

Holland & Knight

1180 West Peachtree Street, Suite 1800 | Atlanta, GA 30309 | T 404.817.8500 | F 404.881.0470
Holland & Knight LLP | www.hklaw.com

Brian Looby
404.898.8121
Brian.Looby@hklaw.com

The CON document in its entirety
consisting of **317 pages** is on file in
the Clerk of Council's Office.

January 4, 2024

Via FedEx

Sandra Davis, Council Clerk
Columbus-Muscogee Council
1111 1st Avenue, 3rd Floor
Columbus, Georgia 31906

Re: Certificate of Need Application

Dear Ms. Davis:

Please find enclosed a Certificate of Need ("CON") application on behalf of the Southeastern Cardiology Associates, P.C. to establish a Positron Emission Service in Columbus, Georgia.

Ga. Comp. R. & Regs. 111-2-2-.06(7) requires a copy of the application be submitted to the county in which the project is proposed.

Sincerely yours,

HOLLAND & KNIGHT LLP



Brian Looby
Partner

BL
Enclosure

Section 2: Project Description

14. Indicate the type of facility that will be involved in the project.


FACILITY TYPE	
<input type="checkbox"/> Birthing Center	<input type="checkbox"/> Hospital
<input type="checkbox"/> Continuing Care Retirement Community (CCRC)	<input type="checkbox"/> Nursing or Intermediate Care Facility
<input type="checkbox"/> Freestanding Ambulatory Surgery Center	<input type="checkbox"/> Personal Care Home
<input type="checkbox"/> Home Health Agency	<input type="checkbox"/> Traumatic Brain Injury Facility
<input type="checkbox"/> Freestanding Emergency Department	
<input checked="" type="checkbox"/> Diagnostic, Treatment or Rehabilitation Center (DTRC)	
<input type="checkbox"/> Freestanding Single-Modality Imaging Center	<input type="checkbox"/> Freestanding Multi-Modality Imaging Center
<input type="checkbox"/> Mobile Imaging	<input checked="" type="checkbox"/> Practice-Based Imaging
<input type="checkbox"/> Other:	


15. Indicate the services that will be involved or affected by this project.

SERVICES	
ACUTE	Hospital Inpatient <input type="checkbox"/> Medical/Surgical <input type="checkbox"/> Open Heart Surgery <input type="checkbox"/> Pediatric <input type="checkbox"/> Obstetrics <input type="checkbox"/> ICU/CCU <input type="checkbox"/> Newborn, ICU/INT <input type="checkbox"/> Newborn/Nursery <input type="checkbox"/> Rehabilitation <input type="checkbox"/> Acute, Burn, Other Specialty <input type="checkbox"/> Long Term Acute Care <input type="checkbox"/> Inpatient, Other <input type="checkbox"/> Psychiatric, Adult <input type="checkbox"/> Substance Abuse, Adult <input type="checkbox"/> Psychiatric, Child/Adolescent <input type="checkbox"/> Substance Abuse, Child/Adolescent <input type="checkbox"/> Psychiatric, Extended Care <input type="checkbox"/> Destination Cancer Hospital
	Diagnostic Services <input type="checkbox"/> Computerized Tomography (CT) Scanner <input type="checkbox"/> Magnetic Resonance Imaging (MRI) <input checked="" type="checkbox"/> Positron Emission Tomography (PET) <input type="checkbox"/> Diagnostic Center, Cancer/Specialty
	Other Outpatient Services <input type="checkbox"/> Ambulatory Surgery <input type="checkbox"/> Birthing Center
LONG-TERM	Clinical/Surgical <input type="checkbox"/> Emergency Medical <input type="checkbox"/> Emergency Medical, Trauma Center <input type="checkbox"/> Adult Cardiac Catheterization <input type="checkbox"/> Gamma Knife <input type="checkbox"/> Lithotripsy <input type="checkbox"/> Pediatric Cardiac Catheterization <input type="checkbox"/> Megavoltage Radiation Therapy
	<input type="checkbox"/> Skilled Nursing Care <input type="checkbox"/> Intermediate Nursing Care <input type="checkbox"/> Continuing Care Retirement Community (CCRC)
OTHER	<input type="checkbox"/> Personal Care Home <input type="checkbox"/> Traumatic Brain Injury (TBI) <input type="checkbox"/> Home Health
	<input type="checkbox"/> Administrative Support <input type="checkbox"/> Non-Patient Care, Other
	<input type="checkbox"/> Grounds/Parking <input type="checkbox"/> Medical Office Building

