

**BEFORE THE STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY**

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Apr 6 2021

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

IN RE:)
)
EAST ALABAMA HEALTH CARE)
AUTHORITY d/b/a EAST ALABAMA)
MEDICAL CENTER (EAMC)) **DR-157**
)
Letter of Non-Reviewability Issued by)
SHPDA to John Mitchell, M.D., and)
The Heart Center Cardiology, P.C.)

PETITION FOR DECLARATORY RULING

COMES NOW Petitioner, The East Alabama Health Care Authority d/b/a East Alabama Medical Center (“EAMC”), and pursuant to Rule 410-1-9-.01 of the Alabama Certificate of Need Program Rules and Regulations submits this Petition for Declaratory Ruling regarding the Letter of Non-Reviewability (“LNR”) issued to John Mitchell, M.D., and The Heart Center Cardiology, P.C. (“Dr. Mitchell”), to perform cardiovascular surgical procedures at 2375 Champions Drive in Auburn, Alabama pursuant to the physician’s office exemption (“POE”).

EAMC respectfully seeks a declaratory ruling that the cardiovascular surgical procedures to be performed by Dr. Mitchell are not customarily performed in a private physician's office; that such procedures are “health services” and “institutional health services” as defined by ALA. CODE § 22-21-260(8) and § 22-21-260(9); that Dr. Mitchell’s private physician’s office is not an appropriate clinical venue for performing the procedures; that performing procedures there does not

qualify for the POE because the catheterization laboratory and related equipment will not be physically located within Dr. Mitchell's private physician's office; that extending the POE to institutional health services would circumvent the CON review process and the State Health Plan; and that a Certificate of Need is required for the cardiovascular surgical procedures to be offered by Dr. Mitchell. In further support hereof, EAMC states as follows:

I. PROCEDURAL BACKGROUND

On October 29, 2020, Dr. Mitchell submitted a request for a Letter of Non-Reviewability ("LNR") to SHPDA, which was assigned Reviewability Determination Request RV 2021-003, to perform cardiovascular surgical procedures at 2375 Champions Drive, Suite 100, Auburn, Alabama. (Exhibit A-1).¹ The request for LNR represented the services Dr. Mitchell intends to perform as follows:

Within the current private practice location for The Heart Center Cardiology, located at 2375 Champions Blvd. Suite 100 Auburn, AL 36830, Dr. Mitchell intends to perform low risk peripheral angiography and interventional procedures, left and right diagnostic heart catheterizations- coronary angiography, elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk ICD and pacemaker implantation, Implantable loop *[sic]* recorder insertion, direct current cardioversion, infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, [and] ventricular and [sic.] nodal

¹ The filings made by Dr. Mitchell and The Heart Center Cardiology, along with filings made by EAMC and communications from SHPDA, in RV 2021-003 are attached as composite Exhibit A. Each individual filing is attached in date order and assigned a number in ascending order. Therefore, the LNR is A-1; SHPDA's Notice to Affected Persons is A-2; EAMC's initial response is A-3, and so on.

ablation procedures within his private practice. No novel procedures will be performed, and all of the procedures requested are standard, commonly performed in both inpatient and outpatient settings. The procedures are low risk, minimally invasive and general anesthesia is not required, nor will it be used in the office setting. Dr. Mitchell has an established care plan including the identification of involved personnel and equipment, to deal with any issues related to unexpected changes in a patient's status. This includes oxygen and masks for ventilation, medications for arrhythmias and reversal of sedation, defibrillation and pacing as well as a pathway to transfer to a higher level of care as needed. All procedures will be limited to adults > 18yo only. Patients will be informed that some of the proposed procedures are “look only” or therapeutic/interventional and may require an additional procedure in a hospital setting. Physicians have been able to perform nearly all electrical cardioversion procedures using moderate to deep sedation (a widely accepted practice,) if patient safety ever requires the use of general anesthesia, the procedure would be scheduled and performed in the hospital setting. No general anesthesia will be used in Dr. Mitchell's office-based lab. In addition, Dr. Mitchell will not be crossing from the right side of the heart to the left for any ablations which would be a higher risk procedure.

(Exhibit A-1 at 1).

Dr. Mitchell contends that the cardiovascular surgical procedures to be performed are non-reviewable under the physician's office exemption (“POE”): “The Heart Center Cardiology and Dr. Mitchell will abide by the office-based surgery requirements for the use of general anesthesia, as set forth in Ala. Admin. Code Rules 540-X-10-.08 and 540-X-10-.09 as well as Rule 540-X-10-.12 and reporting requirements of Rule 540-X-10-.11.” (Exhibit A-1 at 2). He also represents that his annual operating costs will be \$618,000 and that his practice will acquire “Total Major Medical Equipment estimated cost . . . = \$350,000.00.” for

“Diagnostic X-Ray System, patient monitoring equipment, patient recovery equipment, defibrillator and IVUS for arterial and venous procedures and ancillary equipment required for the listed procedures.” (Exhibit A-1 at 3). In summary, Dr. Mitchell’s LNR request states:

With the support of this document, we respectfully request that the Alabama State Health Planning and Development Agency grant a determination of non-reviewability to The Heart Center Cardiology for the proposed “*office-based surgery*” *procedures* described herein.

(Exhibit A-1 at 4) (emphasis added).

After Dr. Mitchell responded to certain questions raised by SHPDA regarding the proposed project, Notice of the LNR Request was disseminated by SHPDA. (Exhibit A-2).

On December 16, 2020, EAMC filed its response in opposition to Dr. Mitchell's LNR request. Initially, EAMC objected to the request because it was substantively identical to a request filed by Leg Health Vascular Centers, Inc. (RV2020-021) to perform cardiovascular surgical procedures under the POE also within the office of Dr. John Mitchell at 2375 Champions Blvd. in Auburn, Alabama, and Dr. Mitchell's request was filed only three days after SHPDA had refused to issue a Letter of Non-Reviewability for Leg Health. (Exhibit B-10).²

² The filings involving Leg Health are attached as Composite Exhibit B. The Leg Health LNR was submitted by Leg Health Vascular Centers, Inc., which represented that it would be the “private practice office” of Dr. John Mitchell and Drs. Jacob Townsend and Robert Yoe, both of whom currently practice with Birmingham Heart

Subsequently, EAMC challenged the efficacy of performing invasive cardiovascular procedures in Dr. Mitchell's physician's office and, specifically, the efficacy of Dr. Mitchell performing the invasive procedures identified by Dr. Mitchell given the conflicting representations made by him or on his behalf to SHPDA. (See Exhibit A-7 at 2) ("Unlike a private physician's office, hospitals are all regulated, licensed and accredited by various authorities, including the Alabama Department of Public Health, The Joint Commission, and others, and are subject to inspection and various reporting requirements. . . . However, no requirements are applicable to The Heart Center because, as the office of a private physician, it is not licensed or accredited.").

On February 19, 2021, SHPDA by and through its Executive Director, Emily Marsal, issued an LNR in favor of Dr. Mitchell and The Heart Center Cardiology, P.C. (Exhibit A-13). In issuing the LNR, SHPDA concluded that the POE applied to the project because it satisfied the four elements of the POE as established in Ex

Clinic and reside in Mountain Brook, Alabama, almost 120 miles from Dr. Mitchell's office in Auburn. (Exhibit B-1 at 1-2). In addition, Leg Health Vascular Centers, Inc., is located in Montgomery, Alabama, and appeared to be a marketing, administrative, and clinical services provider. (Exhibits B-3 and B-5). Therefore, the POE could not apply and SHPDA could not provide Leg Health with a letter of non-review. After a series of letters to SHPDA by Leg Health and EAMC disputing and contesting Leg Health's LNR request, SHPDA responded as follows on October 26, 2020: "The LNR process is not well suited to resolve the competing factual and legal assertions of Leg Health and EAMC. Accordingly, the Agency is unable to determine that this project qualifies for the POE." (Exhibit B-10).

Parte Sacred Heart Health System, Inc., 155 So. 3d 980 (Ala. 2012). Relying solely on representations made by Dr. Mitchell, SHPDA concluded that that: (1) the proposed services provided, and related equipment used, will be exclusively by Dr. Mitchell and his practice, The Heart Center; (2) the proposed services will be provided, and related equipment used, at Dr. Mitchell's office, The Heart Center located at 2375 Champion Blvd., Auburn, AL; (3) billing for the services will be done through and on behalf of Dr. Mitchell's practice, The Heart Center; and (4) the equipment used for the performance of Dr. Mitchell's office-based procedures will not be used for inpatient care, nor by or through or on behalf of a healthcare facility. (Exhibit A-13 at 2-3).

This Petition for Declaratory Ruling follows SHPDA's issuance of the LNR.

II. FACTUAL BACKGROUND

A. EAMC HAS A DIRECT AND PROTECTED INTEREST IN THE APPLICATION OF THE STATE HEALTH PLANNING LAWS TO THE HEART CENTER.

Petitioner EAMC holds CONs to develop and operate multiple healthcare facilities in Lee County, Alabama, where the proposed project by The Heart Center will be located. EAMC operates the only acute-care hospital/regional medical center in Lee County; and EAMC is presently developing the only free-standing ambulatory surgery center and free-standing emergency department in Lee County. EAMC is Lee County's only comprehensive provider of all forms of medical

services, i.e., general, acute-care and specialized medical services. In addition, EAMC provides comprehensive cardiovascular-care services, including CT, five cardiovascular catheterization laboratories, and open-heart surgery services. Accordingly, EAMC has a direct interest in whether the cardiovascular surgical procedures Dr. Mitchell intends to perform will comply with the Alabama CON law and SHPDA's rules and regulations. In addition, EAMC will be substantially and adversely affected if Dr. Mitchell furnishes cardiovascular surgical procedures in violation of the CON law and SHPDA's rules and regulations.

B. THE NATURE AND SCOPE OF DR. MITCHELL AND THE HEART CENTER'S CARDIOVASCULAR SURGICAL PROCEDURES.

Dr. Mitchell represents that he is engaged in the private practice of medicine, doing business as The Heart Center Cardiology, at 2375 Champions Drive, Suite 100, Auburn, Alabama. The building located at 2375 Champions Drive was previously the subject of a declaratory ruling by the CON Review Board in DR110 (Exhibit C), which involved the building's development and the creation of The Institute for Advanced Cardiovascular Care by Dr. Mitchell; The Heart Center Cardiology, P.C.; East Alabama Cardiovascular Associates, P.C.; CathLab Partners, LLC; Advanced Cardiovascular Development, LLC; and Community Medical Development, LLC. As addressed in DR110, the building cost \$9.5 million to build and is a three-story, 58,000 square foot facility. (Exhibit C at 1-2). The building was

developed with the intent of housing a CT scan, heart catheterization laboratory, and office space for “allied medical practices.” (Exhibit C at 1-2). The CON Review Board held in DR110 that the project was not covered by the POE and a CON was required for its development. According to DR110:

In the present case, after considerable review of the evidence and examination by Board members, the Board has concluded that the design and structure of this large multi-floor facility reflects an intent to share and use facilities and equipment for the treatment of patients other than just those of the treating physicians whose primary offices are located at the facility. The Board further concludes that, based on the available evidence, the project involves the provision of a new institutional health service, does not qualify for the Physicians’ Office Exemption, and is thus reviewable.

(Exhibit C at 7).

With the present Petition for Declaratory Ruling, whether Dr. Mitchell’s medical practice is actually limited to The Heart Center is unclear and, although the issue was raised by EAMC, it was never addressed by Dr. Mitchell nor was it expressly considered by SHPDA in giving an LNR to The Heart Center. The Heart Center has its own website, <https://www.theheartcentercardiology.com/> (screen-shots attached as Exhibit D), but Dr. Mitchell also operates a separate clinic, known as “the Chest Pain Walk-In Clinic” at the same address. The Chest Pain Walk-In Clinic likewise has its own website, <https://www.chestpainwalkinclinic.com/> (screen-shots attached as Exhibit E), which contains a picture showing a separate, marked entrance for the clinic. The Chest Pain Walk-In Clinic describes itself as a

means of bypassing the wait at the EAMC emergency room for persons experiencing a cardiac event. (See Exhibit E at 2) (“If you are experiencing a cardiac event, transport will be arranged for immediate transport to EAMC, bypassing the long wait in the emergency department.”). The Heart Center’s earlier LNR request did not mention the Chest Pain Walk-In Clinic, but since they are located at the same address and Dr. Mitchell operates both, then the project at issue here could be used for the Chest Pain Walk-In Clinic, which is advertised as an outpatient clinic for cardiac events. (Exhibit E at 2).

As previously mentioned, Dr. Mitchell proposes to perform a variety of cardiovascular surgical procedures at his 58,000 square foot facility consisting of the following: peripheral angiography and interventional procedures, left and right diagnostic heart catheterizations-coronary angiography, elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk ICD and pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial and ventricular nodal ablation procedures using moderate to deep sedation.

The cardiovascular surgical procedures Dr. Mitchell will perform go beyond mere diagnostic procedures. Instead, they are curative and rehabilitative surgical

procedures customarily furnished in a healthcare facility (i.e., acute care hospital), as discussed hereafter.

III. ALABAMA LAW

As provided by ALABAMA CODE § 22-21-261, a Certificate of Need (CON) program has been established to ensure that healthcare services and facilities are reviewed and meet the public interest. Section 22-21-261 states as follows:

The Legislature of the State of Alabama declares that it is the public policy of the State of Alabama that a certificate of need program be administered in the state to assure that **only those healthcare services and facilities found to be in the public interest** shall be offered or developed in the state. It is the purpose of the Legislature in enacting this article **to prevent the construction of unnecessary and inappropriate healthcare facilities through a system of mandatory reviews** of new institutional health services, as the same are defined in this article.

(Emphasis added).

ALABAMA CODE § 22-21-263(a) also provides “[a]ll new institutional health services which are subject to this article and which are proposed to be offered or developed within the state shall be subject to review under this article.” Section 22-21-263(a) goes on to state that new “institutional health services” include “the construction, development, acquisition through lease or purchase, or other establishment of a new healthcare facility or health maintenance organization.” Section 22-21-263(a) further provides: “No institutional health services which are

subject to this article shall be permitted which are inconsistent with the State Health Plan.”

ALABAMA CODE § 22-21-260(9) defines “institutional health services” to be “health services provided in or through healthcare facilities or health maintenance organizations, including the entities in or through which such services are provided.”

ALABAMA CODE § 22-21-260(6) defines a “healthcare facility” to specifically include hospitals and related facilities such as laboratories, out-patient clinics, and ambulatory surgery centers, stating in part as follows:

General and specialized hospitals, including tuberculosis, psychiatric, long-term care, and *other types of hospitals, and related facilities such as, laboratories, out-patient clinics*, and central service facilities operated in connection with hospitals; skilled nursing facilities; intermediate care facilities; skilled or intermediate care units operated in veterans’ nursing homes and veterans’ homes, owned or operated by the State Department of Veterans’ Affairs, as these terms are described in Chapter 5A (commencing with Section 31-5A-1) of Title 31, rehabilitation centers; public health centers; *facilities for surgical treatment of patients not requiring hospitalization*; kidney disease treatment centers, including free-standing hemodialysis units; community mental health centers and related facilities; alcohol and drug abuse facilities; facilities for the developmentally disabled; hospice service providers; and home health agencies and health maintenance organizations.

(Emphasis added).

ALABAMA CODE § 22-21-260(8) defines “health services” as also expressly including clinically related diagnostic and curative services and services customarily furnished by healthcare facilities:

Clinically related (i.e., diagnostic, curative, or rehabilitative) services, including alcohol, drug abuse, and mental health services customarily furnished on either an in-patient or out-patient basis by healthcare facilities, but not including the lawful practice of any profession or vocation conducted independently of a healthcare facility and in accordance with applicable licensing laws of this state.

(Emphasis added).

The SHPDA Certificate of Need Program Rules and Regulations (“SHPDA Rules”) define a “Certificate of Need” to be:

[A] permit required by law before which no person, except as exempted by statute, shall acquire, construct or operate a new institutional health service or acquire major medical equipment, or furnish or offer, or purport to furnish a new institutional health service, or make arrangement or commitment for financing the offering of the new institutional health service or acquiring the major medical equipment.

SHPDA Rule 410-1-2-.19 (emphasis added).

Accordingly, based upon the above statutes’ regulations, all new health services - - specifically laboratories, hospital related facilities, out-patient clinics, ambulatory surgery centers, and clinically related services *customarily furnished on an inpatient or outpatient basis* - - are subject to Certificate of Need review.

IV. ANALYSIS AND CONCLUSION

A. THE CARDIOVASCULAR SURGICAL PROCEDURES DR. MITCHELL AND THE HEART CENTER CARDIOLOGY, P.C., WILL PERFORM ARE NOT CUSTOMARILY FURNISHED IN A PHYSICIAN'S OFFICE.

As defined by law, "Health Services" are clinical services customarily performed in healthcare facilities, but excluding "the lawful practice of any profession or vocation *conducted independently of a healthcare facility.*" Ala. Code § 22-21-260(8). The cardiovascular surgical procedures Dr. Mitchell will perform are high-risk and are customarily performed in a healthcare facility, and conducting them independently of a healthcare facility is dangerous, will jeopardize patient care, and will be a breach of the standard of care. *In fact, Dr. Mitchell is committed to performing atrial and ventricular nodal ablation but he is not credentialed to perform these procedures at EAMC.*

For example, Dr. Mitchell proposes to furnish pacemaker implantation and internal cardiac defibrillator (ICD). These procedures are not customarily performed in a physician's office because they both have an inherent risk for sudden cardiac death, and they involve multiple serious health risks, including bleeding, allergic reaction and the danger of perforation and/or collapsed lung. (Exhibit F at 1).

Ordinarily pacemaker implant patients are elderly with multiple comorbidities and it is not uncommon for pacemaker implant patients to require overnight

hospitalization. A pacemaker implant patient must be closely monitored during the procedure, including close monitoring of the patient's oxygen levels, and a defibrillator must be available for immediate use by a trained professional.

The same is true for an ICD implant, which also carries a risk of blood vessel damage and the occasional need for overnight hospitalization. An ICD procedure may also require deep sedation and even general anesthesia. (Exhibit F at 1). Again, implanting an ICD is not customarily performed in a physician's office; and the procedure should not be performed independently of a healthcare facility.

There are also numerous serious health and safety risks for the other procedures Dr. Mitchell intends to perform. For example, peripheral angiography and interventional procedures (angioplasty, atherectomy) carry a very real risk of vessel or organ damage or perforation which can require urgent surgical repair as well as the risk of anaphylaxis reactions to contrast agents. (Exhibit F at 1). Likewise, left and right diagnostic heart catheterizations and coronary angiography carry the exact same risks. (Exhibit F at 1). Pacemaker generator changes carry the risk of bleeding, damage to blood vessels, and a collapsed lung. (Exhibit F at 2). Implantable loop recorder insertion carries the risk of bleeding. (Exhibit F at 2). Cardioversion carries the risk of stroke, blood clots, and life threatening arrhythmia. (Exhibit F at 2). Infusaport placement carries the risk of a venous malpositioning of the catheter and perforation with arterial injury, pneumothorax, hemothorax,

thoracic duct injury and cardiac tamponade. (Exhibit F at 2). A transesophageal echocardiogram (“TEE”) carries a risk of bleeding or tearing of the esophagus. (Exhibit F at 3). Implanting a pulmonary artery pressure recording device carries a risk of heart arrhythmias, knotting the catheter, rupture of a pulmonary artery, severely reduce blood flow to part of the lung, and blood clots causing stroke. (Exhibit F at 3).

Atrial and ventricular nodal ablations carry a risk of damage to blood vessels, bleeding, blood clots, puncturing the heart wall, and dislodging the pacemaker lead. (Exhibit F at 3-4). These procedures almost exclusively involve patients with severely reduced cardiac function who are at risk for severe compromise during the procedure. (Exhibit F at 4). Therefore, ablation procedures require significant operator and imaging skill and the utmost professionalism in dealing with life threatening situations because complications may be life-threatening and will develop very quickly. As stated earlier, ***Dr. Mitchell is not credentialed to perform ablations at EAMC.***

Dr. Mitchell represents that the procedures are “low risk, minimally invasive and general anesthesia is not required, nor will it be used in the office setting.” (Exhibit A-5 at 3). However, the procedures are definitely invasive and have multiples risks, including the serious risks previously discussed.

In fact, all cardiac patients are inherently at high risk due to age, prevalence of comorbidities, and baseline reduced cardiac reserve. People age 65 and older (i.e., senior citizens) are the demographic group that suffers most from coronary heart disease, and are most in need of the procedures Dr. Mitchell plans to furnish. This same demographic group also has the most co-morbidities.

Any procedure on a high-risk patient, and especially a complex and invasive coronary surgical procedure that Dr. Mitchell will furnish, is itself hazardous. Performing such a procedure on a cardiac patient in a physician's office versus a healthcare facility is perilous, because the risks are greatly increased, and safety is compromised without any benefit to the patient.

The CON process and SHPDA were created by the Alabama Legislature "to assure that only those healthcare services and facilities found to be in the *public interest* shall be offered or developed in the state." ALA. CODE § 22-21-261 (1975) (emphasis added). Patient safety is a primary concern for determining whether the public interest is served. As stated by the American College of Cardiology and the American Heart Association: "In any catheterization setting, patient safety must be of paramount importance, and must supersede all other considerations." ACC/AHA Guidelines for Cardiac Catheterization & Cardiac Catheterization Laboratories, 84 J. AM. HEART ASSOC. 2212, 2219 (1991).

SHPDA and the CON Review Board exist to ensure that the construction and/or development of “inappropriate healthcare facilities” do not occur. See Ala. Code § 22-21-261., see also, Alabama Renal Stone Institute, Inc. v. State Health Planning Agency, 594 So. 2d 106 (Ala. Civ. App. 1991) (holding that the State Health Planning Agency by statute is the designated agency of the state responsible for state health planning and development). SHPDA has the right to regulate and prohibit inappropriate facilities, including a physician’s office, from performing procedures customarily performed in healthcare facilities when issues of patients’ safety are involved. Therefore, the CON Review Board should enter a declaratory ruling which finds that the cardiovascular surgical procedures Dr. Mitchell intends to perform are not customarily performed in a physician's office, and accordingly, a CON is required if Dr. Mitchell intends to perform such cardiovascular surgical procedures.

B. THE PHYSICIAN’S OFFICE EXEMPTION DOES NOT APPLY TO THE CARDIOVASCULAR SURGICAL PROCEDURES DR. MITCHELL WILL PERFORM AT HIS THREE-STORY, 58,000 SQUARE FOOT FACILITY.

As held by the Alabama Supreme Court in Ex parte Sacred Heart Health System, Inc., 155 So. 3d 980 (Ala. 2012), the POE adopted by the CON Review Board and modified by the Supreme Court is intended “to reflect the legislative

intent expressed in § 22-21-260(6),” which defines “healthcare facilities.” However, as explicitly stated by the Supreme Court:

The POE . . . should not be interpreted as circumventing the statutory language in §§ 22-21-260(6), 22-21-260(8), 22-21-263, and 22-21-265, Ala. Code 1975, or otherwise applicable statutes or administrative regulations pursuant to the “State Health Plan.” The POE application test will provide an objective standard that can be used to determine whether the POE applies to any medical practice, whether the practice is solo or group, large or small, specialized or general.

155 So. 3d at 988.

The statutory language in § 22-21-260(6) defines a “healthcare facility” to include hospital related facilities such a laboratories, out-patient clinics, and facilities for the surgical treatment of patients not requiring hospitalization. The statutory language in § 22-21-260(8) defines a “health services” as clinically related diagnostic, curative, or rehabilitative services *customarily furnished* on an inpatient or outpatient basis by healthcare facilities. The statutory language in § 22-21-263 requires CON review for all new institutional health services, and that new institutional health services must comply with the State Health Plan. The State Health Plan addresses the provision of cardiovascular catheterization services in the acute care hospital setting only.

The definition of “healthcare facility” in § 22-21-260(6) and the definition of “health services” in § 22-21-260(8) both contain the POE but they are not identical. “The exemption for a physician’s practice contained in the definition of health

services is broader than the POE contained in the definition of a health-care facility. It exempts a physician's practice of his or her profession so long as it is conducted independently of a health-care facility." Ex parte Sacred Heart Health System, Inc. 155 So. 3d 985 (Ala. 2012).

As discussed above, the cardiovascular surgical procedures Dr. Mitchell will provide at The Heart Center are customarily furnished in a healthcare facility and, in order to ensure patient safety is not compromised, they should not be conducted independent of a healthcare facility. Therefore, if Dr. Mitchell's cardiovascular surgical procedures cannot satisfy the POE contained in the definition of "health services," they cannot satisfy the less restrictive POE contained in the definition of "healthcare facility."

In addition, Ex parte Sacred Heart Health System holds that the POE applies to the physician's office only. See 115 So. 3d at 983, n. 2 ("In examining the medical-building project as a whole, this Court does not refer to the entire building constructed by Johnson Development, which contains space for medical and non-medical uses, but to the portion of the building leased by the specific physicians' *practice* seeking to apply the physician's office exemption to the CON requirement.") As represented by Dr. Mitchell's attorney: "The proposed services will be provided ***within the same building*** as his current private medical practice is located at 2375 Champions Blvd." (Exhibit A-5 at 5). As previously discussed, the

building located at 2375 Champions Boulevard was the subject of DR110, and the building is a three-story, 58,000 square foot facility developed by Dr. Mitchell at a cost of \$9.5 million dollars, in order to house a CT scan, a heart catheterization laboratory, and office space for “allied medical practices.” (Exhibit C at 1-2). Indeed, the building contains its very own dedicated ambulance bay (Exhibit G) and Dr. Mitchell also operates a separate “Chest Pain Walk-In Clinic” therein. (Exhibit E).

