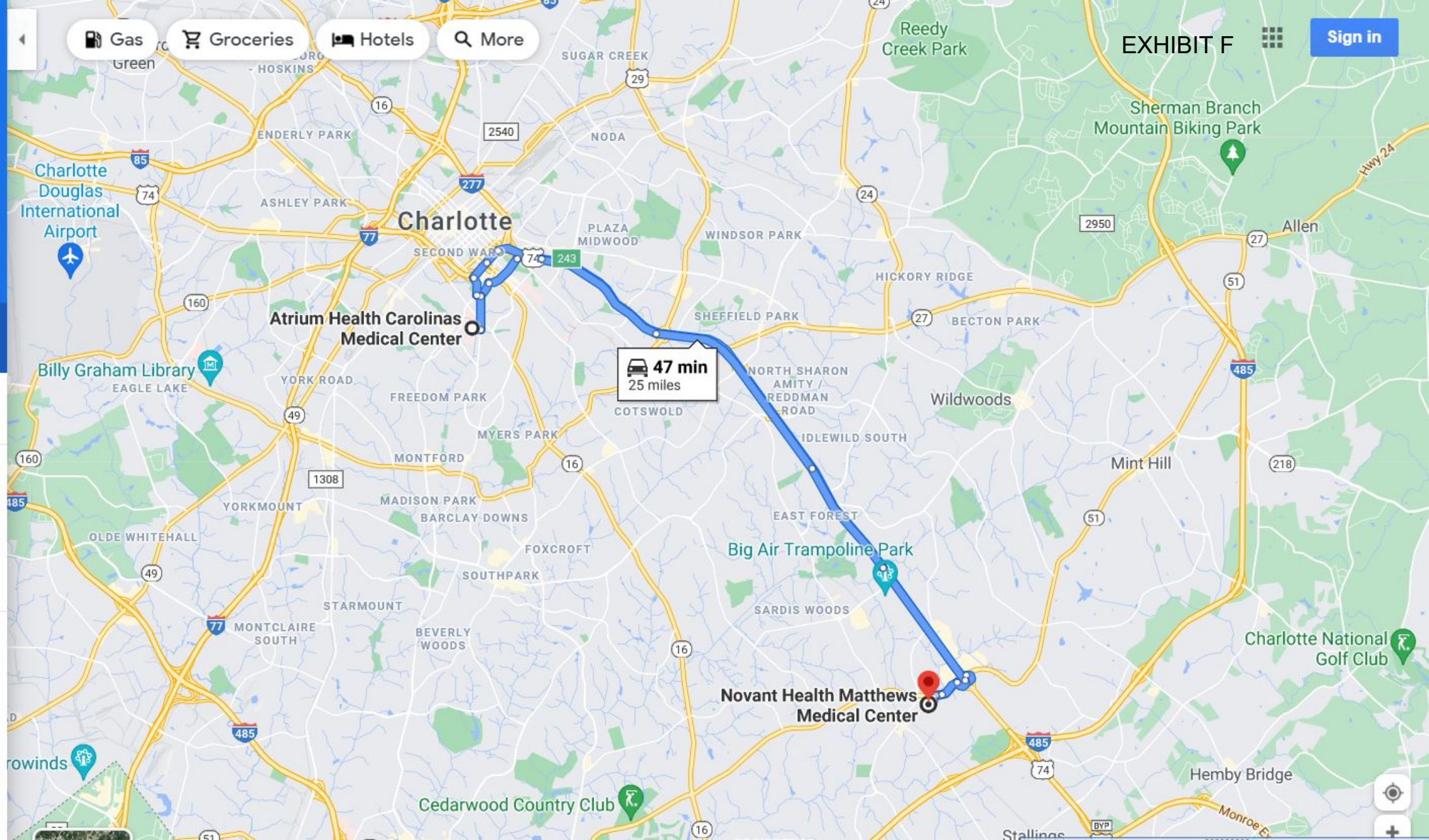
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Charlotte