16. Check the most appropriate category(ies) for this project. Check all that apply.

PROJECT CATEGORY	
<p>Construction</p> <input type="checkbox"/> New Facility <input type="checkbox"/> Expansion of Existing Facility <input type="checkbox"/> Renovation of Existing Facility <input type="checkbox"/> Replacement of Existing Facility	<p>Service Change</p> <input checked="" type="checkbox"/> New Service <input type="checkbox"/> Expansion of Service <input type="checkbox"/> Expansion or Acquisition of Service Area <input type="checkbox"/> Consolidation of Service <input type="checkbox"/> Relocation of Facility <input type="checkbox"/> Other
<p>Procurement of Medical Equipment</p> <input checked="" type="checkbox"/> Purchase <input type="checkbox"/> Lease <input type="checkbox"/> Donation (fair market value must be used)	

17. Please provide the following site information for the facility and services identified in this application. Check the appropriate box to indicate the current status of the site acquisition.  Attach the appropriate documents that provide for the Applicant's entitlement to the site at **APPENDIX D**.

 **NOTE:** If an unsigned lease is attached, include a letter documenting both parties' commitment to participate in the lease once the CON is approved, if applicable.

PROJECT SITE INFORMATION	
Street Address: 2119 Warm Springs Road	
City: Columbus	County: Muscogee
Zip: 31904	
Number of Acres: N/A - Leased	
Status of Site Acquisition	
<input type="checkbox"/> Purchased (attach deed)	<input checked="" type="checkbox"/> Leased (attach lease)
<input type="checkbox"/> Under Option (attach option agreement)	<input type="checkbox"/> Under Contract (attach contract or bill of sale)
<input type="checkbox"/> Other; please specify:	
Zoning	
Is the site appropriately zoned to permit its use for the purpose stated within the application?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
If NO → Describe what steps have been taken to obtain the correct zoning and the anticipated date of re-zoning:	
Encumbrances	
Are there any encumbrances that may interfere with the use of the site, such as mortgages, liens, assessments, easements, rights-of-way, building restrictions, or flood plains?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO

18. Provide a detailed description of the proposed project including a listing of the departments (e.g. ED, ICU), services, (e.g. Home Health, Cardiac Cath), and equipment (e.g. MRI, PET, Cath) involved.

NOTE: If your description exceeds this blocked space, attach additional 8-½ by 11-inch pages, number the first sheet Page 9.1, the second Page 9.2 and so on. Do not alter the main page numbers of this application. Once printed, insert your additional pages 9.1, etc. behind this Page 9.

SCA, a cardiology physician practice located in Columbus, Georgia, proposes to acquire a stand-alone positron emission tomography ("PET") unit without an attached computed tomography ("CT") component to perform PET cardiac imaging. The unit will be located at 2119 Warm Springs Road, Columbus, Muscogee County, Georgia.

DET-EQT-2021-017, the Department of Community Health determined that stand-alone PET units are reviewed under the general review criteria only, and the service specific PET rule is not applicable. See also Ga Comp. R. & Regs. 111-2-2-.41(3)(a)(1)(vi) - Stand-alone PET units shall not be included in the inventory and shall not be subtracted to determine the net numerical unmet need.

The unit to be acquired is a ANCORIS PET Scanner PET10003. The unit has a fair market value of \$360,000.00 including all accessories. The PET unit will be operated by SCA staff in connection with its cardiology practice, and SCA will be the sole billing entity for the scans provided using the proposed cardiac PET unit.

Section 3: General Review Considerations

All Certificate of Need applications are evaluated to determine their compliance with the general review considerations contained in Rule 111-2-2-.09. Please document how the proposed project conforms with the following general review considerations.

Rule 111-2-2-.09(1)(a): Consistency with State Health Plan

The proposed new institutional health service is reasonably consistent with the relevant general goals and objectives of the State Health Plan.

19. Explain how the project is consistent with the State Health Plan or why it does not apply. Also explain how the application is consistent with the Applicant's own long range plans.

NOTE: *If your explanation exceeds this blocked space, attach additional 8-½ by 11-inch pages, number the first sheet Page 10.1, the second Page 10.2 and so on. Do not alter the main page numbers of this application. Once printed, insert your additional pages 10.1, etc. behind this Page 10.*

This project is consistent with the purpose of the State Health Planning Statute, which is set forth in O.C.G.A. 31-6-1 and SCA's long range plans.