Therefore, Dr. Mitchell will perform his cardiovascular surgical procedures in a catheterization laboratory that is not located in his personal physician’s office. In fact, the catheterization laboratory will be located in the same spot where Leg Health unsuccessfully sought to obtain a letter of non-reviewability. Again, as represented by Dr. Mitchell’s attorney: “The cost estimate for the equipment and operations of the same cath lab at the same location being the same as that stated in the previous submission on behalf of Leg Health does not . . . contradict the separate factual disclosure of who would own and operate the lab.”). (Exhibit A-10 at 2)

Accordingly, the POE does not and cannot apply to the cardiovascular surgical services Dr. Mitchell will furnish in a separate catheterization laboratory. To hold otherwise would violate the explicit admonition of the Supreme Court that “[t]he POE . . . should not be interpreted as circumventing the statutory language in §§ 22-21-260(6), 22-21-260(8), 22-21-263, and 22-21-265, Ala. Code 1975, or

otherwise applicable statutes or administrative regulations pursuant to the State Health Plan, and violate the POE defined in Ex parte Sacred Heart Health System.

Dr. Mitchell takes the position that the POE should allow physicians to perform in their office any services or procedures that they are licensed to perform. However, this definition of POE would provide an unlimited application that would swallow the definition of healthcare facility and health services contained in Ala. Code §§ 22-21-260(6) and (8), and render them meaningless.

Accordingly, East Alabama Health Care Authority d/b/a East Alabama Medical Center respectfully requests that the CON Review Board enter declaratory ruling that Dr. Mitchell and The Heart Center Cardiology, P.C., seek to perform cardiovascular surgical procedures not customarily performed in private physician's office and, therefore, a CON is required for cardiovascular surgical procedures to be offered by Dr. Mitchell and The Heart Center Cardiology, P.C.

Respectfully submitted this 6th day of April, 2021.

s/ James E. Williams
JAMES E. WILLIAMS
J. FLYNN MOZINGO
Attorneys for The East Alabama
Healthcare Authority d/b/a East
Alabama Medical Center

OF COUNSEL:

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have served a copy of the foregoing by U.S. Mail and/or email transmission to the individuals listed below, on this the 6th day of April, 2021:

SHPDA Online Filing (shpda.online@shpda.alabama.gov)
Michael K. Wright, Esq. (mwright@starneslaw.com)

s/ James E. Williams
OF COUNSEL

Exhibit A-1



RV2021-003
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Oct 30 2020

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

The Heart Center Cardiology
2375 Suite 100 Champions Blvd.
Auburn, AL 36830
(334) 321-3700

October 29, 2020

Hon. Emily T Marsal
Executive Director
State Health Planning and Development Agency
100 North Union Street
RSA Union Building, Suite 870
Montgomery, AL 36130-3025
Shpda.online@shpda.alabama.gov

Re: Non – Reviewability Determination Request for The Heart Center Cardiology

Dear Ms. Marsal:

On behalf of The Heart Center Cardiology, I am writing pursuant to CON r. 410-1-7-.02 to submit a reviewability determination request in accordance with the Alabama State Health Planning and Development Agency's certificate of need program rules and regulation.

Within the current private practice location for The Heart Center Cardiology, located at 2375 Champions Blvd. Suite 100 Auburn, AL 36830, Dr. Mitchell intends to perform low risk peripheral angiography and interventional procedures, left and right diagnostic heart catheterizations- coronary angiography, elective internal cardio defibrillator (ICD) and planned pacemaker generator changes, low risk ICD and pacemaker implantation, Implantable loop recorder insertion, direct current cardioversion, infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures within his private practice. No novel procedures will be performed, and all of the procedures requested are standard, commonly performed in both inpatient and outpatient settings. The procedures are low risk, minimally invasive and general anesthesia is not required, nor will it be used in the office setting. Dr. Mitchell has an established care plan including the identification of involved personnel and equipment, to deal with any issues related to unexpected changes in a patient's status. This includes oxygen and masks for ventilation, medications for arrhythmias and reversal of sedation, defibrillation and pacing as well as a pathway to transfer to a higher level of care as needed. All procedures will be limited to adults >18yo only. Patients will be informed that some of the proposed procedures are "look only" or therapeutic/interventional and may require an additional procedure in a hospital setting. Physicians have been able to perform nearly all electrical cardioversion procedures using moderate to deep sedation (a widely accepted practice,) if patient safety ever requires the use of general anesthesia, the procedure would be scheduled and performed in the hospital setting. No

The Heart Center Cardiology 2375 Suite 100 Champions Blvd. Auburn, AL 36830

Exhibit

A-1

exhibitsticker.com

general anesthesia will be used in Dr. Mitchell's office-based lab. In addition, Dr. Mitchell will not be crossing from the right side of the heart to the left for any ablations, which would be a higher risk procedure.

When using midazolam or propofol, The Heart Center Cardiology and Dr. Mitchell will abide by the office-based surgery requirements for the use of general anesthesia, as set forth in Ala. Admin. Code Rules 540-X-10-.08 and 540-X-10-.09 as well as Rule 540-X-10-.12 and the reporting requirements of Rule 540-X-10-.11.

ALA. CODE 22-21-263(a)(1) (1975 as amended) includes in the definition of new institutional health services subject to CON review: "the construction, development, acquisition through lease or purchase, or other establishment of a new health care facility or health maintenance organization." Under ALA. CODE 22-21-260(6) (1975 as amended), the definition of a health care facility includes among other things, "facilities for surgical treatment of patients not requiring hospitalization", "laboratories" and "out-patient clinics". Specifically excluded from this definition are "the offices of private physicians or dentists, whether for individual or group practices and regardless of ownership." *Id.*

The definition of new institutional health services also includes any new health services offered through a health care facility. ALA. CODE 22-21-263(a)(4) (1975 as amended). However, a "the lawful practice of any profession or vocation conducted independently of a health care facility and in accordance with applicable licensing laws of this state" is excluded from the health services definition. ALA. CODE 22-21-260(8) (1975 as amended).

The criteria as adopted by the Supreme Court for the Physician Office Exemption are as follows:

1. The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physician's practice for the care of their patients.
2. The proposed services are to be provided, and related equipment used, at any office of such physicians.
3. All patients' billings related to such services are through, or expressly on behalf of, the physician's practice.
4. The equipment shall not be used for inpatient care, nor by, through or on behalf of a healthcare facility.

The Heart Center Cardiology will meet the four requirements for the POE set forth by the Alabama Supreme Court in *Ex parte Sacred Heart Health Sys., Inc.*, 155 So. 3d 980, 988 (Ala. 2012), when it found a facility is exempt from CON review if:

1. Procedures will be performed only by physician owners or physicians employed by The Heart Center Cardiology and the related equipment shall be used exclusively by the physicians identified as owners or employees. Dr. John Mitchell is the only physician owner or employee of The Heart Center Cardiology who is certified to perform office-based surgery. Dr. Mitchell is the only physician seeking a determination letter from the Agency for and on behalf of The Heart Center Cardiology. No other person, entity or facility is involved in this request.
2. All procedures will be performed in the private physician office of The Heart Center Cardiology. All equipment necessary for the performance of the procedures will be used exclusively by Dr. John Mitchell.

3. The patient billing related to such services are through, or expressly on behalf of the private physician offices of The Heart Center Cardiology.
4. At no time will the equipment identified for the performance of the office-based procedures provided in this letter be used for inpatient care, nor by, through or on behalf of a health care facility.

For the purpose of this request, we would like to provide the following Financial Disclosure:

Total Major Medical Equipment estimated cost for the office-based procedures = \$350,000.00

To include: Diagnostic X-Ray System, patient monitoring equipment, patient recovery equipment, defibrillator and IVUS for arterial and venous procedures and ancillary equipment required for the listed procedures.

Estimated annual first year operating cost: Total = \$618,000

1. Building Lease \$48,000.00/annual
2. Equipment Lease \$120,000.00/annual
3. Supplies – \$200,000.00
4. Employee Wages – 250,000.00
5. Land Cost – None
6. Renovation/Construction Cost- None

We can also affirm that the office based surgery services within The Heart Center Cardiology will not exceed any of the certificate of need expenditure thresholds, nor will it constitute a "new institutional health service" under Alabama Code 22-21-263 and the Rules due to the following:

- a) No new health care facility or health maintenance organization will be constructed, developed or acquired;
- b) No major medical equipment will be acquired by or on behalf of a health care facility that exceeds the statutory purchase price or operating expense thresholds;
- c) No new health care facility beds or stations will be added;
- d) No new health service that is currently offered by The Heart Center Cardiology will be provided with the implementation of the procedures described in the document; and
- e) No other event reviewable under the CON law or Rules will occur as a result of our implementation of the procedures described in this document.

The private physician office location for The Heart Center Cardiology; Dr. John Mitchell is 2375 Suite 100 Champions Blvd. Auburn, AL 36830. The service area for this request is Auburn Alabama and surrounding counties. Dr. Mitchell is licensed in the state of Alabama and certified to perform the procedures listed above. Dr. Mitchell's Alabama Medical License is appropriately registered with the Board to perform "office-based surgery." Dr. Mitchell will not perform any acute emergency cardiac interventions nor any coronary angioplasty in the private office setting. In addition, the private office will not be used for inpatient care. No other healthcare facilities have any financial interests in The Heart Center Cardiology. Dr. John Mitchell is the sole owner and the only participating physician for The Heart Center Cardiology.

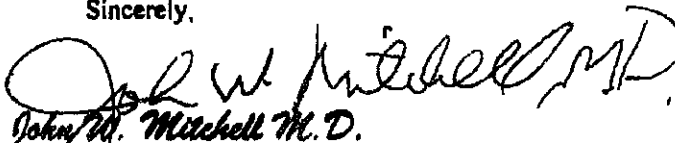
An electronic payment of \$1,000.00 for the filing fee with respect to a request for a reviewability determination will be sent today via the SHPDA online payment portal.

With the support of this document, we respectfully request that the Alabama State Health Planning and Development Agency grant a determination of non-reviewability to The Heart Center Cardiology for the proposed "office-based surgery" procedures described herein.

Please do not hesitate to call or contact me; John Mitchell with any questions.

We appreciate your time and consideration in this matter.

Sincerely,



John W. Mitchell M.D.

John Mitchell M.D., Medical Director/Owner
The Heart Center Cardiology

Affirmation of Requesting Party:

The undersigned, John Mitchell M.D., being first duly sworn, hereby make oath or affirm that he, an **Owner and Medical Director of The Heart Center Cardiology**, has knowledge of the facts in the request, and to the best of his information, knowledge and belief, such facts are true and correct.

Affiant

John W. Mitchell (SEAL)

Subscribed and Sworn to me before this 29th day of October 2020.

Notary Public

Samantha Rowley

My commission expires 4/7/2022


Exhibit A-2



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

100 NORTH UNION STREET, SUITE 870
MONTGOMERY, ALABAMA 36104

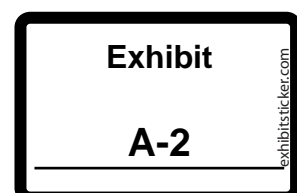
MEMORANDUM

DATE : November 9, 2020
TO: All Interested Parties
FROM: Emily T. Marsal 
Executive Director
SUBJECT: Reviewability Determination Request (RV2021-003)

The attached request for a reviewability determination has been received. Any affected person may file written comments regarding this request, per 410-1-7-.02 of the *Alabama Certificate of Need Program Rules and Regulations*, by December 23, 2020.

Pursuant to ALA. ADMIN. CODE r 410-1-3-.09, all documents to be filed with the Agency must be submitted to shpda.online@shpda.alabama.gov in PDF, text searchable format.

Enclosure: see attached





RV2021-003
RECEIVED
Oct 30 2020
STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

The Heart Center Cardiology
2375 Suite 100 Champions Blvd.
Auburn, AL 36830
(334) 321-3700

October 29, 2020

Hon. Emily T Marsal
Executive Director
State Health Planning and Development Agency
100 North Union Street
RSA Union Building, Suite 870
Montgomery, AL 36130-3025
Shpda.online@shpda.alabama.gov

Re: Non – Reviewability Determination Request for The Heart Center Cardiology

Dear Ms. Marsal:

On behalf of The Heart Center Cardiology, I am writing pursuant to CON r. 410-1-7-.02 to submit a reviewability determination request in accordance with the Alabama State Health Planning and Development Agency's certificate of need program rules and regulation.

Within the current private practice location for The Heart Center Cardiology, located at 2375 Champions Blvd. Suite 100 Auburn, AL 36830, Dr. Mitchell intends to perform low risk peripheral angiography and interventional procedures, left and right diagnostic heart catheterizations- coronary angiography, elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk ICD and pacemaker implantation, Implantable loop recorder insertion, direct current cardioversion, infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures within his private practice. No novel procedures will be performed, and all of the procedures requested are standard, commonly performed in both inpatient and outpatient settings. The procedures are low risk, minimally invasive and general anesthesia is not required, nor will it be used in the office setting. Dr. Mitchell has an established care plan including the identification of involved personnel and equipment, to deal with any issues related to unexpected changes in a patient's status. This includes oxygen and masks for ventilation, medications for arrhythmias and reversal of sedation, defibrillation and pacing as well as a pathway to transfer to a higher level of care as needed. All procedures will be limited to adults >18yo only. Patients will be informed that some of the proposed procedures are "look only" or therapeutic/interventional and may require an additional procedure in a hospital setting. Physicians have been able to perform nearly all electrical cardioversion procedures using moderate to deep sedation (a widely accepted practice,) if patient safety ever requires the use of general anesthesia, the procedure would be scheduled and performed in the hospital setting. No

general anesthesia will be used in Dr. Mitchell's office-based lab. In addition, Dr. Mitchell will not be crossing from the right side of the heart to the left for any ablations, which would be a higher risk procedure.

When using midazolam or propofol, The Heart Center Cardiology and Dr. Mitchell will abide by the office-based surgery requirements for the use of general anesthesia, as set forth in Ala. Admin. Code Rules 540-X-10-.08 and 540-X-10-.09 as well as Rule 540-X-10-.12 and the reporting requirements of Rule 540-X-10-.11.

ALA. CODE 22-21-263(a)(1) (1975 as amended) includes in the definition of new institutional health services subject to CON review: "the construction, development, acquisition through lease or purchase, or other establishment of a new health care facility or health maintenance organization." Under ALA. CODE 22-21-260(6) (1975 as amended), the definition of a health care facility includes among other things, "facilities for surgical treatment of patients not requiring hospitalization", "laboratories" and "out-patient clinics". Specifically excluded from this definition are "the offices of private physicians or dentists, whether for individual or group practices and regardless of ownership." *Id.*

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The criteria as adopted by the Supreme Court for the Physician Office Exemption are as follows:

1. The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physician's practice for the care of their patients.
2. The proposed services are to be provided, and related equipment used, at any office of such physicians.
3. All patients' billings related to such services are through, or expressly on behalf of, the physician's practice.
4. The equipment shall not be used for inpatient care, nor by, through or on behalf of a healthcare facility.

The Heart Center Cardiology will meet the four requirements for the POE set forth by the Alabama Supreme Court in *Ex parte Sacred Heart Health Sys., Inc.*, 155 So. 3d 980, 988 (Ala. 2012), when it found a facility is exempt from CON review if:

1. Procedures will be performed only by physician owners or physicians employed by The Heart Center Cardiology and the related equipment shall be used exclusively by the physicians identified as owners or employees. Dr. John Mitchell is the only physician owner or employee of The Heart Center Cardiology who is certified to perform office-based surgery. Dr. Mitchell is the only physician seeking a determination letter from the Agency for and on behalf of The Heart Center Cardiology. No other person, entity or facility is involved in this request.
2. All procedures will be performed in the private physician office of The Heart Center Cardiology. All equipment necessary for the performance of the procedures will be used exclusively by Dr. John Mitchell.

3. The patient billing related to such services are through, or expressly on behalf of the private physician offices of The Heart Center Cardiology.
4. At no time will the equipment identified for the performance of the office-based procedures provided in this letter be used for inpatient care, nor by, through or on behalf of a health care facility.

For the purpose of this request, we would like to provide the following Financial Disclosure:

Total Major Medical Equipment estimated cost for the office-based procedures = \$350,000.00

To include: Diagnostic X-Ray System, patient monitoring equipment, patient recovery equipment, defibrillator and IVUS for arterial and venous procedures and ancillary equipment required for the listed procedures.

Estimated annual first year operating cost: Total = \$618,000

1. Building Lease \$48,000.00/annual
2. Equipment Lease \$120,000.00/annual
3. Supplies - \$200,000.00
4. Employee Wages - 250,000.00
5. Land Cost - None
6. Renovation/Construction Cost- None

We can also affirm that the office based surgery services within The Heart Center Cardiology will not exceed any of the certificate of need expenditure thresholds, nor will it constitute a "new institutional health service" under Alabama Code 22-21-263 and the Rules due to the following:

- a) No new health care facility or health maintenance organization will be constructed, developed or acquired;
- b) No major medical equipment will be acquired by or on behalf of a health care facility that exceeds the statutory purchase price or operating expense thresholds;
- c) No new health care facility beds or stations will be added;
- d) No new health service that is currently offered by The Heart Center Cardiology will be provided with the implementation of the procedures described in the document; and
- e) No other event reviewable under the CON law or Rules will occur as a result of our implementation of the procedures described in this document.

The private physician office location for The Heart Center Cardiology; Dr. John Mitchell is 2375 Suite 100 Champions Blvd. Auburn, AL 36830. The service area for this request is Auburn Alabama and surrounding counties. Dr. Mitchell is licensed in the state of Alabama and certified to perform the procedures listed above. Dr. Mitchell's Alabama Medical License is appropriately registered with the Board to perform "office-based surgery." Dr. Mitchell will not perform any acute emergency cardiac interventions nor any coronary angioplasty in the private office setting. In addition, the private office will not be used for inpatient care. No other healthcare facilities have any financial interests in The Heart Center Cardiology. Dr. John Mitchell is the sole owner and the only participating physician for The Heart Center Cardiology.

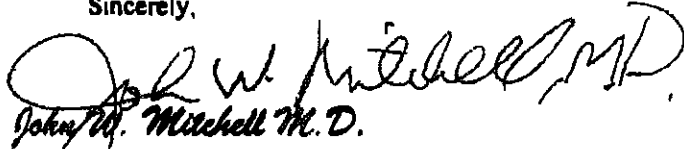
An electronic payment of \$1,000.00 for the filing fee with respect to a request for a reviewability determination will be sent today via the SHPDA online payment portal.

With the support of this document, we respectfully request that the Alabama State Health Planning and Development Agency grant a determination of non-reviewability to The Heart Center Cardiology for the proposed "office-based surgery" procedures described herein.

Please do not hesitate to call or contact me; John Mitchell with any questions.

We appreciate your time and consideration in this matter.

Sincerely,



John W. Mitchell M.D.

John Mitchell M.D., Medical Director/Owner
The Heart Center Cardiology

Affirmation of Requesting Party:

The undersigned, John Mitchell M.D., being first duly sworn, hereby make oath or affirm that he, an **Owner and Medical Director of The Heart Center Cardiology**, has knowledge of the facts in the request, and to the best of his information, knowledge and belief, such facts are true and correct.

Affiant

John W. Mitchell (SEAL)

Subscribed and Sworn to me before this 29th day of October 2020.

Notary Public

Samantha Roney

My commission expires 4/7/2022

Exhibit A-3

LAW OFFICES
MELTON, ESPY & WILLIAMS, P.C.

255 DEXTER AVENUE
MONTGOMERY, AL 36104

JOSEPH C. ESPY, III
JAMES E. WILLIAMS
J. FLYNN MOZINGO
C. MARK BAIN
BENJAMIN J. ESPY*
WILLIAM M. ESPY

* ALSO ADMITTED IN MISSISSIPPI

OAKLEY W. MELTON, JR.
(1927-2013)

December 16, 2020

Via Electronic Filing
(shpda.online@shpda.alabama.gov)

MAILING ADDRESS:
P.O. DRAWER 5130
MONTGOMERY, AL 36103-5130
TELEPHONE (334) 263-0621
FAX (334) 289-9515

Emily T. Marsal, Executive Director
State Health Planning & Development Agency
100 North Union St., Suite 870
Montgomery AL 36104

RE: RV2021-003, The Heart Center Cardiology

Dear Ms. Marsal,

On behalf of East Alabama Medical Center ("EAMC"), I am writing to express EAMC's opposition to the *most recent* letter of non-reviewability request ("LNR"), submitted by The Heart Center Cardiology, on October 29, 2020, concerning the application of the physician office exemption ("POE") to the establishment and operation of an "office based lab" at 2375 Champions Blvd, Suite 100, Auburn, Alabama.¹ The Heart Center Cardiology represents that it is the name of the medical practice of Dr. John Mitchell, and that a vast number of outpatient cardiovascular procedures will be performed in a proposed office-based lab to be operated within the medical practice.

As you aware, The Heart Center Cardiology was the subject of a POE LNR submitted on August 3, 2020, by Leg Health Vascular Centers, Inc., which likewise proposed to establish and operate an "office based lab" at the same address and medical practice. Leg Health's LNR request was the subject of additional filings and information submissions by Leg Health and EAMC, on September 21, 2020; September 28, 2020; October 7, 2020; and concurrent submissions by Leg Health and EAMC on October 20, 2020. SHPDA subsequently refused to issue a LNR, and in so doing stated as follows:

Here, the Agency has received contradictory sworn statements regarding the operation of the project, which, among other things, raises doubt as to whether the new services and equipment are limited to Dr. Mitchell's office-based medical practice. ***The LNR process is not well suited to resolve the competing factual and legal assertions of Leg Health and EAMC. According, the Agency is unable to determine that this project qualifies for the POE.***

Leg Health Vascular Centers, Inc., RV2020-021, October 26 2020 (emphasis added).

Exhibit

A-3

¹ In setting forth its opposition herein, EAMC hereby incorporates its submissions to SHPDA, dated September 21, 2020 and October 20, 2020, regarding Leg Health Vascular Centers, Inc., RV2020-021.

On October 29, 2020, **just three days after SHPDA refused to issue a LNR**, Dr. John Mitchell, by and through The Heart Center Cardiology, filed the immediate LNR request in which he makes factual and legal assertions that are, in most cases, identical to Leg Health's factual and legal assertions. Specifically, Dr. Mitchell's request is identical to Leg Health's LNR request in the following ways:

1. Both requests concern The Heart Center located at 2375 Champions Boulevard;
2. Both requests represent that they involve Dr. John Mitchell's medical practice;
3. Both requests concern plans to perform the same procedures, i.e., peripheral angiography; left and right diagnostic heart catheterizations; coronary angiography; elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes; low risk ICD and pacemaker implantation; implantable loop recorder insertion; direct current cardioversion; infusa port placement; transesophageal echocardiography; pulmonary artery pressure recording devices; and low risk atrial, ventricular and nodal ablation procedures;
4. Both requests concern the development and operation of an "office-based lab;"
5. Both requests represent that the procedures to be performed are commonly performed in inpatient and outpatient settings;
6. Both requests state the procedures to be performed will not require general anesthesia;
6. Both requests assert that the projects satisfy the POE test set forth in Ex parte Sacred Heart Health Systems, Inc., 155 So. 3d 980 (Ala. 2012); and
7. Both requests involve the exact same financial disclosures, consisting of the exact same amounts for major medical equipment; first year operating costs; first year operating lease; building lease; equipment lease; supplies; employee wages; land costs; and renovation/construction costs.

In fact, the LNR requests submitted by Leg Health and by The Heart Center Cardiology are substantively identical in each and every way, except The Heart Center Cardiology's request omits any reference to Leg Health Vascular Centers, Inc.; Dr. Robert Yoe; and Dr. Jacob Townsend. One additional difference is that, although The Heart Center Cardiology represents that general anesthesia will not be required for its procedures, it also states in contradiction: "When using midazolam or propofol, The Heart Center and Dr. Mitchell will abide by the office-based surgery requirements for the use of general anesthesia . . ." (RV2021-003 at 2 October 29, 2020).²

² The Heart Center Cardiology's representations are also contradicted by its website, which states that Dr. Mitchell and The Heart Center Cardiology already offer cardiac catheterization and angioplasty; and pacemaker implantation/therapy. See Exhibit A (<https://www.theheartcentercardiology.com/services.html>) (last visited December 15, 2020).

For the reasons expressed in SHPDA's letter dated October 26, 2020, the LNR request filed by The Heart Center Cardiology cannot be determined by the Agency. SHPDA has now received two competing LNR requests from separate entities, i.e., Leg Health Vascular Centers, Inc., and The Heart Center Cardiology, and both requests contain sworn statements proposing the exact same "office-based lab" to be located at the same address; the exact same medical procedures; and the exact same financial costs. However, key participants in the project identified in Leg Health's LNR request are omitted from The Heart Center Cardiology's request, despite the fact that Leg Health's request was filed on August 3, 2020, less than three months before The Heart Center Cardiology's request.

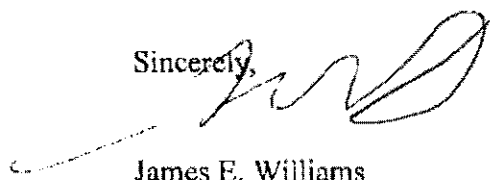
Accordingly, to again quote from SHPDA's letter, dated October 26, 2020, with revisions applicable to The Heart Center Cardiology:

Here, the Agency has received contradictory sworn statements regarding the operation of the project, which, among other things, raises doubt as to whether the new services and equipment are limited to Dr. Mitchell's office-based medical practice. *The LNR process is not well suited to resolve the competing factual and legal assertions of [The Heart Center Cardiology,] Leg Health and EAMC. According, the Agency is unable to determine that this project qualifies for the POE.*

EAMC therefore respectfully requests that SHPDA decline to provide The Health Center Cardiology with a LNR for the reasons stated herein, and for the reasons stated in EAMC's submissions to the Agency on September 1, 2020 and October 20, 2020, regarding Leg Health Vascular Centers, Inc, RV2020-021.