Atrium Health Carolinas Medical Center

47 min
25 miles

Novant Health Matthews Medical Center

Big Air Trampoline Park

Charlotte Douglas International Airport

Billy Graham Library

Reedy Creek Park

Sherman Branch Mountain Biking Park

Charlotte National Golf Club

Cedarwood Country Club

Hemby Bridge

Stallings

Monroe

Rowinds

Montclair South

Beverly Woods

Sardis Woods

Mint Hill

Wildwoods

North Sharon Amity / Reddman Road

Cotswold

Myers Park

Montford

Yorkmount

Olde Whitehall

Southpark

Foxcroft

Starmount

East Forest

Madison Park

Barclay Downs

York Road

Freedom Park

Cotswold

Idlewild South

Becton Park

Sheffield Park

Hickory Ridge

Windsor Park

Plaza Midwood

Ashley Park

Noda

Enderly Park

Sugar Creek

Hoskins

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Allen

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**Technology and Equipment Committee
Agency Report
Petition for Special Need Adjustment for Fixed Cardiac Catheterization
Equipment in Wake County in the
2017 State Medical Facilities Plan**

Petitioner:

Rex Healthcare
4420 Lake Boone Trail
Raleigh, NC 27607

Contact:

Erick Hawkins
System Vice President, Heart and Vascular Services
(919) 784-4586
erick.hawkins@rexhealth.com

Request:

Rex Healthcare (Rex) petitions the State Health Coordinating Council (SHCC) to create an adjusted need determination for two additional units of fixed cardiac catheterization equipment in Wake County in the *2017 State Medical Facilities Plan (SMFP)*.

Background Information:

The *Proposed 2017 SMFP* provides two standard need determination methodologies for cardiac catheterization equipment. Methodology One is the standard methodology for determining need for additional fixed cardiac catheterization equipment and Methodology Two is the need determination methodology for shared fixed cardiac catheterization equipment. Application of these methodologies to utilization data in the *Proposed 2017 SMFP* does not generate a need determination for fixed or shared fixed cardiac catheterization equipment in Wake County.

Chapter Two of the *2016 SMFP* allows persons to petition for an adjusted need determination in consideration of “unique or special attributes of a particular geographic area or institution...” if they believe their needs are not addressed by the standard methodology. Rex has submitted a Petition to add a need determination for two units of fixed cardiac catheterization equipment in Wake County. Rex is requesting the adjusted need determination based on “the unique utilization trends faced by Rex”.

In 2013, New Hanover Regional Medical Center (NHRMC) petitioned the State Health Coordinating Council (SHCC) to remove the need determination for one unit of cardiac catheterization in the New Hanover County. One of the primary reasons cited by the petitioner

was that capacity of the equipment in the service area is greater than calculated in the SMFP. Based on the data presented, the SHCC agreed the need should be removed.

In 2014, Rex petitioned the SHCC twice for changes to the Cardiac Catheterization section of the SMFP. The first Petition was to change the methodology such that the calculations should not apply the threshold to the entire service area, but to each individual hospital/health system irrespective of capacity at other facilities located in the same service area. Thus, the need in each service area would be a total of the needs generated by each facility/health system in the county. This Petition was unsuccessful because the requested changes had the potential to add additional capacity to health service areas that already had surpluses and because procedure volumes were declining. The second request was for an adjusted need determination. The SHCC voted to deny Rex's adjusted need petition because only one year of data showed a deficit.

In 2015, WakeMed petitioned in the spring for a methodology change. This Petition maintained a similar argument to New Hanover Regional Medical Center, stating that the capacity of cardiac catheterization machines is greater than the current methodology assumes. However, one of the reasons this Petition was denied by the SHCC is because each service area has capacity variation; for example, some machines may be underutilized while others are overutilized.

In the summer of 2015, Rex petitioned again for an adjusted need determination. The agency recommended approval of the Petition since the data showed increasing procedures at Rex Hospital with more than one year of data. The Petition was voted on by the SHCC and it was denied.