State Health Plan

O.C.G.A. 31-6-1, in relevant part, provides:

"The policy of this state and the purposes of this chapter are to ensure access to quality health care services and to ensure that health care services and facilities are developed in an orderly and economical manner and are made available to all citizens and that only those health care services found to be in the public interest shall be provided in this state...Health care services and facilities should be provided in a manner that avoids unnecessary duplication of services, that is cost effective, that provides quality health care services, and that is compatible with the health care needs of the various areas and populations of the state."

SCA seeks approval to acquire a stand-alone PET unit without a CT component to provide cardiac PET scans to the practice's patients. The unit will be located at 2119 Warm Springs Road, Columbus, Georgia, and will be used by the practice physicians.

SCA provides health care services to all persons regardless of age, sex, race, national origin, religion, ethnicity, source of payment, or ability to pay, and participates in public and private payors.

There are no service-specific rules applicable to stand-alone PET. As the general considerations demonstrate, the proposed PET scanner is needed to improve the availability of cost-effective, quality, and convenient services in the service area. As a result, the project is in the public interest, avoid unnecessary duplication, is cost-effective, and compatible with the health care needs of the area served by SCA.

Continued on page 10.1

Long Range Plans of SCA

The project is also consistent with the long range plans of SCA to continue to provide access to state-of-the-art, cost-effective, quality, and convenient cardiology services. It is SCA's mission to deliver the best possible cardiology care through a team approach, and utilizing advancements in technology and patient care. Each employee participates in delivering the highest quality of care at SCA. SCA's commitment to its patients is that they will be treated as family - with compassion and consideration.

SCA consists of a world class group of cardiologists embedded within a team that is committed to treating the patient and their loved ones. SCA is set apart by its team of specialized physicians, mid-levels, nurses, technicians and staff who are committed to providing the highest level of service.

SCA provides a range of cardiology services in its office, including:

- Ankle Brachial Index;
- Amyloid Screening;
- Anticoagulation Monitoring;
- Bubble Study;
- Cardiopulmonary Exercise Test;
- Optison Echo (Contrast Echo);
- Nuclear Stress Test;
- Pacemaker Checks;
- Vascular Studies;
- Echocardiogram;
- Electrocardiogram;
- Holter Monitor;
- In-House Labs;
- MUGA Scan;
- Sleep Study;
- Stress Echo; and
- Treadmill Stress Test.

PET has greatly contributed to the understanding cardiac anatomy and pathophysiology. PET plays a pivotal role in assessing epicardial coronary artery anatomy, myocardial perfusion, and ventricular function in patients with known or suspected cardiovascular diseases, and has become an essential tool in the fields of cardiovascular medicine. Cardiac PET has also been proven as an effective noninvasive imaging modality for diagnosing myocardial infiltrative diseases, cardiac ischemia, and cardiac infections.

Indications for cardiac PET include:

- Assessment of hibernating myocardium in patients with left ventricular systolic dysfunction prior to re-vascularisation procedure;
- Assessment of myocardial viability in patients with a fixed defect on single-photon emission cardiac tomography (SPECT), who might benefit from revascularization;

- Assessment of patients prior to referral for cardiac transplantation;
- Diagnosis and assessment of the physiologic significance of coronary artery disease;
- Assessment of coronary artery disease in symptomatic patients where other non-invasive investigations remain equivocal;
- Differentiating ischemic and non-ischemic cardiomyopathy;
- Differentiating underlying mechanisms and causes of non-ischemic cardiomyopathy;
- Differentiation of benign cardiac lesions from malignant lesions;
- Identification of an unknown primary tumor when patients present with metastatic disease or paraneoplastic syndrome;
- Adjunct tool in detecting infiltrative diseases such as cardiac sarcoidosis;
- Monitoring the cardiac effect of chemotherapy on known malignancies.¹

The addition of a dedicated cardiac PET would contribute to SCA achieving its long range plans which include providing the highest quality cardiac care the the region.

SCA's commitment to top quality cardiology care also extends to educating its community and colleagues through actively participating in community health and professional events, such as:

- Presenting at stroke seminars that are free to the public;
- Presenting at professional seminars;
- Participating in health segments on local news channels;
- Promoting the American Heart Association;
- Publications in professional journals; and
- Participating in local heart walks

The following is a sample of testimonials from SCA patients:

"The doctors and staff at Southeastern Cardiology are wonderful. They are all friendly, professional and make you feel at ease. Dr. Darrah saved my life in August of 2015 and Dr. Champion is always available to advise me when I have problems. They are simply the best."
Kimberly T.