If you have any questions, please do not hesitate to contact me. With kindest personal regards, I am

Sincerely,



James E. Williams

JW/JFM/i

cc: John Mitchell, M.D.
Medical Director/Owner
The Heart Center Cardiology

(334) 321-3700



[HOME](#)

[ABOUT US](#)

[PATIENTS](#)

[CONTACT US](#)

SERVICES AVAILABLE AT THE HEART CENTER CARDIOLOGY

Nationally recognized Auburn Cardiologist, Dr. John W. Mitchell, and The Heart Center Cardiology offer state of the art testing and a full range of technologically advanced cardiac services for patients in Auburn, Opelika, Valley, Wetlowee and the surrounding areas.

Services offered include:

EKG

Exercise Stress Tests

Cardiac catheterization & angioplasty

Echocardiography

Holter & event monitoring

Carotid ultrasound

venous and Arterial Leg Studies

Healthy Heart Screenings

Pacemaker implantation/therapy

For more information or to schedule an appointment, call (334) 321-3700

The Heart Center Cardiology
1014 Champions Blvd
Auburn, AL 36830
Phone: (334) 321-3700 Fax: (334) 887-1325

THE HEART CENTER
CARDIOLOGY

Exhibit A

RV2021-003

RV2021-003

Exhibit A-4



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

100 NORTH UNION STREET, SUITE 870

MONTGOMERY, ALABAMA 36104

December 18, 2020

John Mitchell, M.D., Medical Director/Owner
The Heart Center Cardiology
2375 Champions Boulevard, Suite 100
Auburn, Alabama 36830

RE: RV2021-003
The Heart Center Cardiology

Dear Dr. Mitchell:

This letter is written in response to the Reviewability Determination Request received October 30, 2020, on behalf of The Heart Center Cardiology, proposing the addition of an office-based lab to provide low risk peripheral angiography and interventional procedures, left and right diagnostic heart catheterizations-coronary angiography, elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk internal cardiac defibrillator (ICD) and pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures to patients within the private medical practice located at 2375 Champions Boulevard, Suite 100, Auburn, Alabama 36830 through the Physician's Office Exemption (POE), ALA.CODE § 22-21-260(6) (1975 as amended).

On December 16, 2020, the Agency received comments in opposition to this request filed by East Alabama Medical Center (EAMC). A copy of the comments is enclosed. Please provide responses to the concerns outlined by EAMC as you deem appropriate.

ALA. ADMIN. CODE r. 410-1-7-.02(4) allows the Executive Director additional time to evaluate all comments received on behalf of a request prior to rendering a response. In an effort to provide The Heart Center Cardiology an opportunity to respond to these comments and concerns, the Agency is executing its authority to extend the response time.

On October 26, 2020, the Agency sent a letter regarding RV2020-021, filed on behalf of Leg Health Vascular Centers, Inc., which stated that due to the various contradictory sworn statements regarding the operation of the project, which, among other things, raised doubt as to whether the new services and equipment were limited to Dr. Mitchell's office-based medical practice, the LNR process was not well suited to resolve the competing factual and legal assertions of Leg Health and EAMC. Accordingly, the Agency was unable to determine that this request qualified for the POE.

MAILING ADDRESS: P.O. BOX 303025, MONTGOMERY, ALABAMA 36130-3025
PHONE: (334) 242-4103 WWW.SHPDA.ALABAMA.GOV

Exhibit

A-4

exhibitsticker.com

RE: RV2021-003
December 18, 2020
Page Two

By January 4, 2021, it is requested that the Agency be provided with the following information:

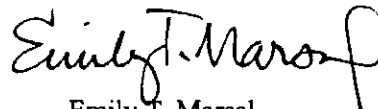
1. Please state with specificity the differences between RV2021-003, the Reviewability Determination Request received October 30, 2020, on behalf of The Heart Center Cardiology and RV2020-021, the Reviewability Determination Request received August 6, 2020, on behalf of Leg Health Vascular Centers, Inc. Please clarify if the contradictory circumstances proposed in RV2020-021 will be addressed in this proposal.
2. Please clarify the specific procedures currently being provided at the private medical practice located at 2375 Champions Boulevard, Suite 100 in Auburn, Alabama and the procedures to be newly offered in the proposed office -based lab at this same location.

Upon receipt of verifications, due consideration will be given to all comments, and a finding issued in accordance with Statute and the *Alabama Certificate of Need Program Rules and Regulations*.

Pursuant to ALA. ADMIN. CODE r. 410-1-3-.09, all documents to be filed must be submitted electronically to shpda.online@shpda.alabama.gov in text searchable, PDF format.

Should you have any questions, please contact the Agency at (334) 242-4103.

Sincerely,



Emily T. Marsal
Executive Director

ETM:mst

cc: James E. Williams, Esquire

Exhibit A-5



The Heart Center Cardiology
2375 Suite 100 Champions Blvd.
Auburn, AL 36830
(334) 321-3700

January 14, 2021

VIA Electronic Filing: Shpda.online@shpda.alabama.gov

Ms. Emily T Marsal
Executive Director
State Health Planning and Development Agency
100 North Union Street, Suite 870
Montgomery, AL 36104

Re: RV2021-003
Response to SHPDA's December 18, 2020 Letter

Dear Ms. Marsal:

On behalf of The Heart Center Cardiology, I am writing in response to your letter dated December 18, 2020, and I appreciate the extension that the Agency granted me as I engaged and conferred with legal counsel on this matter. I understand that my legal counsel will be providing a written submission to the Agency, as well.

The Agency requested clarity regarding The Heart Center's request for a reviewability determination and also provided me with the opportunity to respond to comments in opposition filed by East Alabama Medical Center (EAMC) to my request. I appreciate the Agency providing me the opportunity to address its questions and believe the below should provide sufficient clarity for the Agency to grant my Reviewability Determination Request.

Part I: 12-18-2020 Requests from SHPDA

1. Please state with specificity the differences between RV2021-003, the Reviewability Determination Request received October 30, 2020, on behalf of The Heart Center Cardiology and RV2020-021, the Reviewability Determination Request received August 6, 2020, on behalf of Leg Health Vascular Centers, Inc. Please clarify if the contradictory circumstances proposed in RV2020-021 will be addressed in this proposal.

RV2021-003, the Reviewability Determination Request received October 30, 2020, on behalf of The Heart Center Cardiology and RV2020-021, the Reviewability Determination Request received August 6, 2020, on behalf of Leg Health Vascular Centers, Inc. are separate and distinct requests by two different parties.

a. RV2020-021, the Reviewability Determination Request received August 6, 2020, on behalf of Leg Health Vascular Centers, Inc. ("Leg Health")

In August 2020, I verbally agreed to allow Leg Health to assist in my practice's expansion of in-office based cardiac services. The RV2020-021 request was submitted without legal representation from either Leg Health, The Heart Center, or me. During the course of the responses to RV2020-021 and the opposition comments, I came to understand that Leg Health should not have been included in the Reviewability Determination Request, and the mention of Leg Health only confused what should have been a straightforward request. After the Agency's letter regarding RV2020-021 in October 2020, I determined the best course of action was to submit a request solely under my existing practice, The Heart Center Cardiology, without the involvement of Leg Health. I have also since engaged and conferred with legal counsel on this matter.

The Heart Center and I no longer have any plans to affiliate with Leg Health in the Auburn/Opelika area, and the previously proposed relationship with Leg Health has been terminated. In speaking with a representative for Leg Health, we mutually agreed that the previous request, RV2020-021, should be formally withdrawn. Again, while there was never a written affiliation between The Heart Center or myself and Leg Health, The Heart Center and I have completely disassociated from Leg Health. As reflected in the RV2021-003 request, Leg Health will have no role in providing cardiac services at The Heart Center under the valid proposal set forth in RV2021-003.

b. RV2021-003, the Reviewability Determination Request received October 30, 2020 on behalf of the Heart Center

I filed a new, standalone Reviewability Determination Request on October 30, 2020. There is no mention of Leg Health in this request because the relationship with Leg Health has been terminated, as outlined above. In retrospect and though not required by the rules, I should have provided additional clarity in RV2021-003 regarding the new request, the new party making the request (myself), and background for the request. My goal in omitting this information initially was only to make the request as straightforward as possible and to clearly and directly address the reviewability questions required by the Agency. RV2021-003 demonstrates that my practice and requested services meet the Physician Office Exemption under Alabama law.

2. *Please clarify the specific procedures currently being provided at the private medical practice located at 2375 Champions Boulevard, Suite 100 in Auburn, Alabama and the procedures to be newly offered in the proposed office-based lab at this same location.*

My practice, The Heart Center Cardiology, currently offers general cardiology services common in the private office setting of a cardiology practice. Services include, but are not limited to, patient examinations, cardiac nuclear stress testing, ultrasound, lab work, electrocardiogram, and holter and long-term event monitoring.

Regarding proposed services, I am requesting the Agency's permission to perform low risk peripheral angiography and interventional procedures, left and right diagnostic heart catheterizations- coronary angiography, elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk ICD and pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, infusaport placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures within the private practice. No novel procedures will be performed, and all of the procedures requested are standard, commonly performed in both inpatient and outpatient settings.

The procedures are low risk, minimally invasive and general anesthesia is not required, nor will it be used in the office setting. The hospital's objections demonstrate some confusion with a particular statement in RV2021-003 regarding the use of midazolam and propofol and my reference to the "office-based surgery requirements for the use of general anesthesia." This statement was an incomplete characterization of the scope of the Rules regarding the use of anesthesia in the office setting and was made without the benefit of legal counsel. My intention was to simply inform the Agency that I will comply with the legal and regulatory requirements in Alabama, and in general, for using anesthetic agents.

For absolute clarity, "general" anesthesia will not be used for the proposed services. To alleviate any concern please consider this an amendment to RV2021-003 by which the reference to "general" anesthesia is deleted. Any anesthesia used in connection with the performance of the proposed services will not exceed the level of moderate or deep sedation and will be administered in compliance with any and all applicable State or federal guidance.

The proposed services will be provided within the same building as my current private medical practice located at 2375 Champions Blvd.

My practice (and the proposed services) will at all times function within the current regulatory approvals at the federal level / the state of Alabama (via this Agency and others) as is presently or may subsequently be approved.

Part 2: Response to EAMC Comments

In its December 16, 2020 letter, EAMC submitted several comments in opposition to my Letter of Non-Reviewability Request (RV2021-003). I believe many of these comments have been

addressed by my above statements, but I would like to respond to several of the assertions specifically:

- “Dr. Mitchell’s request is identical to Leg Health’s LNR request[.]”

As mentioned above, it is not identical. RV2021-003 shows that Leg Health is not and will not be involved with the proposed services. Otherwise, the requests do appear similar, but the similarities are simply explained:

1) Both requests reference my practice address, but only one of the applications involves Leg Health. As outlined, I understand the previous request involving Leg Health has been withdrawn. My request in RV2021-003 does not make any reference to Leg Health because Leg Health will not be involved at all. Again, The Heart Center and I are completely dissociated from Leg Health.

2) As EAMC and the Agency know, Alabama physicians regularly apply for in-office based cardiac procedure services with the Agency and many of these letters are similar, if not identical, to RV2021-003. The similarities can be linked to the fact that the proposed services are informed and proposed on guidance from state and federal agencies, and providers in the application process seek to follow that guidance closely.

- “Although The Heart Center Cardiology represents that general anesthesia will not be required for its procedures, it also states in contradiction . . .”

Again, to clarify my original comments, my reference to office-based surgery requirements for the use of anesthesia was only meant to reiterate to the Agency that I will follow all legal and regulatory requirements. I will not be providing any services that require “general” anesthesia, and I have asked the Agency to consider this letter an amendment to RV2021-003 by which the reference to “general” anesthesia is deleted.

- “Accordingly, to again quote from SHPDA’s letter . . the LNR process is not well suited to resolve the competing factual and legal assertions of [Leg Health][.]”

As mentioned previously, Leg Health will play no role in regard to the proposed services sought in RV2021-003. RV2021-003 should be considered as a standalone request. Based on the facts asserted within RV2021-003 and this letter, I feel strongly that my request on behalf of The Heart Center meets the Physician Office Exemption.

Part 3: Request for Approval

Based on my original request (RV2021-003) and this response, I submit to the Agency that RV2021-003 is straightforward and meets the Alabama Physician Office Exemption. I further attest to the Agency that Leg Health is not a party to RV2021-003 and Leg Health will not be involved in the provision of the proposed services in any way. I sincerely request the Agency review RV2021-003 as it was filed—*i.e.* as a separate, standalone request. I appreciate the

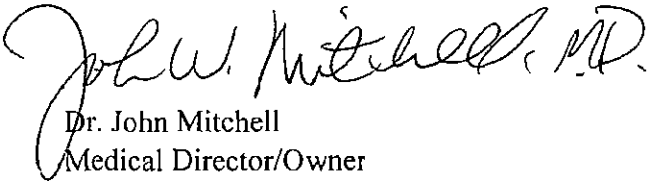
RV2021-003

Response to SHPDA's December 18, 2020 Letter

Page 5

Agency's review and time in considering RV2021-003 and am happy to address any further questions.

Sincerely,

A handwritten signature in black ink, appearing to read "John W. Mitchell, MD". The signature is fluid and cursive, with the "MD" clearly visible at the end.

Dr. John Mitchell
Medical Director/Owner
The Heart Center Cardiology

cc:

Michael K. Wright, via mwright@starneslaw.com

James E. Williams, via jwilliams@mewlegal.com

Exhibit A-6

January 14, 2021

VIA ELECTRONIC FILING:

shpda.online@shpda.alabama.gov

Ms. Emily T. Marsal, Executive Director
State Health Planning & Development Agency
100 North Union St., Suite 870
Montgomery, AL 36104

RE: RV2021-0003, The Heart Center Cardiology
Our File No.: 38685

Dear Ms. Marsal:

We were recently engaged to assist The Heart Center Cardiology and Dr. Mitchell with The Heart Center's October 30, 2020 Reviewability Determination Request (RV2021-003)¹ that is pending with the Agency. We sincerely appreciate your and the State of Alabama Health Planning and Development Agency's assistance thus far and your grant of an extension for Dr. Mitchell's response to the Agency's December 18, 2020 letter while we reviewed the details of RV2021-003, the questions posed by the Agency in response to the RV2021-003 submission, and the objections submitted by Mr. Jim Williams on behalf of East Alabama Medical Center. After thorough consideration of the pertinent materials, regulations and law, including Dr. Mitchell's response to the Agency's specific questions regarding RV2021-003 which are submitted herewith, the Agency should deem RV2021-003 as non-reviewable.

Plainly, RV2021-003:

1. Was submitted properly and with the required information as outlined by the Agency in SHPDA Rule 410-1-7-.02;
2. Is clearly within the requirements of the Physician Office Exemption as outlined in *Ex parte Sacred Heart Health System, Inc.*, 155 So. 2d 980 (Ala. 2012);

¹ RV2021-003 is hereinafter referred to as "Dr. Mitchell's request" or "The Heart Center's request."

{B3717139}

Birmingham

Mobile
starneslaw.com

Nashville

Exhibit

A-6

exhibits.sticker.com

3. Is separate and distinct from the RV2020-021 request from Leg Health Vascular Centers which has been formally withdrawn; and
4. Is substantially similar, if not essentially identical, to numerous other Reviewability Determination Requests that the Agency has deemed non-reviewable based on information we have obtained.

A denial of Dr. Mitchell's request in RV2021-003 would be without reasonable basis in consideration of Alabama law and previous non-reviewability determinations of the Agency.

I. RV2021-003 Was Submitted Pursuant to SHPDA Rule 410-1-3-.09 and Discloses Full Factual Information Pursuant to SHPDA Rule 410-1-7-.02.

First, we understand that RV2021-003 was submitted pursuant to the Agency's electronic filing requirements. RV2021-003 also provides the information for reviewability determinations made pursuant to the Physician's Office Exemption as set forth in Rule 410-1-7-.02 and the seven categories of information identified on the Agency's website. RV2021-003 also contains an appropriate attestation and affirmation by Dr. Mitchell. Any questions posed by the Agency are clarified in Dr. Mitchell's written responses. Mention of compliance with Rules 410-1-3-.09 and 410-1-7-.02 is referenced herein for completeness.

II. RV2021-003 Meets the Physician Office Exemption

Dr. Mitchell's request clearly satisfies the Physician Office Exemption ("POE") criteria set forth in Alabama Code Section 22-21-260 and as clarified by the Alabama Supreme Court in *Ex parte Sacred Heart Health System, Inc.*² In *Ex parte Sacred Heart*, the Alabama Supreme Court clarified the POE language by "adopt[ing] a modified four-part test to be used to determine" whether a proposal qualifies for the POE. 155 So. 3d 980,987-88. The test is straightforward:

- (1) The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physicians' practice for the care of their patients.
- (2) The proposed services are to be provided, and related equipment used, at any office of such physicians.
- (3) All patient billings related to such services are through, or expressly on behalf of, the physicians' practice.

² See ALA. CODE § 22-21-260(6) & (8); *Ex parte Sacred Heart Health System*, 155 So. 2d 980 (Ala. 2012).
{B3717139}

(4) The equipment shall not be used for inpatient care, nor by, through, or on behalf of a health-care facility.

Id., at 988. The Supreme Court stated its intent that “[t]he POE application test will provide an objective standard that can be used to determine whether the POE applies to any medical practice, whether the practice is solo or group, large or small, specialized or general.” *Id.* (emphasis added).

RV2021-003 clearly satisfies this “objective standard” set forth by the Alabama Supreme Court. Dr. Mitchell has attested in RV2021-003 that:

1. The proposed services are to be provided, and the related equipment used, exclusively by Dr. Mitchell (the owner and sole physician at The Heart Center Cardiology) at his practice for the care of his patients.
2. The proposed services are to be provided, and related equipment used, at Dr. Mitchell’s office, The Heart Center.
3. All patient billings related to such services are through, or expressly on behalf of, The Heart Center Cardiology—Dr. Mitchell’s practice.
4. The equipment at Dr. Mitchell’s practice shall not be used for inpatient care, nor by, through, or on behalf of a healthcare facility.

The proposed services requested by Dr. Mitchell are appropriate for in-office care and, on information, have been deemed non-reviewable by the Agency in other substantially similar Reviewability Determination Requests over the past several years.³ Dr. Mitchell has also attested in his responses to the Agency that any services provided will at all times function within the current regulatory approvals at the federal and State level as such services are presently or may subsequently become approved.

Dr. Mitchell has further attested (and reaffirmed/clarified in his response letter) that he will not provide “general anesthesia” or offer any services requiring general anesthesia. East Alabama Medical Center’s objections demonstrate some confusion with the following statement in RV2021-003:

When using midazolam or propofol, The Heart Center Cardiology and Dr. Mitchell will abide by the office-based surgery requirements for the use of general anesthesia, as set forth in Ala. Admin. Code Rules 540-X-10-.08 and

³ As examples, the following requests and related materials are attached as Exhibit A: RV2018-006, RV2018-013, RV2019-032, RV2019-037, and RV2021-002.

540-X-10-.09 as well as Rule 540-X-10-.12 and the reporting requirements of Rule 540-X-10-.11.

The objections characterize this statement as a “contradiction” to other statements within the request stating general anesthesia will not be used in connection with the proposed services.

While perhaps confusing at first blush, the statement was not intended to be contradictory. Without the benefit of counsel, Dr. Mitchell was intending to inform the Agency that he would comply with the applicable Rules for office-based anesthesia, which address moderate sedation, deep sedation, and general anesthesia. The Alabama Administrative Code Rules cited by Dr. Mitchell apply to general anesthesia, but they also extend to moderate sedation or deep sedation. Dr. Mitchell’s reference to “general anesthesia” was an incomplete description or characterization of the scope of the cited Rules and should not be read to suggest that he even contemplates the use of “general anesthesia” for the proposed services as “general anesthesia” is defined within those Rules. His citation to applicable State requirements and guidance regarding the use of anesthetic agents was not required and was only offered to demonstrate that he will comply with any and all applicable guidance for using such agents.

Clearly, Dr. Mitchell will not be performing any of the proposed services utilizing “general anesthesia” as defined in Alabama Administrative Rule 540-X-10-.02(5).⁴ Any anesthesia used in connection with the proposed services will not exceed the level of moderate sedation or deep sedation as defined by Rule 540-X-10-.02(3) & (4)⁵ and will be administered appropriately. The medications referenced in RV2021-003 are commonly used to accomplish moderate or deep sedation in office settings.

⁴ “(5) General anesthesia. A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.” Ala. Admin. R. 540-X-10-.02(5).

⁵ “(3) Moderate Sedation/Analgesia (“Conscious Sedation”). A drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from painful stimulation is NOT considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

(4) Deep Sedation/Analgesia. A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. Reflex withdrawal from painful stimulation is NOT considered a purposeful response. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.” Ala. Admin. R. 540-X-10-.02(3) & (4).

Given the confusion, Dr. Mitchell has withdrawn the reference to “general anesthesia” in RV2021-003.

The proposed services are appropriate for the in-office setting and will be provided within the same building as his current private medical practice located at 2375 Champions Blvd.

Respectfully, RV2021-003 satisfies the POE, and the Agency “do[es] not have the authority to require CON review for entities or matters that are not expressly subject to CON review under the law as set out by the Legislature.” *See generally Prime Lithotripter Operations, Inc. v. LithoMedTech of Alabama, LLC*, 855 So. 3d 1085, 1096 (Ala. Civ. App. 2001). A denial of Dr. Mitchell’s request would be contrary to the law under the facts presented here and would be inconsistent with the Agency’s determinations for other substantially similar and nearly identical requests submitted by other applicants.

III. RV2021-003 and RV2020-021 Represent Two Separate Requests, Requested by Two Separate Parties

The Agency’s December 18, 2020 letter requests that Dr. Mitchell state with specificity the differences between RV2021-003 (Dr. Mitchell’s request) and RV2020-021, a Reviewability Determination Request from Leg Health Vascular Centers, Inc.. As described in further factual detail in Dr. Mitchell’s response letter, Dr. Mitchell and/or The Heart Center Cardiology no longer have any relationship with Leg Health Vascular Centers. Further, Dr. Mitchell is of the understanding that Leg Health Vascular Centers has issued a letter to the Agency to formally withdraw RV2020-021.

The Agency’s Certificate of Need (CON) Program Rules and Regulations for Reviewability Determination Request hold that “[a]ny person may request for informational purposes only a determination as to the current reviewability of an anticipated project[,]” and require an affirmation of a “requesting party” for the request.⁶ Requests RV2021-003 and RV2020-021 were made by different requesting parties, with different attestations. Further, the contents and facts of each request are different, as outlined in Dr. Mitchell’s letter. Leg Health was the only party to the RV2020-21 request. The Heart Center Cardiology (/ Dr. Mitchell) is the sole party to the RV2021-003 request. It is clear based on the different parties, different facts, and even the termination of the RV2020-021 request from Leg Health and complete dissociation of any relationship between The Heart Center Cardiology and Leg Health that RV2021-003 is a standalone request offered solely on behalf of Dr. Mitchell’s private practice, The Heart Center Cardiology.

⁶ SHPDA Rule 401-1-7-.02

East Alabama Medical Center's objections to RV2021-003 are centered around confusion created by the RV2020-021 with respect to the previous relationship between Dr. Mitchell and Leg Health. Those issues have now been clarified by Dr. Mitchell's written responses, the formal termination of RV2020-021, and the present letter from The Heart Center Cardiology and Dr. Mitchell's legal counsel.

There is nothing "contradictory" within the RV2021-003 request, and there are no "competing factual and legal assertions of [The Heart Center Cardiology,] Leg Health and EAMC" as argued in the hospital's objections. In fact, Leg Health is completely irrelevant to the Agency's determination of the reviewability issue posed by RV2021-003—especially after the clarifications submitted since the hospital's objections. In view of the numerous clarifications provided, any injection or reference to a party (Leg Health) that has no interest in the request should not be considered by the Agency in connection with the standalone RV2021-003 request.

The simple issue presented for the Agency is whether RV2021-003, a standalone request made solely on behalf of The Heart Center Cardiology/Dr. Mitchell, satisfies the POE criteria under Alabama law.

IV. The Agency Should Deem RV2021-003 as Non-Reviewable

In light of the foregoing, Dr. Mitchell's original request, and the facts articulated in Dr. Mitchell's response letter to the Agency, the Agency should deem RV2021-003 as non-reviewable. RV2021-003 clearly meets the Physician Office Exemption and all other factual requirements requested by the Agency. Further, the proposed services in RV2021-003 have been reviewed on numerous occasions by the Agency in similar (or identical) requests for non-reviewability.⁷ Indeed, it is our understanding from review of the Agency's website that an essentially identical request, RV2021-002, is on the agenda for Agency's January 2021 meeting. The "tentative agenda" documents "for information purposes only" that the "status" of RV2021-002 is "non-reviewable." Based on Alabama law and the facts set forth in Dr. Mitchell's request, a denial of RV2021-003 would be considered an arbitrary and capricious action, not in keeping with the intended role and function of the Agency. We respectfully request that the Agency deem RV2021-003 non-reviewable consistent with Alabama law and its past determinations of non-reviewability.

Please do not hesitate to contact me if you have any further questions or need any further information regarding The Heart Center Cardiology's request in RV2021-003.


⁷ Examples provided in Exhibit A.

January 13, 2021

Page -7-

Best regards,

STARNES DAVIS FLORIE LLP



Michael K. Wright

MKW/jm

cc: Dr. John W. Mitchell
Allen C. King, Esq.
Catherine G. Kirkland
James E. Williams , Esq.