In 2016, Rex petitioned in the spring to request changes to steps 5 and 6 of the Cardiac Catheterization Methodology One so that "the number of units of fixed cardiac catheterization equipment needed is calculated for each hospital, and a need determination is generated irrespective of surpluses at other hospitals in the service area" with the exception of hospitals under common ownership, where the "surpluses and deficits would be totaled." The SHCC denied this Petition for two reasons: (1) limitations of the methodology as cited in the Petitioner's request and the outcome of the proposed methodology are evident only in Wake County; and (2) data shows a continued decline in cardiac catheterization procedures statewide with relatively few need determinations generated by the current methodology.

Analysis/Implications:

Wake County has a total of 17 cardiac catheterization machines. Of those, Rex has a total current inventory of four machines. Using the standard methodology of 80% utilization, the number of machines for Wake County and Rex is 12.64 and 5.78, respectively. Thus, Rex has a 1.78 machine deficit and Wake County has a 4.36 machine surplus as seen in Table 1 below. Wake County's surplus has remained relatively consistent in the last four years while Rex's deficit has increased each year.

Table 1: Wake County Fixed Cardiac Catheterization Equipment and Weighted Procedures, 2005-2015												
		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Duke Raleigh Hospital	Total Number of Procedures	1288*	202	357	262	770	967	701	366	447	393	463
	No of Machines in Inventory	0	1	1	2	2	2	2	3	3	3	3
	Machines required based on 80% Utilization	1.07	0.17	0.30	0.22	0.64	0.81	0.58	0.30	0.37	0.33	0.39
Rex Hospital	Total Number of Procedures	3,897	4,015	3,646	3,616	3,489	3,002	3,132	3,875	5,029	6,006	6,934
	No of Machines in Inventory	2	3	3	3	4	4	4	4	4	4	4
	Machines required based on 80% Utilization	3.25	3.35	3.04	3.01	2.91	2.50	2.61	3.23	4.19	5.00	5.78
WakeMed	Total Number of Procedures	11,984	11,698	11,657	12,312	12,108	12,618	12,130	10,535	8,570	8,172	7,567
	No of Machines in Inventory	7	8	9	9	9	9	9	9	9	9	9
	Machines required based on 80% Utilization	9.99	9.75	9.71	10.26	10.09	10.52	10.11	8.78	7.14	6.81	6.31
WakeMed-Cary	Total Number of Procedures	498	405	418	393	325	382	325	282	222	223	205
	No of Machines in Inventory	1	1	1	1	1	1	1	1	1	1	1
	Machines required based on 80% Utilization	0.42	0.34	0.35	0.33	0.27	0.32	0.27	0.23	0.19	0.19	0.17
County Totals	Total Number of Procedures	17,667	16,319	16,077	16,582	16,692	16,969	16,287	15,057	14,268	14,794	15,169
	No of Machines in Inventory	10	13	14	15	16	16	16	17	17	17	17
	Machines required based on 80% Utilization	14.72	13.60	13.40	13.82	13.91	14.14	13.57	12.55	11.89	12.33	12.64

Note: The number of machines assigned to each facility is not based on the number that were actually operated by the facility, but the number of machines listed in the inventory for each facility in each year's state medical facility plan.

*Duke Raleigh reported 1288 procedures on the 2006 HLRA, but no fixed cardiac catheterization machine was reported in the plan as in use and procedures were not reported as mobile.

Sources: 2007-2016 SMFPs; Proposed 2017 SMFP

In the face of steady increases and aging of the population in North Carolina, the number of cardiac catheterizations has remained fairly stable over the last decade. Table 2 illustrates the compound annual growth rate (CAGR) and the overall change in the weighted procedures for both Wake County and North Carolina from 2006 to 2015. In Wake County, the last 10 years of data shows an average annual CAGR of -0.81% (a decline) while the NC CAGR over the same time period had an average annual decline of -1.08%. This data indicates an overall decline in the number of procedures for both the County and the State, with Wake County experiencing a slower decline than the State overall.

However, the data presented in Table 2 provides an opportunity to review these utilization trends on an annual basis. In 2015, the most recent data year, Wake County demonstrated an increase in the annual number of procedures by 2.53% while the State experienced a smaller increase of 1.57%. Thus, Wake County is experiencing slightly greater growth compared to statewide trends.