"I would like to take a moment to thank you and your entire staff for the super great care that you all have provided for my sister. I cannot express the true credit that you and your staff deserve. Be it known to all that I would trust my physical life, the physical lives of my family and the physical

¹ Source: Ahmed, Intisar and Pavan Devulapally; "Nuclear Medicine PET Scan Cardiovascular Assessment, Protocols, and Interpretation"; NCBI Bookshelf. A service of the National Library of Medicine, National Institutes of Health; July 30, 2023.

lives of this country in the hands of Dr. Lopez and her staff. All your efforts have contributed to me still having my dear sister with us. God bless all!" Douglas L.

"I have been to every doctor in Macon and no one was able to help me. Dr. Champion walked right in and diagnosed me on the spot. He is the greatest doctor I have ever been to and I am thankful." Margaret S.

SCA's proposed project is consistent with the purpose of the State Health Planning Statute and SCA's long range plans.

Rule 111-2-2-.09(1)(b): Need

The population residing in the area served, or to be served, by the new institutional health service has a need for such services.

20. Please explain the need for your particular project or service. For services for which a need methodology exists in the State Health Plan, please use the said methodology. In submitting information to explain the need for your project, please also use the following guidelines:

- For any population projections, the official projections of the Office of Planning and Budget should be utilized;
- Include maps that clearly define both the primary and secondary service areas and identify all other providers of the proposed service that lie within the primary and secondary service area on such maps;
- Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients, visitors, and employees; and
- For services that already have documented utilization rates, include such historical utilization data, and projections for future utilization.

NOTE: *If your explanation exceeds this blocked space, attach additional 8-½ by 11-inch pages, number the first sheet Page 11.1, the second Page 11.2 and so on. Do not alter the main page numbers of this application. Once printed, insert your additional pages 11.1, etc. behind this Page 11.*

ATTACH: Attach any documentation, such as magazine articles, research papers, or any other document that cannot be reproduced or created in MS Word format and that supports the need for your project into **APPENDIX E**. All documents such as tables, charts, and maps that support your need analysis and that are able to be inserted or created in MS Word format should be inserted following this page according to instructions in the note above.

SCA proposes to acquire a stand-alone PET scanner without an attached computed tomography component. The PET unit will be located at the practice at 2119 Warm Springs Road, Columbus, Muscogee County, Georgia.

In DET-EQT-2021-017, the Department of Community Health determined that stand-alone PET units are reviewed under the general review criteria only, and the service specific PET rule is not applicable. See also Ga Comp. R. & Regs. 111-2-2-.41(3)(a)(1)(vi) - Stand-alone PET units shall not be included in the inventory and shall not be subtracted to determine the net numerical unmet need.

The unit to be acquired is a ANCORIS PET Scanner PET10003. The unit has a fair market value of \$330,000.00 including all accessories. The PET unit will be operated by SCA staff in connection with its cardiology practice, and SCA will be the sole billing entity for the scans provided using the proposed cardiac PET unit.

Need

PET is a powerful, quantitative imaging modality that has greatly contributed to the understanding of cardiac anatomy and pathophysiology. PET is considered the “gold standard” for cardiac imaging because of its quantitative nature, superior detection sensitivity, and its spatial and

Continued on Page 11.1

temporal resolution over other modalities, including single-photon emission computed tomography (“SPECT”). Due to its superior quality, cardiac PET imaging can avoid unnecessary surgical interventions, such as bypass surgery and cardiac transplants and, as a result, PET has been found to be more cost-effective than SPECT. (**Appendix E**, “Cardiac Positron Emission Tomography” J. Am. Coll Cardiol. 2009 Jun.; “Cost-effectiveness of 82-Rubidium PET myocardial perfusion imaging for the diagnosis of myocardial ischemia depending on the prevalence of coronary artery disease”, EJNMMI Res. 2023; 13: 9, Published online 2023 Feb 8; “Impact of Myocardial Perfusion Imaging with PET and Rb on Downstream Invasive Procedure Utilization, Costs, and Outcomes in Coronary Disease Management”, Journal of Nuclear Medicine, July 2007, 48 (7) 1069-1076). As such, there has been a three-fold increase in the use of in-office PET for cardiology between 2010 and 2019, and more widespread use of PET in cardiology overall. (**Appendix E**, “Cardiac Imaging Trends from 2010 to 2019 in the Medicare Population”, Radiology: Cardiothoracic Imaging, Vol. 3, No. 5, Published Online: Sep 30 2021; “Cardiac Positron Emission Tomography”, J. Am. Coll Cardiol. 2009 Jun.).