Exhibit A

**SALAME HEART
& VASCULAR CLINIC, LLC**

Mahomed Y. Salame, M.D., MRCP
Cristin L. Prater, CRNP
Amy K. Holley, AGACNP
Board Certified, Interventional Cardiology & Vascular Medicine

October 2, 2020

RV2021-002

RECEIVED

Oct 16 2020

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

Via email: shpda.online@shpda.alabama.gov

Hon. Emily T. Marsal
Executive Director
State Health Planning and Development Agency
100 North Union Street
RSA Union Building, Suite 870
Montgomery, AL 36130-3025

RE: Non-Reviewability Determination Request for Salame Heart and Vascular Clinic, LLC

Dear Ms. Marsal:

On behalf of Salame Heart and Vascular Clinic, LLC, I am writing pursuant to Ala. Admin. Code r. 410-1-7-.02 to request a determination of non-reviewability in accordance with the Alabama State Health Planning and Development Agency's certificate of need ("CON") program rules and regulations. Specifically, we respectfully request a determination of non-reviewability with respect to the addition of an office-based lab in our office located at **1031 Quintard Avenue, Suite 1A, Anniston, Alabama 36201**. There is no proposed relocation. Salame Heart and Vascular Clinic, LLC is a physician practice solely owned by Dr. Mahomed Y. Salame.

Healthcare services currently offered at Salame Heart and Vascular Clinic include: Comprehensive outpatient cardiovascular services including office consultations, EKG, echocardiography, cardiac stress testing, vascular ultrasound and holter monitoring.

Dr. Salame intends to perform low risk peripheral angiography and peripheral interventional procedures at the above location. No novel procedures will be performed, and all of the procedures requested are standard, commonly performed in both inpatient and outpatient settings. The procedures are low risk, minimally invasive, and general anesthesia is not required, nor will it be used in the office lab setting.

Salame Heart and Vascular has an established emergency care plan including the identification of involved personnel and equipment to deal with any unexpected changes in the patient's status. This includes oxygen, masks for ventilation, medications for arrhythmias and reversal of sedation, defibrillation and pacing as well as a pathway to transfer to a higher level of care as needed. The practice has two BLS/ACLS certified nurse practitioners on staff as well as two BLS/ACLS registered nurses. In addition, four other staff members are BLS certified. Dr. Salame has admitting privileges at Northeast Alabama Regional Medical Center and Stringfellow Memorial Hospital for direct admissions to his service as well as through emergency room services.

**SALAME HEART
& VASCULAR CLINIC, LLC**

Mahomed Y. Salame, M.D., MRCP
Cristin L. Prater, CRNP
Amy K. Holley, AGACNP

Board Certified, Interventional Cardiology & Vascular Medicine

Our goal with this letter is to demonstrate that our request falls within the criteria of the Physician Office Exemption and outside of the thresholds established for CON review. Offices of private physicians are not "health care facilities" per Ala Code 22-21-260(6), and "health services" do not include "the lawful practice of any profession or vocation conducted independently of a health care facility and in accordance with applicable licensing laws of this state" under Ala Code 22-21-260(6).

The service area for this request is rural Calhoun County and surrounding rural counties of Etowah, Cherokee, Talladega, Cleburne, and Randolph. The physician owner of Salame Heart and Vascular Clinic, Dr. Mahomed Y. Salame, is licensed in the state of Alabama and certified to perform the procedures listed above. The physician will not perform any acute emergency cardiac interventions nor any coronary angioplasty in the private practice setting. In addition, the private practice facility will not be used for inpatient care.

The criteria as adopted by the Supreme Court for the Physician Office Exception in *Ex parte Sacred Heart Health Systems, Inc.*, 1455 So. 3rd 980, 988 (Ala. 2012) are as follows:

1. The proposed services are to be provided, and the related equipment used, exclusively by the physicians identified as owners or employees of the physicians' practice for the care of their patients.
2. The proposed services are to be provided, and related equipment used, at any office of such physicians.
3. All patient billings related to such services are through, or expressly on behalf of, the physicians' practice.
4. The equipment shall not be used for inpatient care, nor by, through or on behalf of a healthcare facility.

Salame Heart and Vascular Clinic will meet the four requirements set forth by the Alabama Supreme Court as follows:

1. Procedures will be performed only by Dr. Salame or physicians employed by Salame Heart and Vascular Clinic, and the related equipment shall be used exclusively by physician owners or physician employees of Salame Heart and Vascular Clinic for the care of their patients.
2. All procedures will be performed in the office of Salame Heart and Vascular Clinic. All equipment necessary for the performance of the procedures will be used only in the office of Salame Heart and Vascular Clinic.
3. The patient billing related to such services will be done through, or expressly on behalf of the private physician offices of Salame Heart and Vascular Clinic.
4. At no time will the equipment identified for the performance of the office-based procedures described in this letter be used for inpatient care, nor by, through or on behalf of a health care facility.

**SALAME HEART
& VASCULAR CLINIC, LLC**

Mahomed Y. Salame, M.D., MRCP
Cristin L. Prater, CRNP
Amy K. Holley, AGACNP

Board Certified, Interventional Cardiology & Vascular Medicine

For the purpose of this request, we would like to provide the following financial disclosure:

Total Cost of New Major Medical Equipment purchased for the office-based procedures = \$120,000.00

- a. To include, Diagnostic X-ray system, patient monitoring equipment, patient recovery equipment, and IVUS for arterial procedures. All other equipment is already owned by the private practice.

Estimated annual first year operating cost: Total= \$355,000.00

- a. Equipment Lease- \$130,000.00
- b. Supplies- \$25,000.00
- c. Employee Wages-\$150,000.00
- d. Renovation/Construction Cost- \$50,000

In light of the foregoing analysis, our request meets the criteria adopted by the Alabama Supreme Court for application of the Physician Office Exemption. As noted above, we also affirm that this addition of services within our private physician practice will not exceed any of the certificate of need expenditure thresholds, nor will it constitute a "new institutional health service" under Alabama Code 22-21-263 and the rules due to the following:

- a) No new health care facility or health maintenance organization will be constructed, developed or acquired.
- b) No major medical equipment will be acquired by or on behalf of a health care facility that exceeds the statutory purchase price or operating expense thresholds.
- c) No new health care facility beds or stations will be added.
- d) No new health service that is currently offered by Salame Heart and Vascular Clinic will be provided with the implementation of the procedures described in the document; and
- e) No other event reviewable under the CON law or rules will occur as a result of our implementation of the procedures described in this document.

With the support of this document we respectfully request that the Alabama State Health Planning and Development Agency grant a determination of non-reviewability to Salame Heart and Vascular Clinic, LLC for the proposed procedures described above.

No other healthcare facilities have a financial interest in Salame Heart and Vascular Clinic, LLC.

**SALAME HEART
& VASCULAR CLINIC, LLC**

**Mahomed Y. Salame, M.D., MRCP
Cristin L. Prater, CRNP
Amy K. Holley, AGACNP**

Board Certified, Interventional Cardiology & Vascular Medicine

Payment of \$1000.00 for the filing fee with respect to request for a reviewability determination will be submitted through the SHPDA Electronic Payment Portal.

Please do not hesitate to call or contact me: Mahomed Y. Salame 256-689-0147- salame@bellsouth.net
We appreciate your time and consideration in this matter.

Sincerely,



Mahomed Y. Salame, M.D.

**SALAME HEART
& VASCULAR CLINIC, LLC**

**Mahomed Y. Salame, M.D., MRCP
Cristin L. Prater, CRNP**

Board Certified, Interventional Cardiology & Vascular Medicine

November 2, 2020

RV2021-002

RECEIVED

Nov 02 2020

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

Via email: shpda.online@shpda.alabama.gov

Hon. Emily T. Marsal
Executive Director
State Health Planning and Development Agency
100 North Union Street
RSA Union Building, Suite 870
Montgomery, AL 36130-3025

RE: Non-Reviewability Determination Request for Salame Heart and Vascular Clinic, LLC

Dear Ms. Marsal:

This is response requested to for clarification on the statement of physicians employed by Salame Heart and Vascular Clinic. As of today, Dr. Salame is the owner and only physician employed by Salame Heart and Vascular Clinic. He will be the only physician providing the proposed services and utilizing the related equipment.

Sincerely,



Mahomed Y. Salame, M.D.

Affirmation of Mahomed Y. Salame, M.D. as Requesting Party

The undersigned, being first duly sworn, hereby makes oath or affirms that he is the owner of Salame Heart and Vascular Clinic, LLC, and has knowledge of the facts in this request, and to the best of his information, knowledge and belief, such facts are true and correct.

Affiant (SEAL)

SUBSCRIBED AND SWORN to before me this 30th day of October, 2020.

Margaret Porter
Notary Public

My commission expires: 4/16/24



TENTATIVE AGENDA

CERTIFICATE OF NEED REVIEW BOARD

January 20, 2021, 10:00 a.m.

The meeting is tentatively set to be held virtually. Log-in information will be shared on the Agency's website and through notification as soon as possible.

PRESIDING:

DR. SWAID N. SWAID, CHAIRMAN

- | | | |
|------|------------------------------|----------------------|
| I. | CALL TO ORDER | CHAIRMAN |
| II. | ROLL CALL | Mrs. Emily T. Marsal |
| III. | ADOPTION OF AGENDA | CHAIRMAN |
| IV. | MINUTES OF November 18, 2020 | CHAIRMAN |
| V. | CHAIR'S REPORT | CHAIRMAN |
| VI. | SHPDA ADMINISTRATIVE REPORT | Mrs. Emily T. Marsal |
| VII. | CERTIFICATE OF NEED PROGRAM | Mrs. Emily T. Marsal |

A. AL2014-027, Saad Enterprises, Inc. d/b/a Saad Hospice Services, Mobile, AL: Proposes to establish a new thirty-four (34) bed freestanding residential-based inpatient hospice facility in Region XIII. **Project Modification Request:** The project modification reflects an increase in the total cost of the project from \$6,843,178.00 to \$12,781,824.50, an increase of 86.8%. **Opposition: None**

B. AL2020-044, Brookside Memory and Specialty Care on Cottage Hill, LLC, Mobile County, AL: Proposes to convert the existing thirty-two (32) licensed ALF beds into thirty-two (32) SCALF beds. **Opposition: None**

C. AL2020-045, The Health Care Authority of the City of Huntsville d/b/a Huntsville Hospital, Huntsville, AL: Proposes to lease radiation oncology equipment in order to resume radiation oncology services as a hospital-based department. **Opposition: None**

D. AL2020-046, Washington County Health Care Authority, Inc. d/b/a Washington County Hospital, Chatom, AL: Proposes to certify five (5) general acute care beds as five (5) swing beds pursuant to section 410-2-4-.09 of the 2020-2023 Alabama State Health Plan. **Opposition: None**

- E. **AL2020-047, Choctaw General Hospital, Butler, AL:** Proposes to convert five (5) acute care beds into swing beds pursuant to section 410-2-4-.09 of the 2020-2023 Alabama State Health Plan. **Opposition: None**
- F. **AL2020-048, Rehabilitation Hospital of North Alabama, LLC d/b/a Encompass Health Rehabilitation Hospital of North Alabama, Huntsville, AL:** Proposes to add six (6) inpatient physical rehabilitation beds for a total of eighty-two (82) beds, pursuant to the May 15, 2020 Statistical Update to the Inpatient Physical Rehabilitation section of the 2020-2023 State Health Plan. **Opposition: None**
- G. **AL2020-049, Foley Hospital Corporation d/b/a South Baldwin Regional Medical Center, Foley, AL:** Proposes to undertake significant renovations to modernize the existing spaces and construct a new patient tower. **Opposition: None**

For Informational Purposes Only:

Reviewability Determinations:

RV2020-022, Hale County Hospital, proposes to relocate their administrative office to another site in Hale County, Alabama. **Status: Non-Reviewable**

RV2021-002, Salame Heart & Vascular Clinic, LLC, proposes to add an office-based lab. **Status: Non-Reviewable**

Pending Reviewability Determinations:

RV2020-024, Alabama Home Health Care Providers, proposes to provide home health services in Etowah, Talladega, Calhoun, Jefferson, Marshall, and Madison counties in Alabama. **Status: Pending**

Rural, Cullman Regional Medical Center, proposes the re-opening of a second catheterization lab for vascular surgery and for diagnostic and interventional cardiac catheterization on CRMC' s campus. **Status: Pending**

RV2021-003, The Heart Center Cardiology, proposes to perform low risk peripheral angiography and interventional procedures, left and right diagnostic heart catheterizations- coronary angiography, elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk ICD and pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures within this private practice. **Status: Pending**

RV2021-004, Affinity Healthcare Services, Inc. d/b/a Affinity Home Hospice Services, proposes to establish a hospice branch office in Pell City, St. Clair County,

which is located within the service area the agency is permitted to serve pursuant to CON-2323-HPC. **Status: Pending**

RV2021-005, Techota, LLC d/b/a CV Home Health of Bibb County, proposes to add a drop site in Tuscaloosa County. This request does not include any new or additional services or personnel. **Status: Pending**

RV2021-006, Home Choice of Alabama, Inc. d/b/a Springhill Home Health and Hospice, proposes to relocate their administrative office to another site within Mobile County. **Status: Pending**

RV2021-007, Sereno Ridge Recovery, proposes that the operation of an immersive twelve (12) step addiction recovery program to guests staying at the lodge owned and operated by applicant does not involve the provision of “institutional health services” as defined in Ala. Code 22-21-260. **Status: Pending**

RV2021-008, Comfort Care Home Health Services, LLC, proposes to establish a drop site in Cullman County where they currently have contiguous county authority to provide services. **Status: Pending**

VII. OLD BUSINESS CHAIRMAN

VIII. NEW BUSINESS CHAIRMAN

Declaratory Ruling 156:

Addiction and Mental Health Services, LLC, d/b/a Bradford Health Services, submits this Petition for Declaratory Ruling pursuant to Rule 410-1-9-.01 of the Alabama Certificate of Need Rules and Regulations regarding Institute for Substance Use Disorders, LLC d/b/a Sereno Ridge Recovery, adopting and incorporating Bradford Health Services’ Petition for Declaratory Ruling in DR-155, which was previously dismissed by CONRB without prejudice. DR-155, as filed by Bradford Health Services, sought a declaratory ruling that Sereno Ridge Recovery’s plan to develop and operate a 16-bed, 16,500 -square-foot “Clinically Managed High Intensity Residential Program for Adults and Medically Monitored Residential Detoxification Program” proposed a new institutional health facility and services.

IX. ADJOURNMENT CHAIRMAN

Vein Center
100 Pilot Medical Drive, Suite 185
Birmingham, AL 35235

Northside Medical Home
74 Plaza Drive, Suite 2B
Pell City, AL 35125

Gardendale
2217 Decatur Highway
Gardendale, AL 35071



100 Pilot Medical Drive, Suite 300
Birmingham, AL 35235
(205) 856 2284
F: (205) 815 4777
Birminghamheart.com

RV2019-037

RECEIVED

St. Vincent's Blount
150 Gilbreath Drive
Oneonta, AL 35121

St. Vincent's Downtown
2700 10th Avenue South, POB 2, Suite 305
Birmingham, AL 35205

St. Vincent's One Nineteen
7121 Cahaba Valley Road, Suite 101A
Birmingham, AL 35242

APR 04 2019
FBI - BIRMINGHAM

April 4, 2019

Hon. Emily T Marsal
Executive Director
State Health Planning and Development Agency
100 North Union Street
RSA Union Building, Suite 870
Montgomery, AL 36130-3025

Re: **Addendum to the Non-Reviewability Determination Request for Birmingham Heart Clinic, P.C.**

Dear Ms. Marsal:

I am writing on behalf of the Birmingham Heart Clinic P.C. (BHC) to request a change in our reviewability determination request. Since obtaining our original determination in 2018, we successfully opened an office based catheterization lab and have been providing low risk peripheral angiography and interventional procedures. Our patients have appreciated the ease, convenience and cost savings associated with outpatient access to low risk procedures.

Birmingham Heart Clinic is an Alabama S Corporation, incorporated in 1994. We are wholly physician owned without hospital or outside investor involvement. We have been safely and effectively performing arterial and venous peripheral procedures for the last year, and now wish to broaden the scope of low risk cardiac procedures offered to our patients to include left and right heart catheterizations, elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk ICD and pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures.

BHC will not be performing any acute emergency cardiac interventions nor any coronary angioplasty in this catheterization laboratory. Our lab will continue to be staffed by licensed employees and will not be used for inpatient care.

The criteria as adopted by the Supreme Court for the Physician Office Exemption are as follows:

1. The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physicians' practice for the care of their patients.
2. The proposed services are to be provided, and related equipment used, at any office of such physicians.

Van C. Reeder, Jr., MD, FACC
Robert E. Foster, MD, FACC
C. Andrew Brian, MD, FACC
Brian D. Snoddy, MD, FACC
James R. Trimm, MD, FACC

Michael S. Bailey, MD, FACC
Jason B. Thompson, MD, FACC
Jacob C. Townsend, MD, FACC
Brian A. Flowers, MD, FACC
Robert H. Yoe, IV, MD

James G. Towery, MD, FACC
Joshua N. Cockrell, MD
Corey M. Coleman, MD
Joshua A. Turner, MD
John L. Parks, MD

3. All patients billings related to such services are through, or expressly on behalf of, the physicians practice
4. The equipment shall not be used for inpatient care, nor by, through or on behalf of a health-care facility

Birmingham Heart Clinic will continue, through the performance of the procedures previously reviewed, to meet the above criteria as follows:

1. Procedures will be performed only by physician owners or physician employees of BHC
2. All procedures will be performed in the office of BHC, currently located at the address as stated above. All equipment necessary for the performance of the procedures will be used only in the office of BHC.
3. All patient billing for the procedures will be done on behalf of BHC and its' patients
4. At no time will the equipment used for the performance of our office based procedures be used for inpatient care, nor by, through or on behalf of any health care facility.

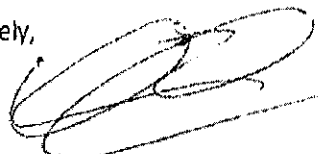
Based on the information provided above, the proposed procedures should meet the criteria adopted by the Alabama Supreme Court for application of the Physician Office Exception. Although the Physician Office Exception serves as a bar to CON review, for your notice we can affirm that this venture will not exceed any of the certificate of need expenditure threshold nor will it constitute a 'new institutional health service' under Alabama Code 22-21-263 and the Rules because:

- a) No new health care facility or health maintenance organization will be constructed, developed or acquired
- b) No major medical equipment will be acquired by on or behalf of a health care facility that exceeds the statutory purchase price or operating expense thresholds
- c) No new health care facility beds or stations will be added
- d) No new health service that is currently offered by BHC will be provided with the implementation of the procedures described in this document
- e) No other event reviewable under the CON law or Rules will occur as a result of our implementation of the procedures described in this document

With the support of this document we respectfully request a determination of non-reviewability to Birmingham Heart Clinic for the expanded list of procedures described above. Please do not hesitate to contact us if you require any further information or have any questions.

A check for the filing fee with respect to a request for reviewability determination in the amount of \$1,000 is enclosed. Thank you for your time and consideration in this matter.

Sincerely,



Van C. Reeder, MD
President

Vein Center
100 Pilot Medical Drive, Suite 185
Birmingham, AL 35235

Northside Medical Home
74 Plaza Drive, Suite 28
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Gardendale
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St. Vincent's One Nineteen
7191 Cahaba Valley Road, Suite 101A
Birmingham, AL 35242

RECEIVED

JUL 08 2019

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

July 3, 2019

Emily T. Marsal
Executive Director, State Health Planning and Development Agency
100 N. Union Street, Suite 870
Montgomery, AL 36104

RE: RV2019-037
Birmingham Heart Clinic, P.C.

Dear Ms Marsal:

Please find our detailed responses addressing the requests for additional information below:

1. **Provide the Agency with the procedures to be performed not currently provided at another facility.**

No novel procedures will be performed in the office based lab. All of the procedures requested are standard, commonly performed in both inpatient (hospital) and outpatient (office based lab) settings already. They have all been previously approved for other office based labs in our state.

2. **Provide the Agency with the approximated costs of the proposed project to include major medical equipment, addition first year annual operating cost for the proposed procedures, and additional capital expenditures as a result of the proposed procedures.**

No capital expenditures or upgrades to our current facility are necessary or planned to add the requested additional procedures. Any changes in operating costs would be estimated at less than \$50,000 going towards the purchase of necessary supplies.

3. **Provide additional information regarding if the current or proposed procedures will be invasive, and if general anesthesia will be used during any procedures.**

All of the planned procedures are minimally invasive and low risk. General anesthesia will not be used.

4. **Provide the Agency with emergency procedures in place on behalf of the proposed procedures.**

Our office based lab (and office as a whole), has an established care plan including the identification of involved personnel and equipment, to deal with any issues related to

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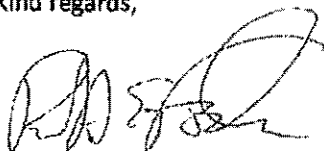
James G. Towery, MD, FACC
Joshua N. Cockrell, MD
Corey M. Coleman, MD
Joshua A. Turner, MD
John L. Parks, MD

unexpected changes in a patient's status. This includes oxygen and masks for ventilation, medications for arrhythmias and reversal of sedation, defibrillation and pacing and a pathway to transfer to a higher level of care as needed.

In summary – we hope to extend the outpatient services we provide our patients under the Physician Office Exception. We do not plan to change our infrastructure or equipment, simply broaden the scope of low risk cardiac procedures performed onsite.

Please let us know if any further clarification would be helpful.

Kind regards,

A handwritten signature in black ink, appearing to read 'R. E. Foster', with a stylized flourish at the end.

Robert E. Foster, M.D.
Newly Elected President

Vein Center
100 Pilot Medical Drive, Suite 185
Birmingham, AL 35235

Northside Medical Home
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Birmingham, AL 35242

July 26, 2019

RECEIVED

Aug 05, 2019

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

Emily T. Marsal
Executive Director, State Health Planning and Development Agency
100 N. Union Street, Suite 870
Montgomery, AL 36104

RE: RV2019-037
Birmingham Heart Clinic, P.C.

Dear Ms Marsal:

Please find our detailed responses addressing the requests for additional information below:

1. BHC is not going into any arrangement with a health care facility in any way to fund or provide current services or additional services requested. The physician owners of BHC and therefore this office based lab are as follows: Van C. Reeder, Jr, MD, Robert E. Foster, MD, C. Andrew Brian, MD, Brian D. Snoddy, MD, James R. Trimm, MD, Michael S. Bailey, MD, Jason B. Thompson, MD, Jacob C. Townsend, MD, Brian A. Flowers, MD, Joshua N. Cockrell, MD and Robert H. Yoe, IV, MD. Other physicians that are existing employees of Birmingham Heart Clinic and on a partnership track are James G. Towery, MD, Corey M. Coleman, MD, Joshua A. Turner, MD, and John L. Parks, MD. They will not be financially responsible for the cost of the lab at this time, but will have the ability to provide services in the lab and the cost of the lab will be factored into partnership for each one as that time arrives. All physicians that will perform procedures in this lab will continue to have full access to the clinic space that is already here. All patient billing for the procedures performed in this lab will be billed out on behalf of, and by employees of, Birmingham Heart Clinic, P.C.
2. Attestation by an officer – I am including the attestation of not only myself, but also the secretary and treasurer.

The undersigned, being first duly sworn, hereby make an oath or affirm that he is the President of Birmingham Heart Clinic and has knowledge of the facts in this request, and to the best of his information, knowledge and belief, such facts are true and correct.

A handwritten signature in black ink, appearing to read "R. Foster", is written over a horizontal line.

Robert E. Foster, MD – President

Van C. Reeder, Jr., MD, FACC
Robert E. Foster, MD, FACC
C. Andrew Brian, MD, FACC
Brian D. Snoddy, MD, FACC
James R. Trimm, MD, FACC

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Robert H. Yoe, IV, MD

James G. Towery, MD, FACC
Joshua N. Cockrell, MD
Corey M. Coleman, MD
Joshua A. Turner, MD
John L. Parks, MD

SUBSCRIBED AND SWORN to before me this 1 day of August, 2019

Pamela Dwyer

Notary Public

My commission expires: 4/30/2023

The undersigned, being first duly sworn, hereby make an oath or affirm that he is the Secretary of Birmingham Heart Clinic and has knowledge of the facts in this request, and to the best of his information, knowledge and belief, such facts are true and correct.

Jacob C. Townsend

Jacob C. Townsend, MD - Secretary

SUBSCRIBED AND SWORN to before me this 1 day of August, 2019

Pamela Dwyer

Notary Public

My commission expires: 4/30/2023

The undersigned, being first duly sworn, hereby make an oath or affirm that he is the Secretary of Birmingham Heart Clinic and has knowledge of the facts in this request, and to the best of his information, knowledge and belief, such facts are true and correct.

C. Andrew Brian

C. Andrew Brian, MD - Treasurer

SUBSCRIBED AND SWORN to before me this 1 day of August, 2019

Pamela Dwyer

Notary Public

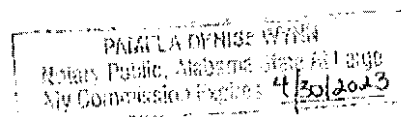
My commission expires: 4/30/2023

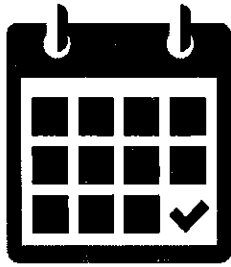
Please let me know if there is anything further that you need to be able to process our request. If you have any questions, please feel free to contact our Practice Administrator, Tonya White or myself at 205-856-2284.