		2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	CAGR 2006-2015
Wake	Total Procedures (weighted)	16,319	16,077	16,582	16,692	16,969	16,287	15,057	14,268	14,794	15,169	-0.81%
	Annual Change		-1.48%	3.14%	0.66%	1.66%	-4.02%	-7.55%	-5.24%	3.69%	2.53%	

		2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	CAGR 2006-2015
NC	Total Procedures (weighted)	118,892	113,643	119,910	115,865	115,017	114,567	112,060	109,885	106,185	107,853	-1.08%
	Annual Change		-4.41%	5.51%	-3.37%	-0.73%	-0.39%	-2.19%	-1.94%	-3.37%	1.57%	

Sources: 2007-2016 SMFPs; Proposed 2017 SMFP

Rex’s Petition suggests they have had unique utilization trends in recent years. The Petition cites an increase in procedure volume as a result of the professional affiliation with Wake Heart & Vascular Associates (WHV). A review of the data in Table 3 provides support for this assertion.

As seen in Table 3 below, Rex is the only provider in Wake County that has shown a consistent increase in the number of procedures over the last five years. More notably, in the most recent three years, Rex has demonstrated utilization greater than 80% – the utilization threshold for determining a need in the health service area. Application of the methodology does generate deficits for this facility. However, the standard methodology considers procedure volume and number of machines in the entire service area. Thus, Rex’s deficit is offset by a surplus of machines in Wake County as a whole. Finally, Rex’s utilization has increased from 84% two years ago to 116% in the most current year of data, which exceeds the need for one additional machine.

		2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Duke Raleigh Hospital	Total weighted procedures	202	357	262	770	967	701	366	447	393	463
	No of Machines	1	1	2	2	2	2	3	3	3	3
	Procedures for 100% Utilization	1,500	1,500	3,000	3,000	3,000	3,000	4,500	4,500	4,500	4,500
	Utilization	13%	24%	9%	26%	32%	23%	8%	10%	9%	10%

Rex Hospital	Total weighted procedures	4,015	3,646	3,616	3,489	3,002	3,132	3,875	5,029	6,006	6,934
	No of Machines	3	3	3	4	4	4	4	4	4	4
	Procedures for 100% Utilization	4,500	4,500	4,500	6,000	6,000	6,000	6,000	6,000	6,000	6,000
	Utilization	89%	81%	80%	58%	50%	52%	65%	84%	100%	116%

WakeMed	Total weighted procedures	11,698	11,657	12,312	12,108	12,618	12,130	10,535	8,570	8,172	7,567
	No of Machines	8	9	9	9	9	9	9	9	9	9
	Procedures for 100% Utilization	12,000	13,500	13,500	13,500	13,500	13,500	13,500	13,500	13,500	13,500
	Utilization	97%	86%	91%	90%	93%	90%	78%	63%	61%	56%

WakeMed Cary	Total weighted procedures	405	418	393	325	382	325	282	222	222	205
	No of Machines	1	1	1	1	1	1	1	1	1	1
	Procedures for 100% Utilization	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500
	Utilization	27%	28%	26%	22%	25%	22%	19%	15%	15%	14%

Note: The number of machines assigned to each facility is not based on the number that were actually operated by the facility, but the number of machines listed in the inventory for each facility in each year’s state medical facility plan.

*Duke Raleigh reported 1288 procedures on the 2006 HLRA, but no fixed CC machine was reported in the plan as in use and procedures were not reported as mobile.

Sources: 2007-2016 SMFPs; Proposed 2017 SMFP

Agency Recommendation:

The Agency supports the standard methodology for fixed cardiac catheterization equipment. The current methodology calculates a 1.78 machine deficit for Rex. As discussed above, the deficits at Rex in the last three years have been offset by the surpluses at other facilities in Wake County. Wake County, and in particular Rex, are experiencing increases in the utilization of cardiac catheterization laboratories. Given available information and comments submitted by the August 12, 2016 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends approval of the Petition.