PET plays a pivotal role in assessing epicardial coronary artery anatomy, myocardial perfusion, and ventricular function in patients with known or suspected cardiovascular diseases, and has become an essential tool in the fields of cardiovascular medicine. Cardiac PET has also been proven as an effective noninvasive imaging modality for diagnosing myocardial infiltrative diseases, cardiac ischemia, and cardiac infections.

Indications for cardiac PET include:

- Assessment of hibernating myocardium in patients with left ventricular systolic dysfunction prior to re-vascularisation procedure;
- Assessment of myocardial viability in patients with a fixed defect on single-photon emission cardiac tomography (SPECT), who might benefit from revascularization;
- Assessment of patients prior to referral for cardiac transplantation;
- Diagnosis and assessment of the physiologic significance of coronary artery disease;
- Assessment of coronary artery disease in symptomatic patients where other non-invasive investigations remain equivocal;
- Differentiating ischemic and non-ischemic cardiomyopathy;
- Differentiating underlying mechanisms and causes of non-ischemic cardiomyopathy;
- Differentiation of benign cardiac lesions from malignant lesions;
- Identification of an unknown primary tumor when patients present with metastatic disease or paraneoplastic syndrome;
- Adjunct tool in detecting infiltrative diseases such as cardiac sarcoidosis; and

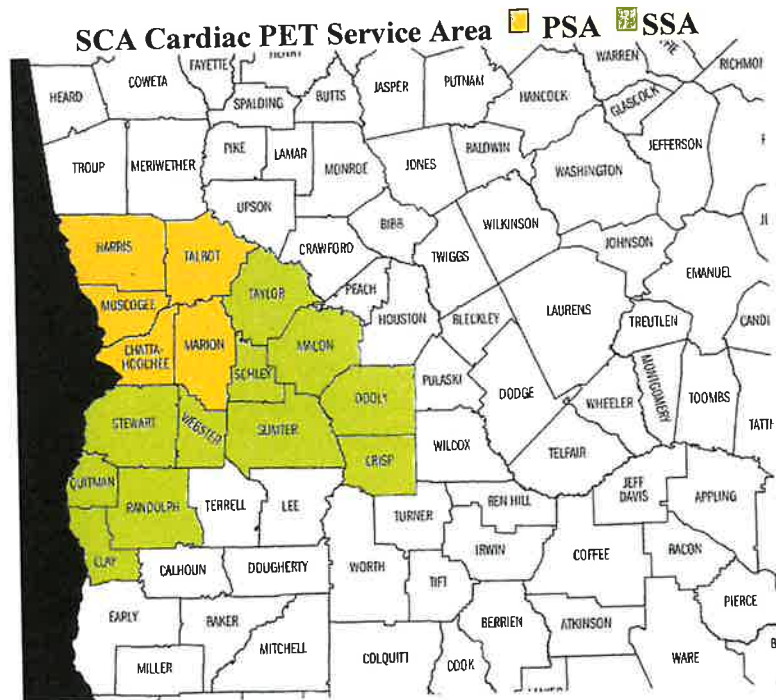
- Monitoring the cardiac effect of chemotherapy on known malignancies.

(Appendix E, “Nuclear Medicine PET Scan Cardiovascular Assessment, Protocols, and Interpretation”; July 30, 2023.)

Cardiovascular disease includes all diseases of the heart and blood vessels, including ischemic heart disease, stroke, congestive heart failure, hypertension and atherosclerosis. It is the single leading cause of death in Georgia, accounting for more than 22,000 deaths a year, and most of which are premature and preventable.¹

Service Area

SCA’s proposed primary service area (“PSA”) is Chattahoochee, Harris, Marion, Muscogee, and Talbot Counties. The secondary service area (“SSA”) consists of Clay, Crisp, Dooly, Macon, Quitman, Randolph, Schley, Stewart, Sumter, Taylor, and Webster Counties. A map of the proposed service area, which encompasses all of HPA 8, follows.



The proposed service area will have modest overall population growth through the horizon year due to an increase in the population of the PSA and a slight decrease in the population of the SSA. However, for age 65 and over, the group at the highest risk of heart disease, the population is projected to grow substantially.

¹ Georgia Department of Public Health, Heart Disease, <https://dph.georgia.gov/chronic-disease-prevention/heart-disease>.