Kind regards,

Robert E. Foster

Robert E. Foster, M.D.
President





**TENTATIVE AGENDA
CERTIFICATE OF NEED
REVIEW BOARD**

**September 18, 2019
10:00 A.M.
STATE CAPITOL AUDITORIUM
UNION STREET ENTRANCE
MONTGOMERY, ALABAMA**

PRESIDING:

**DR. SWAID N. SWAID
CHAIRMAN**

TENTATIVE AGENDA

- | | | |
|------|-----------------------------|----------------------|
| I. | CALL TO ORDER | CHAIRMAN |
| II. | ADOPTION OF AGENDA | CHAIRMAN |
| III. | MINUTES OF August 21, 2019 | CHAIRMAN |
| IV. | CHAIR'S REPORT | CHAIRMAN |
| V. | SHPDA ADMINISTRATIVE REPORT | Mrs. Emily T. Marsal |
| VI. | CERTIFICATE OF NEED PROGRAM | Mrs. Emily T. Marsal |

The Applicant requested this project be carried over until the next CONRB meeting

- A. AL2019-015, Great Oaks Management, LLC, Wetumpka, AL:** Proposes to renovate and convert an existing sixteen (16) bed Assisted Living Facility (ALF) to a Specialty Care Assisted Living Facility (SCALF), and add sixteen (16) additional SCALF beds, for a total of thirty-two (32) SCALF beds in Elmore County, pursuant to the September 5, 2018 statistical update. **Opposition: None**
- B. AL2019-018, Bio-Medical Applications of Alabama, Inc. d/b/a USA Midtown, Mobile, AL:** Proposes to relocate two (2) existing home training stations from Fresenius Medical Care University of South Alabama, an End Stage Renal Disease clinic in Mobile County, and add one (1) home training station to Midtown's ESRD treatment facility currently under construction, for a total of seventeen (17) stations in Mobile County, Alabama. CON 2661-ESRD was issued to USA Midtown January 30, 2014, to establish and operate a new fourteen (14) station dialysis treatment facility in Mobile County. **Opposition: None**
- C. AL2019-019, Mobile Infirmary Association d/b/a J. L. Bedsole/Rotary Rehabilitation Hospital, Mobile, AL:** Proposes to relocate twelve (12) existing inpatient rehabilitation facility (IRF) beds within Region VI from Thomas Hospital in

Fairhope, Baldwin County, Alabama, to the J. L. Bedsole /Rotary Rehabilitation Hospital located in Mobile Infirmary Medical Center in Mobile, Mobile County, Alabama, for a total of fifty-four (54) inpatient rehabilitation beds. **Opposition: Springhill Hospitals, Inc, d/b/a Springhill Medical Center filed opposition/intervention.**

- D. **AL2019-020, AltaPointe Health Systems, Inc., Mobile, AL:** Proposes to add thirty-four (34) inpatient psychiatric beds, eighteen (18) adult and sixteen (16) adolescent, to BayPointe Hospital, an existing inpatient psychiatric facility in Mobile County, Southwest Region. **Opposition: None**
- E. **AL2019-022, DVA Renal Healthcare, Inc. d/b/a Red Mountain Home Training Dialysis, Birmingham, AL:** Proposes to expand the existing End Stage Renal Disease (ESRD) treatment facility, consisting of ten (10) home training stations, with the addition of eight (8) new home training stations to be used alternatively for home hemodialysis training and peritoneal dialysis treatment and training, for a total of eighteen (18) home training stations. **Opposition: None**
- F. **AL2019-023, Grow Pediatric Therapy, Anniston, AL:** Proposes to establish and operate a multi-specialty rehabilitation facility providing pediatric outpatient speech, physical and occupational therapy services in Calhoun County. The applicant is currently authorized to provide pediatric outpatient speech therapy services through RV2019-024. **Opposition: None**
- G. **AL2019-024, Fresenius Kidney Care Union Springs, LLC d/b/a Fresenius Kidney Care Union Springs, Union Springs, AL:** Proposes to expand an existing End Stage Renal Disease (ESRD) dialysis treatment center, consisting of eight (8) in-center hemodialysis stations, one (1) home training station, and one (1) isolation station, through the addition of six (6) in-center hemodialysis stations, for a total of sixteen (16) stations in Union Springs, Bullock County, Alabama, pursuant to ALA. ADMIN. CODE r. 410-2-3-.05(1)(c). **Opposition: None**

For Informational Purposes Only:

Reviewability Determinations:

RV2019-037, Birmingham Heart Clinic, P.C., requests to broaden the scope of the low risk cardiac procedures currently offered through the Physician Office Exemption by adding left and right heart catheterizations, elective internal cardiac defibrillator and planned pacemaker generator changes; pacemaker implantation; implantable loop recorder insertion; direct current cardioversion; infusa port placement; transesophageal echocardiography; pulmonary artery pressure recording devices and low risk atrial; ventricular and nodal ablation procedures.

Status: Non-Reviewable

RV2019-039, Rehab Associates, LLC d/b/a Champion Sports Medicine, requests to relocate the existing single specialty rehabilitation clinic in Greenville, Alabama.

Status: Non-Reviewable

Pending Reviewability Determinations:

RV2019-040, Rehab Associates, LLC d/b/a Champion Sports Medicine, requests to relocate the existing single specialty rehabilitation clinic in Hoover, Alabama.

Status: Pending

RV2019-041, ProHealth of Northeast Alabama, LLC, requests to relocate the home health administrative office to another site in Cherokee County.

Status: Pending

- | | | |
|-------|--------------|----------|
| VII. | OLD BUSINESS | CHAIRMAN |
| VIII. | NEW BUSINESS | CHAIRMAN |
| IX. | ADJOURNMENT | CHAIRMAN |

CARDIOLOGY CONSULTANTS, PC

RV2019-032

WILLIAM A. HILL, JR., M.D., F.A.C.C.
JOHN A. MANTLE, M.D., F.A.C.C.
JEFFREY K. ANDERSON, M.D., F.A.C.C.
L. ANNE LEWIS, M.D., F.A.C.C.
AMIT SHAH, M.D.
EDWARD A. CARRAWAY, M.D.
J. BRADLEY PROCTOR, M.D.

April 10, 2019

VIA EMAIL (shpda.online@shpda.alabama.gov)
AND FEDERAL EXPRESS

The Honorable Emily T. Marsal
Executive Director
Alabama State Health Planning & Development Agency
RSA Union Building
100 North Union Street, Suite 870
Montgomery, Alabama 36104

Re: Non-Reviewability Determination Request for Cardiology Consultants, P.C.

Dear Ms. Marsal:

On behalf of Cardiology Consultants, P.C. ("CCPC"), I am writing to submit a reviewability determination request in accordance with the rules and regulations of the Alabama State Health Planning and Development Agency's Certificate of Need ("CON") program. CCPC plans to add an office-based laboratory (the "OBL") to its practice in order to provide its patients with convenient and safe access to peripheral angiography and endovascular procedures within the offices of CCPC. This letter provides an overview of the scope of procedures to be performed and the costs associated with establishing the OBL. In addition, this letter will demonstrate that the OBL will meet the criteria for the Physician Office Exemption from CON review set forth by the Alabama Supreme Court in *Ex parte Sacred Heart Health System, Inc.*, 155 So. 3d 980 (Ala. 2012).

CCPC is an Alabama professional corporation founded in 1983 by William A. Hill, Jr., M.D. and currently owned by Dr. Hill, John A. Mantle, M.D., Jeffrey K. Anderson, M.D., L. Anne Lewis, M.D., Amit K. Shah, M.D., Edward A. Carraway, M.D. and J. Bradley Proctor, M.D., all of whom are actively engaged in the practice of cardiology through CCPC. There are no outside investors in CCPC and no hospital involvement in CCPC. CCPC's offices are located at the DCH Medical Tower, 701 University Boulevard, East, Suites 400 and 608, Tuscaloosa, Alabama 35401. CCPC serves patients in Tuscaloosa County and numerous other counties in Alabama, through its offices in Tuscaloosa and through monthly travel clinics in Bibb, Fayette, Marengo and Pickens Counties.

CCPC physicians currently perform low-risk outpatient peripheral angiography and endovascular procedures (including renal interventions, iliac interventions, tibial/peroneal interventions, femoral/popliteal interventions, and atherectomy procedures with or without stents and with or without percutaneous transluminal angioplasty) (collectively, and together with

{BH384006.1}

similar low-risk outpatient procedures, "Vascular Procedures") at DCH Medical Center. CCPC believes that it can provide these Vascular Procedures at greater convenience to patients and with equal or higher quality within its own offices through the development of the OBL. CCPC does not intend to provide any cardiac or coronary interventions or procedures requiring general anesthesia at the OBL, and no inpatient services will be provided at the OBL.

The criteria established by the Supreme Court for the Physician Office Exemption from CON review are:

1. The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physicians' practice for the care of their patients.
2. The proposed services are to be provided, and related equipment used, at any office of such physicians.
3. All patient billings related to such services are through, or expressly on behalf of, the physicians' practice.
4. The equipment shall not be used for inpatient care, nor by, through, or on behalf of a healthcare facility.

CCPC will meet these criteria with respect to the proposed OBL:

1. The services to be provided by the OBL will be provided, and related equipment used, exclusively by physicians who are owners, employees or contractors of CCPC and only for the care of such physicians' patients. Initially, the services will be provided by Drs. Hill, Anderson, Carraway and Proctor, who are all owners of CCPC, and by W. Ford Simpson, Jr., M.D., who will work for CCPC on a regularly scheduled, part-time basis as a contractor treating CCPC patients. The independent contractor arrangement between CCPC and Dr. Simpson will provide that Dr. Simpson will provide his services at CCPC on a regularly scheduled basis, that all patients treated by Dr. Simpson at CCPC are patients of CCPC and not of Dr. Simpson individually, that CCPC will bill for all services provided by Dr. Simpson at CCPC and retain all collections therefrom, and that Dr. Simpson will be compensated by CCPC for his services to CCPC on a basis consistent with the compensation paid to CCPC owners and employee with respect to OBL services. If any additional physicians provide services at the OBL in the future, such physicians will be owners, employees or contractors of CCPC.
2. All OBL procedures will be performed, and all related equipment will be used, at the offices of CCPC. CCPC is adding an additional 1,950 square feet to its current office space to accommodate the OBL.

3. All patient billings relating to services provided at the OBL will be done through CCPC under provider agreements and billing numbers assigned to CCPC, and all collections resulting from such billings will be the property of CCPC, just as is the case for all other physician services provided by CCPC.
4. The equipment at the OBL will not be used for inpatient care nor by, through or on behalf of a healthcare facility; rather, such equipment will be used only for office-based, outpatient Vascular Procedures provided by CCPC physicians.

Although the Physician Office Exemption provides a bar to the application of the CON laws and regulations, we provide the following additional information for the benefit of the Agency in reviewing this request for a determination of non-reviewability:

- CCPC will expand its leased space at its current offices by 1,950 square feet to accommodate the OBL, at a rental rate of \$16.50 per square foot. This will add an additional \$2,681.00 per month to CCPC's current office lease expense, representing an increase of approximately 15.45% in office lease expense. CCPC will incur construction costs of approximately \$355,724 to build out the additional leased space.
- CCPC will acquire a Philips Medical Mobile Verdius Unity Flat Panel C-Arm, Full Screen collimation, vascular configuration with video paper/transparency printer, which comes with an Aspect 100-4T G3 Complete Table and Package, including a black anti-fatigue Mat, and a Core M2 Vascular Imaging System – IVUS for arterial and venous procedures, as well as related equipment. The total equipment cost for purchased equipment will be approximately \$351,717; CCPC also has a rental agreement with Philips Medical for a Spectranics Laser – CV 300P Excimer Laser system to be used as needed.
- CCPC anticipates incurring additional miscellaneous start-up costs of approximately \$142,559, resulting in total construction, equipment and start-up costs of approximately \$850,000. These costs will be financed through a 60-month loan to CCPC arranged through Bryant Bank of Tuscaloosa.
- First-year annual operating costs for the OBLG are estimated at \$950,000 for medical and non-medical supplies, space rental, salaries and benefits, equipment service and maintenance and similar routine expenses.

Based on the above, we respectfully request that the Agency grant a determination of non-reviewability to CCPC for the proposed OBL project described above. CCPC's check for \$1,000 in payment of the filing fee for this request is enclosed with the hard copy of this letter, which is being sent today by Federal Express. Please do not hesitate to contact our counsel, William W. Horton, at (205) 244-5221 or whorton@joneswalker.com if you require any further information or have any questions.

We appreciate your attention, and look forward to hearing from you.

The Honorable Emily T. Marsal
April 10, 2019
Page 4

Very truly yours,

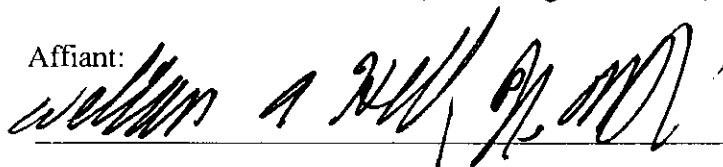


William A. Hill, Jr., M.D.
President, Cardiology Consultants, PC

Affirmation of Requesting Party:

The undersigned, being first duly sworn, hereby make oath or affirm that he is William A. Hill, Jr., M.D. of Cardiology Consultants, P.C., has knowledge of the facts in this request, and to the best of his/her/their information, knowledge and belief, such facts are true and correct.

Affiant:

 (SEAL)

SUBSCRIBED AND SWORN to before me this 10th day of April, 2019.



Notary Public

My commission expires: 09-15-2021

CARDIOLOGY CONSULTANTS, PC

WILLIAM A. HILL, JR., M.D., F.A.C.C.
JOHN A. MANTLE, M.D., F.A.C.C.
JEFFREY K. ANDERSON, M.D., F.A.C.C.
L. ANNE LEWIS, M.D., F.A.C.C.
AMIT SHAH, M.D.
EDWARD A. CARRAWAY, M.D.
J. BRADLEY PROCTOR, M.D.

May 20, 2019

VIA EMAIL (shpda.online@shpda.alabama.gov)
AND FEDERAL EXPRESS

The Honorable Emily T. Marsal
Executive Director
Alabama State Health Planning & Development Agency
RSA Union Building
100 North Union Street, Suite 870
Montgomery, Alabama 36104

**Re: Supplemental Information for Non-Reviewability Determination Request for
Cardiology Consultants, P.C./ RV2019-032**

Dear Ms. Marsal:

On behalf of Cardiology Consultants, P.C. ("CCPC"), I am writing to submit supplemental information in connection with CCPC's reviewability determination request (SHPDA File No. RV2019-032) relating to the proposed addition of an office-based laboratory (the "OBL") to its practice in order to provide its patients with convenient and safe access to peripheral angiography and endovascular procedures within the offices of CCPC. This letter provides supplemental information modifying the information set forth in CCPC's initial request letter dated April 10, 2019.

CCPC understands from discussions with Karen McGuire, Executive Secretary of SHPDA, that the Agency is concerned with the availability of the Physician Office Exemption to the proposed project in light of CCPC's indication in its original request that the services to be performed at the OBL would be provided by physicians who were owners, employees or independent contractors of CCPC. We understand the Agency's concern to be that the articulation of the Physician Office Exemption by the Alabama Supreme Court in *Ex parte Sacred Heart Health System, Inc.*, 155 So. 3d 980 (Ala. 2012) did not specifically address the provision of services by independent contractors.

Accordingly, CCPC has modified its plans to eliminate the provision of any physician services at the OBL by independent contractor physicians. In light of that change we request that the Agency treat our reviewability determination request as being modified by substituting the following revised language for the corresponding portion of the April 10 determination request (i.e., the portion that begins with "CCPC will meet these criteria ..." on page 2 of the April 10 request and ends at the conclusion of numbered paragraph 4 on page 3 of that request):

(BH389239.1)

CCPC will meet these criteria with respect to the proposed OBL:

1. The services to be provided by the OBL will be provided, and related equipment used, exclusively by physicians who are owners or employees of CCPC and only for the care of such physicians' patients. Initially, the services will be provided by Drs. Hill, Anderson, Carraway and Proctor, who are all owners of CCPC, and by W. Ford Simpson, Jr., M.D., who will work as a part-time employee of CCPC on a regularly scheduled basis. In that regard, we advise you all patients treated by Dr. Simpson at CCPC will patients of CCPC and not of Dr. Simpson individually, that CCPC will bill for all services provided by Dr. Simpson at CCPC and retain all collections therefrom, and that Dr. Simpson will be compensated by CCPC for his services to CCPC on a basis consistent with the compensation paid to CCPC owners and other CCPC employees with respect to OBL services. If any additional physicians provide services at the OBL in the future, such physicians will be owners or employees CCPC.
2. All OBL procedures will be performed, and all related equipment will be used, at the offices of CCPC. CCPC is adding an additional 1,950 square feet to its current office space to accommodate the OBL.
3. All patient billings relating to services provided at the OBL will be done through CCPC under provider agreements and billing numbers assigned to CCPC, and all collections resulting from such billings will be the property of CCPC, just as is the case for all other physician services provided by CCPC.
4. The equipment at the OBL will not be used for inpatient care nor by, through or on behalf of a healthcare facility; rather, such equipment will be used only for office-based, outpatient Vascular Procedures provided by CCPC physicians.

Except as so modified, the remainder of CCPC's reviewability determination request is hereby ratified and incorporated by reference in this letter.

Based on the above, we respectfully request that the Agency grant a determination of non-reviewability to CCPC for the proposed OBL project described in the April 10 request letter, as modified by this letter. Please do not hesitate to contact our counsel, William W. Horton, at (205) 244-5221 or whorton@joneswalker.com if you require any further information or have any questions.

We appreciate your attention, and look forward to hearing from you.

The Honorable Emily T. Marsal
May 20, 2019
Page 3

Very truly yours,

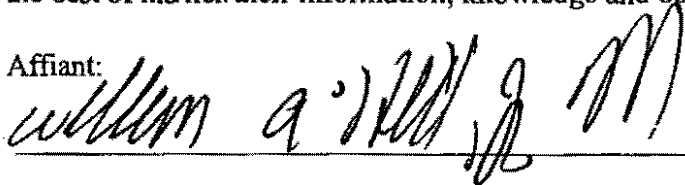


William A. Hill, Jr., MD
President, Cardiology Consultants, PC

Affirmation of Requesting Party:

The undersigned, being first duly sworn, hereby make oath or affirm that he/she is William A. Hill Jr., MD of Cardiology Consultants, P.C., has knowledge of the facts in this request, and to the best of his/her/their information, knowledge and belief, such facts are true and correct.

Affiant:

 (SEAL)

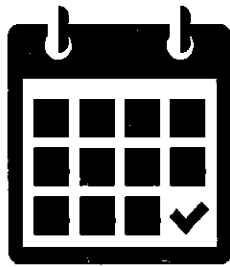
SUBSCRIBED AND SWORN to before me this 20th day of May, 2019.



Notary Public

My commission expires: 9-15-2021

(seal)



**TENTATIVE AGENDA
CERTIFICATE OF NEED
REVIEW BOARD**

**July 17, 2019
10:00 A.M.
STATE CAPITOL AUDITORIUM
UNION STREET ENTRANCE
MONTGOMERY, ALABAMA**

PRESIDING:

**DR. SWAID N. SWAID
CHAIRMAN**

TENTATIVE AGENDA

- | | | |
|------|-----------------------------|----------------------|
| I. | CALL TO ORDER | CHAIRMAN |
| II. | ADOPTION OF AGENDA | CHAIRMAN |
| III. | MINUTES OF June 19, 2019 | CHAIRMAN |
| IV. | CHAIR'S REPORT | CHAIRMAN |
| V. | SHPDA ADMINISTRATIVE REPORT | Mrs. Emily T. Marsal |
| VI. | CERTIFICATE OF NEED PROGRAM | Mrs. Emily T. Marsal |

This project was carried over from the May 15, 2019 Board meeting

- A. AL2019-006, SEES Group Alabama, LLC, Jefferson County, AL:** Proposes to establish a private-practice ambulatory surgery center for ocular and periorbital surgery consisting of three (3) operating rooms and one (1) laser procedure room.
Opposition: None

The applicant requested this project be carried over until the next Certificate of Need Review Board meeting

- B. AL2019-011, East Montgomery Community Dialysis, LLC d/b/a Physicians Choice of East Montgomery, Montgomery, AL:** Proposes to establish and operate a new End Stage Renal Disease ("ESRD") dialysis treatment center consisting of ten (10) in-center hemodialysis stations and one (1) peritoneal dialysis station.
Opposition: Renal Treatment Centers – Southeast, LP d/b/a Majestic Dialysis
- C. AL2019-013, Board of Trustees of the University of Alabama for the University of Alabama Hospital, Birmingham, AL:** Proposes to add two (2) additional cardiac catheterization laboratories to the existing four (4) catheterization labs, resulting in a total of six (6) catheterization labs and renovate two (2) procedure rooms, modify the existing equipment, and hire additional staff. **Opposition: None**

D. Reconsideration Request

AL2018-042, Tuscaloosa Operations, LLC d/b/a The Crossings at North River, Tuscaloosa, AL: Proposes to construct and operate thirty-two (32) specialty care assisted living beds as part of a senior housing community consisting of ninety-one (91) independent living units and seventy-two (72) assisted living beds. **Opposition: Crimson Village, LLC filed opposition/intervention and request for contested case hearing. The ALJ approved this project.**

The Board granted, in part, and denied, in part, with the applicant being granted sixteen (16) SCALF beds at the May 15, 2019 CONRB meeting.

AL2018-043, Crimson Village, LLC, Tuscaloosa, AL: Proposes to convert thirty-two (32) of the seventy-eight (78) assisted living beds at The Tides at Crimson Village, a senior living community, resulting in forty-six (46) ALF beds and sixty-four (64) SCALF beds. **Opposition: Tuscaloosa Operations, LLC d/b/a The Crossings at North River filed opposition/intervention and a request for contested case hearing. The ALJ denied this project.**

The Board granted, in part, and denied, in part, with the applicant being granted sixteen (16) SCALF beds at the May 15, 2019 CONRB meeting.

For Informational Purposes Only:

Reviewability Determinations:

RV2019-031, Cullman Regional Medical Center, requests to establish an urgent care physician's clinic to be located at 1549 Highway 13 NW, Hartselle, Alabama, under the physician's office exemption. **Status: Non-Reviewable**

RV2019-032, Cardiology Consultants, P.C., requests to add an office-based laboratory in order to provide patients with convenient and safe access to peripheral angiography and endovascular procedures. **Status: Non-Reviewable**

EQR2019-004, St. Vincent's East, requests to replace the existing cardiac catheterization equipment. **Status: Approved**

Pending Reviewability Determinations:

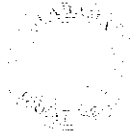
RV2019-033, GBR, LLC d/b/a Tuscaloosa Home Dialysis, requests that the proposed facility providing home dialysis training only to patients, is exempt. The facility consists of five (5) training rooms. **Status: Pending**

RV2019-035, Huntsville Cardiovascular Clinic, P.C., requests to add Cardiac PET scanning services. **Status: Pending**

RV2019-036, Children's Hospital of Alabama, requests to establish a psychiatric intensive outpatient program setting and partial hospitalization program setting as a part of the continuum of medically necessary pediatric psychiatric services settings currently provided by Children's in existing space. **Status: Pending**

RV2019-038, Mobile Open MRI, LLC, requests to add an ultrasound machine to the existing MRI center. **Status: Pending**

VII.	OLD BUSINESS	CHAIRMAN
VIII.	NEW BUSINESS	CHAIRMAN
IX.	ADJOURNMENT	CHAIRMAN



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

100 NORTH UNION STREET, SUITE 870
MONTGOMERY, ALABAMA 36104

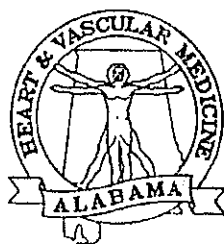
February 1, 2018

NOTICE

RE: Request for letter of non-reviewability -- RV2018-013

This is written to notify you that the attached request for a letter of non-reviewability has been received. Any affected person may file written comments regarding this request, per 410-1-7-.02 of the *Alabama Certificate of Need Program Rules and Regulations*.

Enclosure: see attached



RV2018-013

ALABAMA HEART & VASCULAR MEDICINE

RECEIVED

Jan 31 2018

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

November 27, 2017

State Health and Planning Development Agency
100 North Union Street
RSA Union Building, Suite 870
Montgomery, Alabama 36130-3025

RE: Non-Reviewability Determination Request for Bama Heart Doc, P.C. dba Alabama Heart and Vascular Medicine

Dear Mr. Lambert:

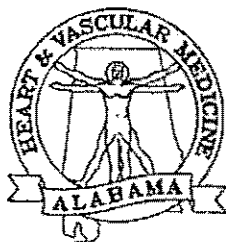
On behalf of Alabama Heart and Vascular Medicine, I am writing to submit a reviewability request in accordance with the Alabama State Health Planning and Development Agency's Certificate of Need (CON) program rules and regulations (410-1-7-.02). This letter is subsequent to a letter sent on January 11, 2017 – RV-2017-011 – in which we stated that we would perform fluoroscopic-based angiographic, arterial and venous interventions limited to the vessels of the upper and lower extremities. This request was deemed non-reviewable on March 29, 2017.

Alabama Heart and Vascular Medicine (AHVM) would like to further request non-reviewability to include low-risk cardiac procedures, such as left and right diagnostic catheterizations, low-risk ICD and pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, thrombectomy of dialysis grafts, and transesophageal echocardiogram. For precedence of this requested LNR, please see RV-2016-007.

These procedures would be in addition to arterial and venous interventions of the vessels of the upper and lower extremities currently performed in our facility. Since March 29, 2017, AHVM has performed over 80 procedures authorized in RV-2017-011 and can report overwhelmingly positive patient outcomes and patient satisfaction. AHVM would like to further extend to its patients the procedures listed above with the same positive patient outcomes and patient satisfaction. AHVM will not be performing any acute emergency cardiac intervention or any coronary angioplasty in this cardiac catheterization laboratory.

The criteria as adopted by the Supreme Court for the Physician Office Exemption are as follows:

- 1) The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employee of the physician's practice for the care of their patients.



ALABAMA HEART & VASCULAR MEDICINE

- 2) The proposed services are to be provided, and related equipment used, at any office of such physicians.
- 3) All patient billing related to such services are through, or expressly on behalf of, the physicians' practice.
- 4) The equipment shall not be used for inpatient care, nor by, through or on behalf of a health-care facility.

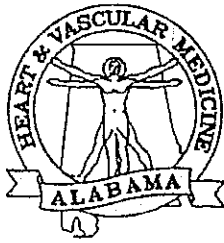
Alabama Heart and Vascular Medicine will, through the performance of the procedures previously reviewed, meet the above criteria respectively as follows:

- 1) Procedures will be performed only by physician's owners or physician employee of Alabama Heart and Vascular Medicine.
- 2) All procedures will be performed in the office of Alabama Heart and Vascular Medicine currently located at 100 Rice Mine Road Loop, Suite 104, Tuscaloosa, Alabama 35406. All equipment necessary for the performance of the above procedures will be used only in the office of Alabama Heart and Vascular Medicine.
- 3) All patient billing for the procedures performed will be done on behalf of Alabama Heart and Vascular Medicine.
- 4) At no time will the equipment used for the performance of our office-based procedures be used for inpatient care, nor by, through or on behalf of any other healthcare facility.

Based on the information given above, the proposed procedures in this matter should meet the criteria adopted by the Alabama Supreme Court for application of the Physician Office Exemption. Although the Physician Office Exemption serves as a bar to CON review, for your notice and information, we can also affirm that this venture will not exceed the CON expenditure threshold nor will it constitute a "new institutional health service" under Alabama Code 22-21-263 and the Rules because:

- a) No new health care facility or health maintenance organization will be constructed, developed, or acquired;
- b) No major medical equipment will be acquired by or on behalf of a health care facility that exceeds the statutory purchase price or operating expense thresholds;
- c) No new health care facility beds or stations will be added;
- d) No new health service that is currently offered by AHVM will be provided with the implementation of the procedures described in this document; and
- e) No other event reviewable under the CON law or Rules will occur as a result of our implementation of the procedures described in this document.

With the support of this document we request that the Alabama State Health Planning and Development Agency grant a determination of non-reviewability to Bama Heart Doc, P.C. dba Alabama Heart and Vascular Medicine for the proposed procedures as described above.



ALABAMA HEART & VASCULAR MEDICINE

No other healthcare facilities or groups have any financial interests in this reviewability determination request.

An electronic payment for the filing fee in the amount of \$1000.00 will be made today via the SHPDA online portal. Please see the attached financial breakdown.

Please do not hesitate to contact us directly 205-561-5243 if you require any further information or have any questions.

Affirmation of Requesting Party:

The undersigned, being first duly sworn, hereby make oath or affirm that he is the Owner, has knowledge of the facts in this request, and to the best of his information, knowledge and belief, such facts are true and correct.

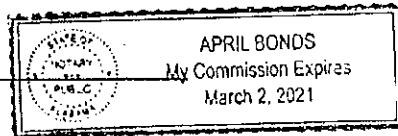
Affiant _____

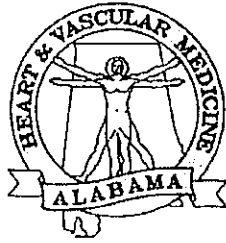
SUBSCRIBED AND SWORN to before me this _____

day of _____

Notary Public

My commission expires: _____

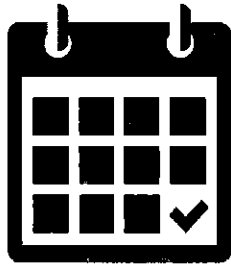




ALABAMA HEART & VASCULAR MEDICINE

Financial Breakdown

- 1) Equipment: Total = \$725,000.00
 - a. Medical equipment including c-arm, patient monitoring equipment, defibrillator, and IVUS for arterial and venous procedures = \$725,000
 - b. All other necessary equipment is already owned
- 2) Estimated annual operating costs: Total = \$1,014,637.88
 - a. Building Lease - \$67,279.36
 - b. Equipment Lease - \$153,038.52
 - c. Supplies - \$600,000
 - d. Wages - \$221,320.00
- 3) Capital costs: Total = \$67,279.36
 - a. Building Lease - \$67,279.36



**TENTATIVE AGENDA
CERTIFICATE OF NEED
REVIEW BOARD**

May 16, 2018

10:00 a.m.

**STATE CAPITOL AUDITORIUM
UNION STREET ENTRANCE
MONTGOMERY, ALABAMA**

PRESIDING:

**DR. SWAID N. SWAID
CHAIRMAN**

TENTATIVE AGENDA

- | | | |
|------|-----------------------------|-----------------|
| I. | CALL TO ORDER | CHAIRMAN |
| II. | ADOPTION OF AGENDA | CHAIRMAN |
| III. | MINUTES OF April 18, 2018 | CHAIRMAN |
| IV. | CHAIR'S REPORT | CHAIRMAN |
| V. | SHPDA ADMINISTRATIVE REPORT | ALVA M. LAMBERT |
| VI. | CERTIFICATE OF NEED PROGRAM | ALVA M. LAMBERT |

A. AL 2018-013, Thrive at Gadsden, LLC, Rainbow City, AL: Proposes to Construct a thirty-five (35) bed specialty care assisted living facility as part of a fifty-seven (57) bed community. This is pursuant to a Plan Adjustment to the *Alabama State Health Plan* approved by Governor Ivey. **Opposition: None**

B. This project was Tabled at the February 21, 2018 Certificate of Need Review Board meeting until the May 16, 2018 meeting

AL2017-030, Doctors Surgery Center of East Alabama, LLC, Auburn, AL:
Proposes to establish an Ambulatory Surgery Center consisting of four (4) operating rooms and two (2) procedure rooms. **Opposition: East Alabama Medical Center**

For Informational Purposes Only:

Reviewability Determinations:

Rural, Vaughan Regional Medical Center, requests to establish a hospital-provider based Wound Care Center in Dallas County. **Status: Non-Reviewable**

RV2018-005, Southern Alabama Surgery Center d/b/a Surgery Center South, requests to add four (4) additional fully-constructed operating rooms.
Status: Non-Reviewable
Opposition: Southeast Alabama Medical Center

RV2018-013, Bama Heart Doc, P.C. d/b/a Alabama Heart and Vascular Medicine, requests to provide low-risk cardiac procedures, such as left and right diagnostic catheterizations, low risk ICD and pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, thrombectomy of dialysis grafts, and transesophageal echocardiogram in a physician's office.
Status: Non-Reviewable
Opposition: DCH Health System

Pending Reviewability Determinations:

RV2016-030, Vascular Associates of South Alabama, LLC, requests to provide vascular surgery and related medical services located at 1551 Old Shell Road Mobile, AL, through a contract with vascular surgeons. **Status: Pending**
Opposition: Mobile Infirmary and AVA Mobile Holdings, LLC

RV2018-015, ARCH Therapy Services, LLC, an Alabama Corporation, requests to provide Comprehensive Outpatient Rehabilitation Facility (CORF) services, physical, occupational, speech therapy, social services and physician services, to the residents of Somerby at Jones Farm, d/b/a Brookdale Jones Farm, an Assisted Living Retirement Community, in Huntsville, Alabama.
Status: Pending

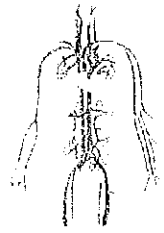
RV2018-016, Forum Green, Inc. d/b/a Senior Rehab & Recovery at Limestone Health Facility, requests to provide outpatient physical therapy services in a building located on property contiguous to the existing skilled nursing facility. **Status: Pending**

RV2018-017, LHCG XXII, LLC d/b/a Alabama Hospice Care of Tuscaloosa, requests to relocate the administrative offices of the hospice agency to another site also within Tuscaloosa County. **Status: Pending**

VII.	OLD BUSINESS	CHAIRMAN
VIII.	NEW BUSINESS	CHAIRMAN
IX.	ADJOURNMENT	CHAIRMAN

RV 2018-006

ALABAMA VASCULAR SOLUTIONS
632 2ND Street NE, Alabaster, AL 35007
WWW.ALABAMAVASCULARSOLUTIONS.COM



STEVE M. TAYLOR, M.D.
VASCULAR AND ENDOVASCULAR SURGERY

JAN 05 2017

STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY

September 25, 2017

Hon. Alva M. Lambert
Executive Director
State Health Planning and Development Agency
100 North Union Street
RSA Union Building, Suite 870
Montgomery, Alabama 36130-3025

Re: Non-Reviewability Determination Request for Alabama Vascular Solutions.

Dear Mr. Lambert:

On behalf of Alabama Vascular Solutions(AVS), I am writing to submit a reviewability determination request in accordance with the Alabama State Health Planning and Development Agency's Certificate of Need (CON) program rules and regulations. We are planning to add office-based, minimally invasive catheterization suite to our practice. This document will give an overview of the scope of procedures involved. We will also show how the criteria of the Physician Office Exemption, and thus non-reviewability, will be met by our office-based performance of those procedures.

Alabama Vascular Solutions is an Alabama LLC, founded in 2015, and is 100% owned by Dr Steve Taylor M.D. There are no investors and no hospital involvement with our practice. Dr. Taylor attended Undergrad school at the University of Alabama Birmingham from 1990-1992. He attended Medical school at the University of Alabama from 1992-1996. He did his General surgery residency from 1996 to 2001 at University of Alabama Birmingham and Vascular surgery fellowship at University of Alabama Birmingham from 2001 to 2004. He is Board Certified in General and Vascular Surgery. He is a Registered Physician in Vascular Interpretation (RPVI) and is one of few physicians in the Birmingham area that is PEVAR (Percutaneous Endovascular Aneurysm Repair) certified. Hyperbaric Chamber Certified for wound care.

Dr. Taylor has been published numerous times in various Vascular and Medical Journals. Prior to beginning his own practice in 2012, Dr. Taylor was an Associate Professor at UAB Hospital in the Dept of Vascular Surgery, training Surgical Residents, Vascular Fellows, as well as working with the Physican Assistants residents through the Surgical PA Program at UAB.

Dr. Taylor has over 14 years of experience in the treatment of arterial and venous disorders.

Our main office is located at 1004 1st street north suite 150 Alabaster Al, 35007. AVS wishes to construct a catheterization laboratory within this medical office to perform low risk Vascular procedures, such as left and right diagnostic peripheral catheterizations, upper and lower extremity revascularizations, upper and lower arterial and venous angiograms,

AVS will not be performing any acute emergency cardiac interventions nor any coronary angioplasty in this Vascular catheterization laboratory.

We wish to offer patients the ease and convenience of an outpatient lab for the low risk procedures. This lab will be fully staffed by licensed employees for low risk outpatient procedures and it will not be used for inpatient care.

The total cost of the construction renovation related to this project is \$42,576. AVS is purchasing medical equipment including a GE9800 mobile c-arm, patient monitoring equipment, defibrillator, ultra sound, etc at a total cost of \$226,465. We anticipate our first year annual operating costs to be a total of \$655,109 which consists of the following:

Equipment/Construction Loan	\$63,780
Supplies/Consumables	\$416,000
Additional Wages/Benefits	\$175,329
Additional Rent/Lease	-0-

The criteria as adopted by the Supreme Court for the Physician Office Exemption are as follows:

1. The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physicians' practice for the care of their patients.
2. The proposed services are to be provided, and related equipment used, at offices of such physicians.
3. All patient billings related to such services are through, or expressly on behalf of, the physicians' practice.
4. The equipment shall not be used for inpatient care, nor by, through, or on behalf of a health-care facility. Alabama Vascular Solutions will, through the performance of the procedures previously reviewed, meet the above criteria respectively as follows:
 1. Procedures will be performed only by physician owners or physician employees of AVS.
 2. All procedures will be performed in the office of Alabama Vascular Solutions.
 3. All equipment necessary for the performance of the procedures will be used only in the offices of AVS.
 4. All patient billing for the procedures performed will be done on behalf of and by employees of AVS.
 5. At no time will the equipment used for the performance of our office-based procedures be used for inpatient care, nor by, thru, or on behalf of any other health-care facility.

Based on the information given above, the proposed procedures in this matter should meet the criteria adopted by the Alabama Supreme Court for application of the Physician Office Exemption. Although the Physician Office Exemption serves as a bar to CON review, for your notice and information, we can also affirm that this venture will not exceed any of the certificate of need expenditure threshold nor will it constitute a "new institutional health service" under Alabama Code 22-21-263 and the Rules because:

- a) no new health care facility or health maintenance organization will be constructed, developed or acquired;
- b) no major medical equipment will be acquired by or on behalf of a health care facility that exceeds the statutory purchase price or operating expense thresholds;
- c) no new health care facility beds or stations will be added;
- d) no new health service that is currently offered by AVS will be provided with the implementation of the procedures described in this document; and

e.) no other even reviewable under the CON law or the Rules will occur as result of our implementation of the procedures described in this document.

With the support of this document we respectfully request that the Alabama State Health Planning and Development Agency grant a determination of non-reviewability to Alabama Vascular Solutions, LLC for the proposed procedures as described above. Please do not hesitate to contact us (office: 205-664-2420) if you require any further information or have any questions.

A check for the filing fee with respect to a request for a reviewability determination of \$1000, made payable to the Alabama State Health Planning and Development Agency, is enclosed. Thank you so much for your time and consideration in this matter.

Sincerely,

Steve Taylor, MD

Dr. Steve Taylor
Alabama Vascular Solutions

Affirmation of Requesting Party:

The undersigned, being first duly sworn, hereby makes oath or affirms that he is a physician owner of Alabama Vascular Solutions, and to the best of his information, knowledge and belief, such facts are true and correct.

Affiant Steve Taylor, MD

SUBSCRIBED AND SWORN to before me this 5 day of Jan, 2018

SEAL

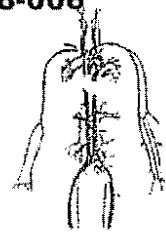
Gilda Steadman

Notary Public

My commission expires: 6/8/21

RV2018-006

ALABAMA VASCULAR SOLUTIONS
1004 1st street north suite 150 Alabaster Al, 35007
WWW.ALABAMAVASCULARSOLUTIONS.COM



STEVE M. TAYLOR, M.D.
VASCULAR AND ENDOVASCULAR SURGERY

September 25, 2017

RECEIVED

Dec 19 2017

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

Hon. Alva M. Lambert
Executive Director
State Health Planning and Development Agency
100 North Union Street
RSA Union Building, Suite 870
Montgomery, Alabama 36130-3025

Re: Non-Reviewability Determination Request for Alabama Vascular Solutions.

Dear Mr. Lambert:

On behalf of Alabama Vascular Solutions(AVS), I am writing to submit a reviewability determination request in accordance with the Alabama State Health Planning and Development Agency's Certificate of Need (CON) program rules and regulations. We are planning to add office-based, minimally invasive catheterization suite to our practice. This document will give an overview of the scope of procedures involved. We will also show how the criteria of the Physician Office Exemption, and thus non-reviewability, will be met by our office-based performance of those procedures.

Alabama Vascular Solutions is an Alabama LLC, founded in 2015, and is 100% owned by Dr Steve Taylor M.D. There are no investors and no hospital involvement with our practice. Dr. Taylor attended Undergrad school at the University of Alabama Birmingham from 1990-1992. He attended Medical school at the University of Alabama from 1992-1996. He did his General surgery residency from 1996 to 2001 at University of Alabama Birmingham and Vascular surgery fellowship at University of Alabama Birmingham from 2001 to 2004. He is Board Certified in General and Vascular Surgery. He is a Registered Physician in Vascular Interpretation (RPVI) and is one of few physicians in the Birmingham area that is PEVAR (Percutaneous Endovascular Aneurysm Repair) certified. Hyperbaric Chamber Certified for wound care.

Dr. Taylor has been published numerous times in various Vascular and Medical Journals. Prior to beginning his own practice in 2012, Dr. Taylor was an Associate Professor at UAB Hospital in the Dept of Vascular Surgery, training Surgical Residents, Vascular Fellows, as well as working with the Physician Assistants residents through the Surgical PA Program at UAB.

Dr. Taylor has over 14 years of experience in the treatment of arterial and venous disorders.

Our main office is located at 1004 1st street north suite 150 Alabaster Al, 35007. AVS wishes to construct a catheterization laboratory within this medical office to perform low risk Vascular procedures, such as left and right diagnostic peripheral catheterizations, upper and lower extremity revascularizations, upper and lower arterial and venous angiograms,

AVS will not be performing any acute emergency cardiac interventions nor any coronary angioplasty in this Vascular catheterization laboratory.

We wish to offer patients the ease and convenience of an outpatient lab for the low risk procedures. This lab will be fully staffed by licensed employees for low risk outpatient procedures and it will not be used for inpatient care.

The total cost of the construction renovation related to this project is \$42,576. AVS is purchasing medical equipment including a GE9800 mobile c-arm, patient monitoring equipment, defibrillator, ultra sound, etc at a total cost of \$226,465. We anticipate our first year annual operating costs to be a total of \$655,109 which consists of the following:

Equipment/Construction Loan	\$63,780
Supplies/Consumables	\$416,000
Additional Wages/Benefits	\$175,329
Additional Rent/Lease	-0-

The criteria as adopted by the Supreme Court for the Physician Office Exemption are as follows:

1. The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physicians' practice for the care of their patients.
2. The proposed services are to be provided, and related equipment used, at offices of such physicians.
3. All patient billings related to such services are through, or expressly on behalf of, the physicians' practice.
4. The equipment shall not be used for inpatient care, nor by, through, or on behalf of a health-care facility. Alabama Vascular Solutions will, through the performance of the procedures previously reviewed, meet the above criteria respectively as follows:
 1. Procedures will be performed only by physician owners or physician employees of AVS.
 2. All procedures will be performed in the office of Alabama Vascular Solutions.
 3. All equipment necessary for the performance of the procedures will be used only in the offices of AVS.
 4. All patient billing for the procedures performed will be done on behalf of and by employees of AVS.
 5. At no time will the equipment used for the performance of our office-based procedures be used for inpatient care, nor by, thru, or on behalf of any other health-care facility.

Based on the information given above, the proposed procedures in this matter should meet the criteria adopted by the Alabama Supreme Court for application of the Physician Office Exemption. Although the Physician Office Exemption serves as a bar to CON review, for your notice and information, we can also affirm that this venture will not exceed any of the certificate of need expenditure threshold nor will it constitute a "new institutional health service" under Alabama Code 22-21-263 and the Rules because:

- a) no new health care facility or health maintenance organization will be constructed, developed or acquired;
- b) no major medical equipment will be acquired by or on behalf of a health care facility that exceeds the statutory purchase price or operating expense thresholds;
- c) no new health care facility beds or stations will be added;
- d) no new health service that is currently offered by AVS will be provided with the implementation of the procedures described in this document; and

Page Three
State Health Planning and Development Agency
September 25, 2017

- e) no other event reviewable under the CON law or the Rules will occur as result of our implementation of the procedures described in this document.

With the support of this document we respectfully request that the Alabama State Health Planning and Development Agency grant a determination of non-reviewability to Birmingham Heart Clinic, P.C. for the proposed procedures as described above. Please do not hesitate to contact us (office: 205-664-2420) if you require any further information or have any questions.

A check for the filing fee with respect to a request for a reviewability determination of \$1300, made payable to the Alabama State Health Planning and Development Agency, is enclosed. Thank you so much for your time and consideration in this matter.

Sincerely,

S. Taylor, MD
Dr. Steve Taylor

Alabama Vascular Solutions

Affirmation of Requesting Party:

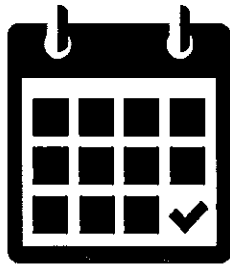
The undersigned, being first duly sworn, hereby makes oath or affirms that he is a physician owner of Alabama Vascular Solutions, and to the best of his information, knowledge and belief, such facts are true and correct.

Affiant S. Taylor, MD

(SEAL)

SUBSCRIBED AND SWORN to before me this 26 day of September 2017.

Jilda Stephenson
Notary Public
My commission expires: 6/8/21



**TENTATIVE AGENDA
CERTIFICATE OF NEED
REVIEW BOARD**

**March 21, 2018
10:00 a.m.
CAPITOL AUDITORIUM,
UNION STREET ENTRANCE
MONTGOMERY, ALABAMA**

PRESIDING:

**DR. SWAID N. SWAID
CHAIRMAN**

TENTATIVE AGENDA

- | | | |
|------|------------------------------|-----------------|
| I. | CALL TO ORDER | CHAIRMAN |
| II. | ADOPTION OF AGENDA | CHAIRMAN |
| III. | MINUTES OF February 21, 2018 | CHAIRMAN |
| IV. | CHAIR'S REPORT | CHAIRMAN |
| V. | SHPDA ADMINISTRATIVE REPORT | ALVA M. LAMBERT |
| VI. | CERTIFICATE OF NEED PROGRAM | ALVA M. LAMBERT |

This Project was postponed from the February 21, 2018 CONRB meeting for lack of a voting quorum.

- A. AL 2018-002, Gulf Health Hospitals, Inc. d/b/a North Baldwin Infirmary, Bay Minette, AL:** Proposes to relocate eight (8) psychiatric beds from Mobile Infirmary Medical Center to the Senior Behavioral Health inpatient geropsychiatric unit at North Baldwin Infirmary for a total of twenty-three (23) psychiatric beds.
Opposition: None
- B. AL2018-004, The East Alabama Health Care Authority d/b/a East Alabama Medical Center, Auburn, AL:** Proposes to establish a Freestanding Emergency Department ("FED") to be located in the Auburn Research Park adjacent to Auburn University. **Opposition: None**
- C. AL2018-006, Anniston Health and Rehab Services, LLC, Anniston, AL:** Proposes to relocate and construct a replacement skilled nursing facility, which will be a one-story building consisting of approximately 54,000 square feet.
Opposition: None

D. AL2018-007, Gulf Health Hospitals, Inc. d/b/a Thomas Hospital, Fairhope, AL:

Proposes to purchase and relocate twenty-five (25) inpatient rehabilitation beds that currently exist in the Alabama State Health Plan to expand its current twelve bed Inpatient Rehabilitation Facility. The twenty-five (25) beds will be purchased from Kindred Health Care. **Opposition: None**

E. Contested Case

AL2017-031, Physicians Choice Dialysis of Montgomery, LLC d/b/a

Montgomery Community Dialysis, Montgomery, AL: Proposes to establish a new End Stage Renal Dialysis Treatment Center consisting of ten (10) in-center hemodialysis stations. Administrative Law Judge filed an order granting Monarch's Motion to Dismiss the application and recommends the CON Review Board dismiss application, AL2017-031. **Opposition: Renal Treatment Centers-Southeast, LP d/b/a Monarch Dialysis filed Intervention/Opposition and Request for a Contested Case Hearing.**

For Informational Purposes Only:

Reviewability Determinations:

RV2018-006, Alabama Vascular Solutions, requests to add an office-based, minimally invasive catheterization lab to perform low risk vascular procedures, such as left and right diagnostic peripheral catheterizations, upper and lower extremity revascularizations, upper and lower arterial and venous angiograms.

Status: Non-Reviewable

Pending Reviewability Determinations:

RV2016-030, Vascular Associates of South Alabama, LLC, requests to provide vascular surgery and related medical services located at 1551 Old Shell Road Mobile, AL, through a contract with vascular surgeons. **Status: Pending**
Opposition: Mobile Infirmary and AVA Mobile Holdings, LLC

RV2018-005, Southern Alabama Surgery Center d/b/a Surgery Center South, requests to add four (4) additional fully-constructed operating rooms.
Status: Pending

RV2018-007, Aldridge Physical Therapy, LLC, requests to establish a single specialty rehab facility providing physical therapy in Montgomery County.
Status: Pending

RV2018-008, Aldridge Physical Therapy, LLC, requests to establish a single specialty rehab facility providing physical therapy in Lee County.
Status: Pending

RV2018-009, Aldridge Physical Therapy, LLC, requests to establish a single specialty rehab facility providing physical therapy in Autauga County.
Status: Pending

RV2018-010, Aldridge Physical Therapy, LLC, requests to establish a single specialty rehab facility providing physical therapy in Butler County.
Status: Pending

RV2018-011, Aldridge Physical Therapy, LLC, requests to establish a single specialty rehab facility providing physical therapy in Elmore County.
Status: Pending

RV2018-012, Southeast Alabama HomeCare, LLC d/b/a Southeast Alabama HomeCare, requests to relocate the administrative office to 1435 Ross Clark Circle, Suite 2, Dothan Alabama. **Status: Pending**

RV2018-013, Bama Heart Doc, P.C. d/b/a Alabama Heart and Vascular Medicine, requests to provide low-risk cardiac procedures, such as left and right diagnostic catheterizations, low risk ICD and pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, thrombectomy of dialysis grafts, and transesophageal echocardiogram in a physician's office.
Status: Pending

RV2018-014, Saad Enterprises, Inc. d/b/a Saad Healthcare Services, requests to relocate the current Branch Office from 1813 N. McKenzie Street, Foley, Alabama to 6510 Spanish Fort Boulevard, Spanish Fort, Alabama. **Status: Pending**

Rural, Vaughan Regional Medical Center, requests to establish a hospital-provider based Wound Care Center in Dallas County.

VII.	OLD BUSINESS	CHAIRMAN
VIII.	NEW BUSINESS	CHAIRMAN
IX.	ADJOURNMENT	CHAIRMAN

Exhibit A-7

LAW OFFICES
MELTON, ESPY & WILLIAMS, P.C.
255 DEXTER AVENUE
MONTGOMERY, AL 36104

JOSEPH C. ESPY, III
JAMES E. WILLIAMS
J. FLYNN MOZINGO
C. MARK BAIN
BENJAMIN J. ESPY*
WILLIAM M. ESPY
* ALSO ADMITTED IN MISSISSIPPI

OAKLEY W. MELTON, JR.
(1927-2011)

January 28, 2021

Via Electronic Filing
(shpda.online@shpda.alabama.gov)

MAILING ADDRESS:
P.O. DRAWER 5130
MONTGOMERY, AL 36103-5130
TELEPHONE (334) 283-0621
FAX (334) 259-9515

Emily T. Marsal, Executive Director
State Health Planning & Development Agency
100 North Union St., Suite 870
Montgomery AL 36104

Exhibit

A-7

RE: RV2021-003, The Heart Center Cardiology

Dear Ms. Marsal,

On behalf of East Alabama Medical Center (EAMC), the following response is provided in rebuttal to the letter to SHPDA from Michael K. Wright, dated January 14, 2021; and the letter to SHPDA from Dr. John Mitchell, also dated January 14, 2021, both submitted in RV2021-003 involving the request for a letter of non-review ("LNR") by The Heart Center Cardiology and Dr. Mitchell (hereafter referred to as The Heart Center's request).

The letters from Dr. Mitchell and Mr. Wright do not clarify the muddled and conflicting representations between this LNR request and the LNR request by Leg Health in RV2020-021. To the contrary, they further muddy the water and remove any doubt that The Heart Center's request cannot be granted, and should be submitted for CON review. Mr. Wright may argue that SHPDA does not have the authority to require CON review, but his client initiated this process by requesting that SHPDA issue an LNR. The power to issue an LNR includes the power to declare that CON review is necessary.

The CON process and SHPDA were created by the Alabama Legislature "to assure that only those health care services and facilities found to be in the public interest shall be offered or developed in the state." ALA. CODE § 22-21-261 (1975). Patient safety is a primary concern for determining whether the public interest is served. The Heart Center proposes to offer numerous services, traditionally performed in a hospital or ambulatory surgery center, in the private physician's office of Dr. Mitchell.¹ Dr. Mitchell contends the procedures are "low risk, minimally invasive and

¹ Whether Dr. Mitchell's medical practice is actually limited to The Heart Center is also unclear. The Heart Center has its own website, <https://www.theheartcentercardiology.com/>, but Dr. Mitchell also operates a separate clinic, known as "the Chest Pain Walk-In Clinic" at the same address. The Chest Pain Walk-In Clinic likewise has its own website, <https://www.chestpainwalkinclinic.com/>, which contains a picture showing a separate, marked entrance for the clinic. The Chest Pain Walk-In Clinic describes itself as a means of bypassing the wait at the EAMC emergency room for persons experiencing a cardiac event. See <https://www.chestpainwalkinclinic.com/> ("If you are experiencing a cardiac event, transport will be arranged for immediate transport to EAMC, bypassing the long wait in the emergency department."). The Heart Center's LNR request does not mention the Chest Pain Walk-In Clinic, but since they are

general anesthesia is not required, nor will it be used in the office setting.” (Correspondence from The Heart Center, Jan. 14, 2021, at p. 3). EAMC rejects Dr. Mitchell’s statement as an oversimplification of complicated medical procedures, and as an opinion statement that is unsupported by statistical data or studies.

Dr. Mitchell does not define “low risk” or “minimally invasive,” but the procedures he plans to perform are definitely invasive and, undisputably, have a variety of risks including bruising; bleeding; risk of stroke; damage to or puncturing the artery, nerves, and veins requiring surgery or transfusion; blood clotting; swelling; pneumothorax; and death. In addition, people age 65 and older (i.e., senior citizens) are the demographic group that suffers most from coronary heart disease, and are most in need of the procedures Dr. Mitchell plans to perform. This same demographic group also has the most co-morbidities. In representing that the procedures are low risk, Dr. Mitchell may be referring to the risk of death or serious bodily injury, but the seriousness of the risk is correlated to the environment in which the procedures are performed and the risk factors for each patient being treated. Consequently, Dr. Mitchell plans to perform complex, invasive vascular and coronary procedures on senior citizens with co-morbidities in his office, which is more than four miles away from EAMC, the closest medical facility.

Unlike a private physician’s office, hospitals are all regulated, licensed and accredited by various authorities, including the Alabama Department of Public Health, The Joint Commission, and others, and are subject to inspection and various reporting requirements. The licensing and/or accreditation requirements govern the types of life-saving and emergency equipment which must be available during a cardiovascular procedure; the medications that may be used and who may administer them; and the medical practitioners who must be present or accessible. However, no requirements are applicable to The Heart Center because, as the office of a private physician, it is not licensed or accredited.²

An invasive cardiovascular procedure performed in a hospital is less risky because the equipment, medications, and professionals needed to address complications or technical failure are present or readily available. The same is not true in a private physician’s office, and the risk of serious harm is therefor greater. In fact, the medical data supporting the risk assessment for invasive cardiovascular procedures was gathered in a health care facility setting. EAMC is unaware of any studies that have examined the proficiency, safety and risks of performing invasive cardiovascular procedures in the physician’s office setting alone. Therefore, EAMC takes issue with Dr. Mitchell’s representations that the invasive cardiovascular procedures he proposes to perform are “low risk and minimally invasive.”

located at the same address and Dr. Mitchell operates both, then the project at issue here could be used for the Chest Pain Walk-In Clinic, and would not qualify under the physician’s office exemption.

² With no licensing, accreditation or oversight, The Heart Center may apply its own subjective patient selection criteria that fails to ensure that only true “low risk” patients are treated in-office, and that certain proposed procedures are never or rarely performed on patients who have complex and/or severe cardiac disease.

EAMC also takes issue with Mr. Wright's representations regarding the use of general anesthesia at The Heart Center. Mr. Wright states: "Clearly, Dr. Mitchell will not be performing any of the proposed services utilizing 'general anesthesia' . . ." (Correspondence from Michael K. Wright, Jan. 14, 2021, at p. 4). Dr. Mitchell states however: "Any anesthesia used . . . will not exceed the level of moderate or **deep sedation** . . ." (Correspondence from The Heart Center, Jan. 14, 2021, at p. 3). "Deep sedation is nearly the same as general anesthesia."³ Dr. Mitchell also admits that he will be using midazolam or propofol. "Propofol is used as an 'induction agent' - the drug that causes loss of consciousness - for general anesthesia in major surgery."⁴ Historically, propofol was used almost exclusively by anesthesiologists,⁵ but its growing use by other health care providers, including its use in physician offices, led the State of Pennsylvania to issue the following warning:

[P]ractitioners may develop a false sense of security, allowing the perceived safety profile of propofol to influence their belief that the drug poses minimal risk. In untrained hands, propofol can be deadly. Administration to a non-ventilator-assisted patient by a practitioner who is not trained to administer drugs that cause deep sedation and general anesthesia is not safe, even if the drug is given under the supervision of a physician performing the procedure.⁶

Midazolam is a benzodiazepine that is used to suppress the central nervous system. Due to its potential abuse, the FDA has also issued a warning that midazolam is associated with respiratory depression and respiratory arrest, especially when used for sedation in noncritical care settings.⁷

The Heart Center has not identified and has not disclosed the identity or qualifications for any health care professionals who will participate in the administration of anesthesia or otherwise contribute to the procedures Dr. Mitchell plans to perform. The Heart Center's failure to disclose this information is all-the-more troubling because it underscores the potential risks to patient safety inherent in performing complex cardiovascular procedures in a physician's office.

³ *Types of Anesthesia*, UCLA Anesthesiology & Perioperative Medicine - UCLA Health, Los Angeles, CA, [https://www.uclahealth.org/apes/types-of-anesthesia#:~:text=There%20are%20four%20main%20categories,%22\)%2C%20and%20local%20anesthesia](https://www.uclahealth.org/apes/types-of-anesthesia#:~:text=There%20are%20four%20main%20categories,%22)%2C%20and%20local%20anesthesia), (last visited Jan. 26, 2021).

⁴ Peter Wehrwein, *Propofol: the drug that killed Michael Jackson*, Harvard Health Publishing, Harvard Medical School (Nov. 7, 2011, 5:02 PM) <https://www.health.harvard.edu/blog/propofol-the-drug-that-killed-michael-jackson-201111073772#:~:text=Prosecutors%20built%20a%20strong%20case.gave%20himself%20the%20lethal%20dose>, (Last visited Jan. 26, 2021).

⁵ *Id.*

⁶ *Who Administers Propofol in Your Organization?* Patient Safety Advisory, Pennsylvania Patient Safety Reporting System, http://patientsafety.pa.gov/ADVISORIES/Pages/200603_01b.aspx (last visiting Jan. 26, 2021).

⁷ *Benzodiazepines Safety Alert September 2020*, Midazolam: Drug Information - UpToDate, https://www.uptodate.com/contents/midazolam-drug-information?topicRef=15664&source=see_link (last visiting Jan. 26, 2021).

The Heart Center has also not identified the equipment it will purchase. To the extent Leg Health identified the equipment it planned to purchase, Dr. Mitchell has disavowed Leg Health's request, which he claims has no relevance whatsoever to his request. In fact, the letters from Dr. Mitchell and Mr. Wright share the same theme that Dr. Mitchell's request is "separate and distinct" and "stands-alone" from the request by Leg Health. Furthermore, both letters are devoted to clarifying or explaining away, or both, contradictions and admissions between Leg Health's request and The Heart Center's request, which should convince SHPDA that The Heart Center's request is not appropriate for, and does not satisfy, the purpose of giving an LNR.

Despite Dr. Mitchell's and Mr. Wright's argument to the contrary, it is obvious that Leg Health's request and The Heart Center's request involve the exact same project. In fact, The Heart Center has still failed to address the eight (8) ways in which Leg Health's request and The Heart Center's request are identical. As set forth in my letter on behalf of EAMC, dated December 16, 2020:

Specifically, Dr. Mitchell's request is identical to Leg Health's LNR request in the following ways:

1. Both requests concern The Heart Center located at 2375 Champions Boulevard;
2. Both requests represent that they involve Dr. John Mitchell's medical practice;
3. Both requests concern plans to perform the same procedures, i.e., peripheral angiography; left and right diagnostic heart catheterizations; coronary angiography; elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes; low risk ICD and pacemaker implantation; implantable loop recorder insertion; direct current cardioversion; infusa port placement; transesophageal echocardiography; pulmonary artery pressure recording devices; and low risk atrial, ventricular and nodal ablation procedures;
4. Both requests concern the development and operation of an "office-based lab;"
5. Both requests represent that the procedures to be performed are commonly performed in inpatient and outpatient settings;
6. Both requests state the procedures to be performed will not require general anesthesia;
6. [sic.] Both requests assert that the projects satisfy the POE test set forth in Ex parte Sacred Heart Health Systems, Inc., 155 So. 3d 980 (Ala. 2012); and

7. Both requests involve the exact same financial disclosures, consisting of the exact same amounts for major medical equipment; first year operating costs; first year operating lease; building lease; equipment lease; supplies; employee wages; land costs; and renovation/construction costs.

Indeed, the last factor is the most telling in that, despite Dr. Mitchell's request being separate and distinct and standing-alone, both requests have the exact same dollar figures for major medical equipment; first year operating costs; building lease; equipment lease; supplies; employee wages; land costs; and renovation/construction costs. The conclusion from this and the other factors is obvious - there is no difference whatsoever between the two requests except for the identity of the persons submitting them.

This distinction regarding identity of parties leads us back to where EAMC's opposition began, as stated in my letter dated December 16, 2020:

SHPDA has now received two competing LNR requests from separate entities, i.e., Leg Health Vascular Centers, Inc., and The Heart Center Cardiology, and both requests contain sworn statements proposing the exact same "office-based lab" to be located at the same address; the exact same medical procedures; and the exact same financial costs. However, key participants in the project identified in Leg Health's LNR request are omitted from The Heart Center Cardiology's request, despite the fact that Leg Health's request was filed on August 3, 2020, less than three months before The Heart Center Cardiology's request.

Accordingly, to again quote from SHPDA's letter, dated October 26, 2020, with revisions applicable to The Heart Center Cardiology:

Here, the Agency has received contradictory sworn statements regarding the operation of the project, which, among other things, raises doubt as to whether the new services and equipment are limited to Dr. Mitchell's office-based medical practice. ***The LNR process is not well suited to resolve the competing factual and legal assertions of [The Heart Center Cardiology,] Leg Health and EAMC. According, the Agency is unable to determine that this project qualifies for the POE.***

Furthermore, Leg Health's request for an LNR was denied before it was withdrawn, assuming it was withdrawn in that we never received notice of a withdrawal. Given SHPDA's finding that the LNR process is ill suited for competing factual and legal assertions, such withdrawal, if any, is irrelevant. Leg Health's request was made on behalf of Dr. Mitchell, The Heart Center Cardiology, and others; and Dr. Mitchell admits such in his letter dated January 14, 2021, on page 2. ("In August, 2020, I verbally agreed to allow Leg Health to assist in my practice's expansion of in-office based cardiac services."). ***Sworn*** factual and legal assertions, once made in a legal process, remain binding. 13 A.L.R. 925 ("It may be laid down as a general rule that a party will not be allowed in a subsequent judicial proceeding to take a position in conflict with a position taken by him in a former

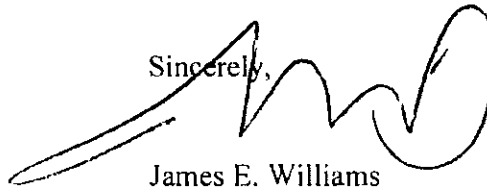
judicial proceeding, where the later position is to the prejudice of the adverse party, and the parties and the questions involved are the same.”)

In addition, the fact that The Heart Center’s LNR request contains the same or similar talisman language used by other cardiologists in their request for an LNR, does not change the conclusion that an LNR cannot be granted for The Heart Center. It does not appear from SHPDA’s records that any of the other LNR requests involved two separate parties seeking an LNR for the exact same project. Furthermore, each request stands on its own merit and there is no record that the other LNR requests were opposed. The Heart Center’s request, however, is strongly opposed by EAMC, the same as EAMC strongly opposed Leg Health’s request.

Therefore, EAMC respectfully requests that SHPDA decline to provide The Health Center Cardiology and Dr. John Mitchell with an LNR for the reasons stated herein, and for the reasons stated in EAMC’s submissions to SHPDA on December 16, 2020; October 20, 2020; and September 1, 2020, regarding RV2021-003 and RV2020-021.

If you have any questions, please do not hesitate to contact me. With kindest personal regards, I am

Sincerely,

A handwritten signature in black ink, appearing to read 'James E. Williams', with a large, stylized loop at the end.

James E. Williams

JW/JFM/i

cc: John Mitchell, M.D.
Medical Director/Owner
The Heart Center Cardiology
Michael K. Wright, Esq.

Exhibit A-8

February 5, 2021

VIA ELECTRONIC FILING:

shpda.online@shpda.alabama.gov

Ms. Emily T. Marsal, Executive Director
State Health Planning & Development Agency
100 North Union St., Suite 870
Montgomery, AL 36104

RE: RV2021-0003, The Heart Center Cardiology
Our File No.: 38685

Dear Ms. Marsal:

Please allow this letter to serve as a reply to Mr. Williams' response submitted on behalf of EAMC on January 28, 2021. Respectfully, EAMC's response is an effort to distract the Agency from the pertinent and dispositive questions before it in the non-reviewability determination process by confusing the issues and ignoring the objective criteria that are clearly set forth in *Ex parte Sacred Heart Health System, Inc.* for whether a proposal qualifies for the Physician's Office Exemption.

Tellingly, the hospital's January 28 letter contains no substantive reference or discussion regarding the objective test outlined by the Alabama Supreme Court in *Ex parte Sacred Heart Health System, Inc.* for whether the POE applies. *See* 155 So. 3d 980, 988.¹ This is more than a tacit admission by the hospital that the RV2021-003 proposal satisfies

¹ Indeed, the only substantive reference to *Ex parte Sacred Heart* by EAMC at any point was in a letter dated September 21, 2020 regarding the separate, and now withdrawn, request of RV2020-021. There, the hospital attempted to distinguish *Ex parte Sacred Heart* by arguing: "the record reflects that the physicians are not actually practicing medicine as one group. Therefore, the physician's office exemption does not apply to Leg Health's project despite its representations." (EAMC RV2020-021 Letter, p. 4-5) The basis of the argument was that Dr. Mitchell was not practicing as a physician with Leg Health. This attempted distinction from *Ex parte Sacred Heart*, even if it were deemed meritorious, does not and cannot apply to the present proposal RV2021-003. As outlined exhaustively, Dr. Mitchell was previously a party to the RV2020-021 proposal, but that request has been withdrawn and the previous relationship between Dr. Mitchell and Leg Health has been terminated.

{B3735137}

Birmingham

Mobile

starneslaw.com

Exhibit

A-8

Nashville

the “objective standard” for application of the POE. *Id.* While the Agency certainly knows the POE test, it is provided here, again, for completeness:

- (1) The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physicians' practice for the care of their patients.
- (2) The proposed services are to be provided, and related equipment used, at any office of such physicians.
- (3) All patient billings related to such services are through, or expressly on behalf of, the physicians' practice.
- (4) The equipment shall not be used for inpatient care, nor by, through, or on behalf of a health-care facility.

Ex parte Sacred Heart Health System, Inc., 150 So. 2d 980, 988 (Ala. 2012). EAMC and Mr. Williams offer no basis whatsoever to demonstrate or suggest that Dr. Mitchell and The Heart Center do not satisfy this criteria. It is EAMC and Mr. Williams who are trying to “muddy the water,” to borrow his terminology, by making meaningless or otherwise baseless assertions.

As set forth in RV2021-003 and the January 14, 2021 letters from Dr. Mitchell and from undersigned counsel on his behalf, the proposal before the Agency fits squarely within the POE as set forth by the Alabama Supreme Court. It is in this context—i.e. where a proposal fits squarely within the law—that the Agency “do[es] not have the authority to require CON review for entities or matters that are not expressly subject to CON review under the law as set out by the Legislature.” *See generally Prime Lithotripter Operations, Inc. v. LithoMedTech of Alabama, LLC*, 855 So. 3d 1085, 1096 (Ala. Civ. App. 2001).²

The January 14, 2021 submissions also answer the two questions posed by the Agency in its December 18, 2020 letter to Dr. Mitchell (1) to clarify / state the differences between the RV2021-003 request on behalf of The Heart Center and the RV2020-021 request on behalf of Leg Health Vascular Centers; and (2) to clarify the current procedures and then the proposed new or additional procedures to be offered at The Heart Center

² The hospital misconstrues or misrepresents the statement in the January 14, 2021 letter relating to the circumstances under which the Agency lacks authority to require CON review. Clearly, SHPDA has the authority to defer a request for non-reviewability to the Certificate of Need process when appropriate. However, the Agency “does not have the authority to require CON review for ... matters that are not expressly subject to CON review under the law...” *See Prime Lithotripter Operations*, 855 So. 3d at 1096 (emphasis added) Here, RV2021-003 is due to be granted a LNR “under the law,” as the POE criteria are satisfied. *See Ex parte Sacred Heart*, 155 So. 2d 980 (Ala. 2012); Ala. Code § 22-21-260(6) & (8).

January 14, 2021

Page -3-

location. Of course, should the Agency have further questions in that or any other regard we are happy to provide any and all needed information.

Respectfully, the state of the record remains the same even after EAMC's January 28, 2021 response. As previously outlined on January 14, 2021, RV2021-003:

1. Was submitted properly and with the required information as outlined by the Agency in SHPDA Rule 410-1-7-.02;
2. Is clearly within the requirements of the Physician Office Exemption as outlined in *Ex parte Sacred Heart Health System, Inc.*, 155 So. 2d 980 (Ala. 2012);
3. Is separate and distinct from the RV2020-021 request from Leg Health Vascular Centers which has been formally withdrawn; and
4. Is substantially similar, if not essentially identical, to numerous other Reviewability Determination Requests that the Agency has deemed non-reviewable based on information we have obtained.

The record demonstrates a denial of Dr. Mitchell's request in RV2021-003 would be without reasonable basis in consideration of Alabama law and previous non-reviewability determinations of the Agency.

It is of no moment that EAMC objects here where other hospitals have not. Moreover, that EAMC stands alone in objecting where other hospitals have not serves to underscore how untenable the objections truly are when considered in light of the foregoing.

While the above points are dispositive of the reviewability determination for RV2021-003, I will briefly address a few of the hospital's peripheral arguments below. In so doing, the Agency should bear in mind that the hospital cannot refute that **RV2021-003** satisfies the POE test under Alabama law, and the proposal should therefore be deemed non-reviewable.

1. **The proposed services are appropriate for in-office care, and Dr. Mitchell is a board-certified cardiologist who is qualified to perform the services.**

EAMC essentially argues that the proposed procedures should not be performed in the office-setting because they carry risk, and they should be performed in the hospital, not the office, because the hospital is subject to "licensing and/or accreditation requirements" that promote patient safety. While the practice of medicine is not devoid of risk in any setting, there is a clear recognition that certain invasive procedures or services can be

appropriately performed in the office setting. As one example, the Alabama Board of Medical Examiners has devoted an entire Chapter to “Office-Based Surgery” that set forth guidance for the performance of office-based procedures. *See* Ala. Admin. R. Rule 540-X-10-.02.

Further to the point of patient safety, Dr. Mitchell is a board-certified cardiologist whom EAMC has certified as competent to perform these procedures on an outpatient basis. The hospital has indeed benefitted from his expertise in that regard over the years but now suggests that it has concerns as to whether he could perform those very procedures safely in the office-setting.³ It is within the purview of the physician, in the exercise of his or her education, training and experience and in conjunction with any and all applicable State and federal guidance/regulatory approvals,⁴ to make clinical judgments with respect to the types of patients that may need certain procedures and the risks and benefits associated therewith. Such judgments would include whether a patient’s risk stratification is such that he or she may need inpatient care. The hospital’s suggestion that Dr. Mitchell is now somehow unable to make those clinical determinations or judgments because he would like to offer his patients the benefit of receiving certain outpatient services in his office is an illogical attempt to unilaterally restrict his practice to its facility. The reality is that EAMC is unqualified under Alabama law to speak to the standard of care to be exercised by a board-certified cardiologist who has practiced interventional cardiology for decades.

While I am unaware of any specific requirement from SHPDA or under *Ex parte Sacred Heart* to provide this type information, RV2021-003 specifically addresses some of the safety “concerns” posed in the hospital’s objection:

- “Dr. Mitchell has an established care plan including the identification of involved personnel and equipment, to deal with any issues related to unexpected changes in a patient’s status. This includes oxygen and masks for ventilation, medications for arrhythmias and reversal of sedation,

³ The Agency should take note of what is perhaps EAMC’s greatest inconsistency in arguing against the office-based practice outlined in RV2021-003 on the basis of patient safety by considering that EAMC actually leased space in the same building located at 2375 Champions Blvd, Auburn, AL and operated an offsite catheterization lab during 2011. On information and in that very setting, certain cardiologists on staff with EAMC performed or were permitted to perform right and left heart catheterizations and other minimally invasive procedures. It is indeed a shallow/hollow argument to imply that the modern practice of cardiology, including patient selection and risk analysis, mandate that the procedures outlined in RV2021-003, which include a number of the very procedures performed at the same address by other EAMC staff cardiologists, must now be performed in a hospital setting.

⁴ Dr. Mitchell attested in his responses to the that any services provided will at all times function within the current regulatory approvals at the federal and State level as such services are presently or may subsequently become approved.

defibrillation and pacing as well as a pathway to transfer to a higher level of care as needed.”

- “Physicians have been able to perform nearly all electrical cardioversion procedures using moderate to deep sedation (a widely accepted practice,) if patient safety ever requires the use of general anesthesia, the procedure would be scheduled and performed in the hospital setting.”⁵
- “Dr. Mitchell will not perform any acute emergency cardiac interventions nor any coronary angioplasty in the private office setting. In addition, the private office will not be used for inpatient care. No other healthcare facilities have any financial interests in The Heart Center Cardiology.” (emphasis in original)

The plan of care would also take into consideration applicable State and federal guidance regarding the performance of office-based procedures and any other patient-specific circumstances that may arise.

The proposed services requested by Dr. Mitchell are appropriate for in-office care and, on information and as previously outlined, have been deemed non-reviewable by the Agency in other substantially similar (or identical) Reviewability Determination Requests over the past several years.⁶ Under the hospital’s logic and if the true concern or dispositive issue was that the proposed services are unsafe, the Agency could never deem a proposal including these proposed services as non-reviewable, and the Agency’s previous determinations of those substantially similar or identical requests would have been made in error. The hospital’s argument is irrational in this sense.

Based on Alabama law and the facts set forth in Dr. Mitchell’s request, a denial of RV2021-003 would be considered an arbitrary and capricious action, not in keeping with the intended role and function of the Agency.

2. The proposed services do not involve the provision of general anesthesia, and any anesthesia utilized will be in accordance with Alabama Rules.

The hospital’s response does not address the straightforward and applicable Alabama Administrative Rules and definitions for general anesthesia. Instead, it directs the Agency to unauthenticated secondary sources to manufacture various definitions of “anesthesia” and then improperly suggests that our representations regarding anesthesia

⁵ See further discussion regarding anesthesia, below.

⁶ See Wright January 14 Letter, Exhibit A. An essentially identical request, RV2021-002, was on the agenda for Agency’s January 2021 meeting. The “tentative agenda” documents “for information purposes only” that the “status” of RV2021-002 is “non-reviewable.”

are inaccurate. As previously stated, “Dr. Mitchell will not be performing any of the proposed services utilizing ‘general anesthesia’ **as defined** in Alabama Administrative Rule 540-X-10-.02(5).” (Wright January 14 Letter) (underline in original, bold added) The applicable definitions were quoted in the January 14, 2021 letter. To remove any even *potential* confusion, the references to “general anesthesia” in RV2021-003 were omitted through the January 14, 2021 letters. Yet, EAMC still attempts to mislead the Agency by implying RV2021-003 should be considered in light of some other anesthesia definition than that of the Alabama Administrative Rule. RV2021-003 generally outlines that Dr. Mitchell will comply with Rule 540-X-10.

It is also a matter of fact that the Alabama Administrative Code Rules for office-based anesthesia expressly extend to moderate and deep sedation. EAMC’s argument that the Agency should consider this to be the equivalent of “general anesthesia” under the governing Rule is a fiction designed, again, to mislead the Agency or improperly influence the decision.⁷ There is no dispute that the medications referenced in RV2021-003 are commonly used to accomplish moderate or deep sedation in office settings, and there is no dispute that these levels of sedation are recognized as appropriate in the office-based setting.⁸

Likely in recognition of the fact that these medications are accepted and commonly used to accomplish the appropriate level sedation in the office-based setting, the hospital attempts to challenge RV2021-003 on the basis that it does not outline the specific “identity or qualifications for any health care professionals who will participate in the administration of anesthesia or otherwise contribute to the procedures he performs.” There is no requirement that the proposal outline the specifics of “who will participate” in the administration of anesthesia, or otherwise, under SHPDA Rule 410-1-7-.02, the factual information required for disclosure that is identified on the SHPDA website, or in *Ex parte Sacred Heart*.⁹ Dr. Mitchell’s citation to applicable State requirements and guidance

⁷ See Wright January 14 Letter, FN 5.

⁸ See Ala. Admin. R. 540-X-10, “Office Based Surgery”; Ala. Admin. R. 540-X-10-.02(3) & (4), “Definitions – Levels of Anesthesia.”

⁹ “Any person may request for informational purposes only a determination as to the current reviewability of an anticipated project or determination of exemption for replacement equipment. Such request shall be submitted pursuant to Rule 410-1-3-.09 disclosing full factual information as may be more specifically identified on the SHPDA website, supplemented by any additional information or documentation which the Executive Director may deem necessary.”

Rule 410-1-7-.02(1)

* * *

“1. Name of company seeking the reviewability determination.

2. Address and contact information for the authorized company representative seeking the determination.

{B3735137}

regarding the use of anesthetic agents was not required under the application criteria and was only offered to demonstrate that he will comply with any and all applicable guidance for using such agents—which of course includes the requirements within Chapter 540-X-10 that address personnel. Indeed, Dr. Mitchell will of course comply with any and all applicable guidance regarding office-based procedures in conjunction with his education, training, and experience in treating patients and performing procedures for which he is qualified and that are approved.

3. RV2021-003 properly satisfies the disclosure requirements related to equipment and approximated costs.

In the January 28, 2021 letter, the hospital states “The Heart Center has also not identified the equipment it will purchase.” First, identifying what specific equipment will be purchased is not required under the Rules for these type proposals. (See FN. 9, above, quoting applicable Rules) The requirement is that the proposal outline “approximated costs” for the equipment.¹⁰ RV2021-003 specifically outlines estimated costs and categories of equipment:

Total Major Medical Equipment estimated cost for the office-based procedures = \$350,000.00

To include: Diagnostic X-Ray System, patient monitoring equipment, patient recovery equipment, defibrillator and IVUS for arterial and

-
3. Service area for the proposed service/equipment.
 4. Any new/additional services to be provided under the proposed project.
 5. Approximated costs of the proposed project for:
 - a. Equipment
 - b. First year annual operating costs
 - c. Capital costs, to include
 1. Leases
 2. Land/Building costs
 3. Construction costs
 6. Disclosure of financial interests in the entity requesting the reviewability determination held by any other healthcare facilities or groups.
 7. Attestation by an officer, partner or authorized agent of the company having knowledge of the facts disclosed....”

“Factual Information Required for Reviewability Determination Requests (SHPDA Rule 410-1-7-.02)”

* * *

Ex parte Sacred Heart test cited above.

¹⁰ See “Factual Information Required for Reviewability Determination Requests (SHPDA Rule 410-1-7-.02) (emphasis added)

venous procedures and ancillary equipment required for the listed procedures.

(RV2021-003, p. 3)

The hospital's January 28, 2021 letter also suggests that RV2021-003 should be denied because the proposal contains the same dollar figures related to approximated costs as RV2020-021. The hospital cites no authority for why this would, or could even, render RV2021-003 as falling outside the POE as outlined in Alabama law. The estimated costs and financial disclosures within RV2021-003 satisfy the disclosure requirements outlined by the Agency. (See FN. 9, above, outlining "factual information required for reviewability determination requests")

4. RV2021-003 is separate and distinct from the now withdrawn RV2020-021 request, and Dr. Mitchell has terminated any previous relationship with Leg Health.

EAMC's letter improperly and repeatedly continues to inject Leg Health into the consideration process for RV2021-003. In fact, the basis of the hospital's objection appears to truly center around the previous relationship between Dr. Mitchell and Leg Health, and it argues that the "confusion" created by the RV2020-021 request has not been resolved.¹¹ This is simply a false assertion. The record is clear that there is no relationship between Dr. Mitchell and Leg Health, and there are no contradictions within RV2021-003.

The previously raised questions by EAMC and the Agency were centered around the relationship of Dr. Mitchell / The Heart Center and Leg Health as it related to the "operation of the project" and whether the new services were limited to Dr. Mitchell's office-based practice as opposed to a new medical practice"—i.e. Leg Health. To illustrate, on December 18, 2020, the Agency referenced a letter sent in connection with the (now withdrawn) RV2020-021 request filed on behalf of Leg Health Vascular Centers that referenced statements "regarding the **operation of the project**, which, among other things, raised doubt as to whether the new services and equipment **were limited to Dr. Mitchell's office-based medical practice...**" (emphasis added)¹² The Agency's December 18, 2020 letter requested that Dr. Mitchell state with specificity the differences between RV2021-003 (Dr. Mitchell's request) and RV2020-021, a Reviewability Determination Request from Leg Health Vascular Centers, Inc.

¹¹ "[The] distinction regarding identity of parties leads us back to where EAMC's opposition began...." (EAMC January 28 Letter, p. 5)

¹² As previously stated, Dr. Mitchell was not represented by counsel in connection with RV2020-021 and the proposal has been withdrawn.

January 14, 2021

Page -9-

As described in the previous submissions, Dr. Mitchell and/or The Heart Center Cardiology no longer have any relationship with Leg Health Vascular Centers. Further, RV2020-021 has been formally withdrawn. There is nothing “contradictory” within the RV2021-003 request, and there are no “competing factual and legal assertions of [The Heart Center Cardiology,] Leg Health and EAMC” as the hospital continues to argue. In fact, Leg Health is completely irrelevant to the Agency’s determination of the reviewability issue posed by RV2021-003—especially after the clarifications submitted since the hospital’s objections.

The simple issue presented for the Agency is whether RV2021-003, a standalone request made solely on behalf of The Heart Center Cardiology/Dr. Mitchell, satisfies the POE criteria under Alabama law. Indeed, the hospital has argued in the January 28 letter that “each request stands on its own merit,” and there is presently no reason that RV2021-003 should not be evaluated as a standalone request on “its own merit.” The hospital has provided no valid reason why RV2021-003 fails to meet the Physician Office Exemption. In fact, EAMC does not, and cannot, demonstrate a single criteria that RV2021-003 does not satisfy.

The reality and, indeed, the driving force behind EAMC’s objection is purely financial. EAMC is seeking to restrict Dr. Mitchell’s private practice through a campaign of misleading and irrelevant argument; thereby attempting to lead this Agency into an unwarranted decision that would have no basis in law or fact.

We, again, respectfully request that the Agency deem RV2021-003 non-reviewable consistent with Alabama law and its past determinations of non-reviewability. Please do not hesitate to contact me if you have any further questions or need any further information regarding The Heart Center Cardiology’s request in RV2021-003.

Best regards,

STARNES DAVIS FLORIE LLP



Michael K. Wright

MKW/

cc: Dr. John W. Mitchell
Catherine G. Kirkland, Esq.
Allen C. King, Esq.
James E. Williams, Esq.

Exhibit A-9

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BENJAMIN J. ESPY*
WILLIAM M. ESPY
* ALSO ADMITTED IN MISSISSIPPI

OAKLEY W. MELTON, JR.
(1927-2011)

February 12, 2021

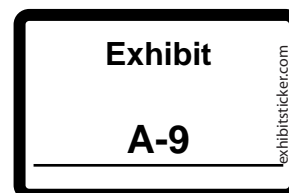
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Emily T. Marsal, Executive Director
State Health Planning & Development Agency
100 North Union St., Suite 870
Montgomery AL 36104

RE: RV2021-003, The Heart Center Cardiology

Dear Ms. Marsal:



On behalf of East Alabama Medical Center (EAMC), I provide you with this response to Mr. Michael Wright's correspondence to SHPDA, dated February 5, 2021, on behalf of The Heart Center Cardiology.

The Heart Center apparently does not understand that EAMC's opposition to its request for a letter of non-review specifically involves the application of the POE test established in Ex parte Sacred Heart, 155 So. 2d 980 (Ala. 2012). As Mr. Wright acknowledges in his correspondence, the POE test is as follows:

- (1) The proposed services are to be provided, and related equipment used, *exclusively by the physicians identified as owners or employees of the physicians' practice* for the care of their patients.
- (2) The proposed services are to be provided, and related equipment used, at any office of such physicians.
- (3) All patient billings related to such services are through, or expressly *on behalf of, the physicians' practice*.
- (4) *The equipment shall not be used for inpatient care, nor by, through, or on behalf of a health-care facility.*

(Emphasis added).

As emphasized above, three of the four elements for applying the POE focus on the "physician's practice." It is, and has always been, the position of EAMC that conflicting and contradictory representations have been made to SHPDA regarding the operation of a cath-lab at the office of Dr. Mitchell. On December 15, 2021, EAMC submitted its initial response to The Heart

Center's request for letter of non-review:

As you aware, The Heart Center Cardiology was the subject of a POE LNR submitted on August 3, 2020, by Leg Health Vascular Centers, Inc., which likewise proposed to establish and operate an "office based lab" at the same address and medical practice. Leg Health's LNR request was the subject of additional filings and information submissions by Leg Health and EAMC, on September 21, 2020; September 28, 2020; October 7, 2020; and concurrent submissions by Leg Health and EAMC on October 20, 2020. SHPDA subsequently refused to issue a LNR, and in so doing stated as follows:

Here, the Agency has received contradictory sworn statements regarding the operation of the project, which, among other things, raises doubt as to whether the new services and equipment are limited to Dr. Mitchell's office-based medical practice. *The LNR process is not well suited to resolve the competing factual and legal assertions of Leg Health and EAMC. According, the Agency is unable to determine that this project qualifies for the POE.*

Leg Health Vascular Centers, Inc., RV2020-021, October 26 2020 (emphasis added).

On October 29, 2020, **just three days after SHPDA refused to issue a LNR**, Dr. John Mitchell, by and through The Heart Center Cardiology, filed the immediate LNR request in which he makes factual and legal assertions that are, in most cases, identical to Leg Health's factual and legal assertions. Specifically, Dr. Mitchell's request is identical to Leg Health's LNR request in the following ways:

1. Both requests concern The Heart Center located at 2375 Champions Boulevard;
2. Both requests represent that they involve Dr. John Mitchell's medical practice;
3. Both requests concern plans to perform the same procedures, i.e., peripheral angiography; left and right diagnostic heart catheterizations; coronary angiography; elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes; low risk ICD and pacemaker implantation; implantable loop recorder insertion; direct current cardioversion; infusa port placement; transesophageal echocardiography; pulmonary artery pressure recording devices; and low risk atrial, ventricular and nodal ablation procedures;
4. Both requests concern the development and operation of an "office-based lab;"

5. Both requests represent that the procedures to be performed are commonly performed in inpatient and outpatient settings;
6. Both requests state the procedures to be performed will not require general anesthesia;
6. [sic.] Both requests assert that the projects satisfy the POE test set forth in *Ex parte Sacred Heart Health Systems, Inc.*, 155 So. 3d 980 (Ala. 2012); and
7. Both requests involve the exact same financial disclosures, consisting of the exact same amounts for major medical equipment; first year operating costs; first year operating lease; building lease; equipment lease; supplies; employee wages; land costs; and renovation/construction costs.

In fact, the LNR requests submitted by Leg Health and by The Heart Center Cardiology are substantively identical in each and every way, except The Heart Center Cardiology's request omits any reference to Leg Health Vascular Centers, Inc.; Dr. Robert Yoe; and Dr. Jacob Townsend.

(Correspondence from Jim Williams to SHPDA, dated December 15, 2020, at pp. 1-2).

Accordingly, The Heart Center's statement - - "EAMC and Mr. Williams offer no basis whatsoever to demonstrate or suggest that Dr. Mitchell and The Heart Center do not satisfy this criteria" - - is just wrong!

In fact, as twice pointed out by EAMC, The Heart Center has never explained why or how its project, and the project proposed by Leg Health which involved Doctors Mitchell, Yoe, Townsend, and Leg Health, can have the exact same financial disclosures, consisting of the exact same amounts for major medical equipment; first year operating costs; first year operating lease; building lease; equipment lease; supplies; employee wages; land costs; and renovation/construction costs.

Therefore, as SHPDA itself recognized: "The LNR process is not well suited to resolve the competing factual and legal assertions of Leg Health and EAMC." These factual and legal assertions go to the very heart of whether The Heart Center satisfies the POE. Therefore, The Heart Center's request for letter of non-review must be denied.

The Heart Center is also mistaken in stating that SHPDA does not have the authority to require CON review. SHPDA certainly has the power to deny a request for letter of non-review, and its must deny the request if there is a factual and legal dispute as to whether the elements for the POE are satisfied, as is this case with The Heart Center. Indeed, SHPDA cannot conclude that a project is non-reviewable if there are factual and legal disputes involving the project raised by an "affected person" entitled to notice and the right to comment as provided by ALA. ADMIN. CODE r. 410-1-7-.02(3).

It is short-sighted for The Heart Center to argue that patient safety has no place in a discussion as to whether a request for letter of non-review, that is opposed by a health care facility, should be granted. The CON laws exist to "assure that only those health care services and facilities found to be in the public interest shall be offered or developed in the state." ALA. CODE § 22-21-261 (1975). The Heart Center has voluntarily come before SHPDA, the agency that exists to enforce the CON laws, and requested a formal opinion from it. In responding to The Heart Center's request, SHPDA may certainly consider that statutory basis for its existence.

In fact, as with its request for letter of non-review, The Heart Center's recent comments omit substantive factual details and context, and its representations are misleading without them. In footnote 3 of Mr. Wright's letter, The Heart Center states:

The Agency should take note of what is perhaps EAMC's greatest inconsistency in arguing against the office-based practice outlined in RV2021-003 on the basis of patient safety by considering that EAMC actually leased space in the same building located at 2375 Champions Blvd, Auburn, AL and operated an offsite catheterization lab during 2011. On information and in that very setting, certain cardiologists on staff with EAMC performed or were permitted to perform right and left heart catheterizations and other minimally invasive procedures. It is indeed a shallow/hollow argument to imply that the modern practice of cardiology, including patient selection and risk analysis, mandate that the procedures outlined in RV2021-003, which include a number of the very procedures performed at the same address by other EAMC staff cardiologists, must now be performed in a hospital setting.

As provided in RV2011-027, SHPDA issued a letter of non-review for EAMC to relocate back to EAMC its **CON-authorized** cardiac cath-lab at The Institute of Advanced Cardiovascular Care, 2375 Champions Boulevard in Auburn, Alabama. (Exhibit A). The cath-lab had originally been at EAMC but was moved to The Institute of Advanced Cardiovascular Care as a result of a mediation agreement between EAMC and The Institute. (Exhibit B). EAMC returned the cath-lab to its former location at the hospital after receiving the letter of non-review from SHPDA in RV2011-027.

However, as a CON-authorized facility, the cath-lab operated by EAMC at The Institute was subject to all health planning laws and health care regulations applicable to health care facilities, including, but not limited to, § 410-2-3.03 of the State Health Plan concerning fixed-based cardiac catheterization laboratories. Among these regulations, EAMC had to comply with § 410-2-3.03(1)(b)2.d., which requires that at least two physicians, licensed in Alabama, with training and experience in cardiac catheterization shall provide coverage at the facility; and § 410-2-3.03(1)(b)5.a. - d., which require the existence of written transfer agreements, participation in national registries for cardiac catheterizations and PC procedures, a clearly defined patient consent and notice process, quarterly quality review, etc.

The Heart Center will not be obligated to comply with any of these requirements; yet, The Heart Center claims that EAMC's is "shallow/hollow . . . to imply that the modern practice of

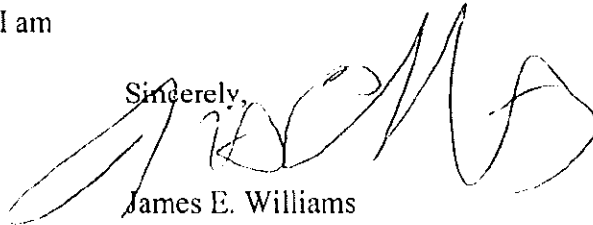
cardiology . . . must now be performed in a hospital setting.” It is the position of EAMC that cardiology procedures performed in a physician’s office are not subject to the same high standards for quality care applicable to health care facilities, and that such procedures entail greater risks to patient safety when conducted in a physician’s office. If The Heart Center disagrees, it is welcome to present empirical data accepted by the healthcare community to support its position.

In summary, the merits of The Heart Center’s representations to SHPDA in its request for a letter of non-review are contested and disputed; because The Heart Center’s representations are contested and disputed, SHPDA cannot give a letter of non-review stating that The Heart Center satisfies the POE; the operation of a cath-lab in the physician’s office setting is not subject to the same high-standards governing patient safety and health care quality applicable to healthcare facilities; and the operation of a cath-lab in a physician’s office carries with it more risks to patient safety, and greater risks, than in a health care facility.

Accordingly, EAMC respectfully requests that SHPDA deny The Heart Center’s request for a letter of non-review.

With kindest personal regards, I am

Sincerely,



James E. Williams

JW/FM/1

Exhibits attached

cc: John Mitchell, MD

(theheartcenterjm@gmail.com)

Michael K. Wright, Esq.

(mwright@starneslaw.com)



RV2021-003

Exhibit A

The Heart Center Cardiology

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

**100 NORTH UNION STREET, SUITE 870
MONTGOMERY, ALABAMA 36104**

August 18, 2011

Terry Andrus, President
East Alabama Medical Center
2000 Pepperell Parkway
Opelika, Alabama 36801-5422

RE: RV2011-027
East Alabama Medical Center

Dear Mr. Andrus:

This is written in response to your original letter received on June 10, 2011, in which you requested to relocate the CON-authorized cardiac catheterization lab located at 2375 Champions Boulevard in Auburn back to East Alabama Medical Center at 2000 Pepperell Parkway in Opelika. This project would not entail offering any new health services, new annual operating costs, nor establishing new health care facilities. Based on this information, your request is approved.

Pursuant to Rule 410-1-2-.05 of the *Alabama Certificate of Need Program Rules and Regulations* and according to the facts that have been provided, a Certificate of Need would not be required. This approval is made with a clear understanding that this proposal will not result in the offering of any new inpatient health services or any capital expenditure in excess of the Certificate of Need capital expenditure thresholds, as they currently exist.

Pursuant to Rule 410-1-7.02 of the *Alabama Certificate of Need Program Rules and Regulations*, this opinion is for informational purposes only and is based on circumstances, as they currently exist. This approval is also based on the assumption that you have disclosed all pertinent information relative to this request. Should there be any deviations from the facts and premises, which you provided to this Agency and should circumstances prove to be other than represented, this letter will become null and void.

Sincerely,

Alva M. Lambert
Executive Director

AML:mdc

cc: Ray Shorer

MAILING ADDRESS: P.O. BOX 303025, MONTGOMERY, ALABAMA 36130-3025
PHONE: (334) 242-4103 FAX: (334) 242-4113

RV2021-003

Exhibit B

The Heart Center Cardiology

RECEIVED

JUN 10 2011

STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY

June 9, 2011

Mr. Alva M. Lambert
Executive Director
State Health Planning and Development Agency
P.O. Box 303025
Montgomery, Alabama 36130-3025

Re: Reviewability Determination Request to Move Cardiac Catheterization Lab

Dear Mr. Lambert:

East Alabama Medical Center currently provides cardiac catheterization services to its inpatients and outpatients. These cardiac catheterization services are provided on one of East Alabama Medical Center's CON authorized cardiac catheterization labs. The majority of these labs are located in East Alabama Medical Center; however, one of the labs is located in Auburn, Alabama. The cardiac catheterization lab located in Auburn was originally located in East Alabama Medical Center but was relocated to 2375 Champions Boulevard in Auburn at the Institute of Advanced Cardiovascular Care pursuant to equipment replacement, EQR2008-021. This original equipment replacement and relocation was a result of the mediation agreement between East Alabama Medical Center and the Institute for Advanced Cardiovascular Care.

East Alabama Medical Center would like to relocate its CON-authorized cardiac catheterization lab that is located at 2375 Champions Boulevard in Auburn back to East Alabama Medical Center at 2000 Pepperell Parkway in Opelika. The Institute for Advanced Cardiovascular Care is in agreement with this relocation. Once the cardiac catheterization lab is relocated to East Alabama Medical Center, all of East Alabama Medical Center's cardiac catheterization labs will be located at the hospital.

No new services would be provided as a result of this relocation. There will be no capital expenditures for major medical equipment for this relocation, there will be no new annual operating costs, and the other capital expenditures to relocate this equipment are minimal and will be less than \$500,000. This proposal does not include the conversion of any new beds, and no bed capacity is involved.

Based on the above stated criteria, we respectfully request that you grant our request for nonreviewability and issue the same at your earliest convenience. As required, we have enclosed a check for \$500.00 for the filing fee in this matter. Thank you for your consideration in this matter. If you need any further information, please do not hesitate to contact me at (334) 528-1300.

Sincerely,

Terry Andrus
President



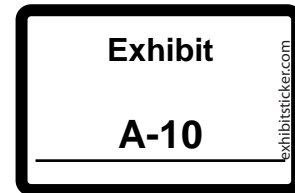
Exhibit A-10

February 12, 2021

VIA ELECTRONIC FILING:

shpda.online@shpda.alabama.gov

Ms. Emily T. Marsal, Executive Director
State Health Planning & Development Agency
100 North Union St., Suite 870
Montgomery, AL 36104



RE: RV2021-0003, The Heart Center Cardiology
Our File No.: 38685

Dear Ms. Marsal:

In his continued quest to have the last word, Mr. Williams' most recent "reply" of today offers nothing new and nothing substantive for SHPDA's consideration. At the risk of being perceived as perhaps engaging in a "last word" campaign of my own, I am submitting this final commentary on behalf of Dr. Mitchell and The Heart Center ("THC"), though I acknowledge that this endeavor is or, at least should be, unnecessary.

The question before SHPDA, in consideration of RV2021-003 is: Will Dr. Mitchell and The Heart Center be given the same fair and unbiased consideration that has been applied to multiple other identical or near identical applications which SHPDA has determined to be non-reviewable? Surely, the answer to this question must be: yes. If that is indeed the case, RV2021-003 is due to be determined: allowed and non-reviewable.

In these replies on behalf of EAMC, Mr. Williams repeatedly raises questions which are either irrelevant to SHPDA's consideration of RV2021-003 (or which have been answered previously), on the pretense that the questions remain unaddressed, and otherwise offers no substantive information having any bearing on the issue of review.

Mr. Williams states that the merits of the THC representations to SHPDA in RV2021-003 are "contested and disputed." RV2021-003 is simply opposed by EAMC, which seeks to restrain Dr. Mitchell's ability to practice his specialty in the exact manner which SHPDA has found to be appropriate and non-reviewable on multiple prior applications, and at the very location where EAMC previously operated a cath lab. The motivation here seems to be an effort to extinguish local competition in the performance

{B3745254}

February 12, 2021

Page -2-

of these procedures. Consider that EAMC has offered ZERO evidence to refute the submission by Dr. Mitchell and THC which has clearly demonstrated that the POE test set out in *Ex Parte Sacred Heart*, 155 So. 2d 980 (2012) is satisfied.

We have confirmed in previous correspondence and submissions that Leg Health has no relationship to THC, Dr. Mitchell nor to RV2021-003. There is no application pending on behalf of Leg Health. We understand that the Leg Health application has been withdrawn. There are no competing factual and legal assertions nor contradictory sworn statements relating to RV2021-003. Any suggestion to the contrary, at this point, is inaccurate and misleading. RV2021-003 stands on its own, completely independent of Leg Health. This has been stated clearly in the past, yet Mr. Williams continues to insinuate otherwise, without basis.

We have previously confirmed that RV2021-003 is applicable only to Dr. Mitchell and his practice, THC. Likewise, we have previously confirmed that the equipment is not being used for inpatient care and is not being used in connection with or on behalf of any healthcare facility, as so defined.

It is completely immaterial to the SHPDA consideration of RV 2021-003 that the withdrawn application of Leg Health had previously proposed a cath lab at 2375 Champions Blvd. and that RV2021-003 submitted solely by Dr. Mitchell and THC, having no affiliation with Leg Health, seeks to establish a physician based office practice exception for a cath lab at the same address (which happens to be a building owned by Dr. Mitchell).

Mr. Williams' letter places emphasis on the financial disclosures submitted in RV2021-003 as being the same estimates that were submitted for the now withdrawn application of Leg Health. The Agency simply requires a statement of the "approximate cost of the proposed project...." (See SHPDA Rule 410-1-7-0.2). Otherwise, Dr. Mitchell has attested that only he and THC will operate the lab. The cost estimate for the equipment and operations of the same cath lab at the same location being the same as that stated in the previous submission on behalf of Leg Health does not imply or contradict the separate factual disclosure of who would own and operate the lab. If Mr. Williams is implying that physicians other than Dr. Mitchell will be performing the procedures, that has been directly addressed, explained and eliminated from consideration by Dr. Mitchell.

Inasmuch as the costs are estimated, it is logical that estimates would be the same for the same lab, location, etc. It is not incumbent on THC or Dr. Mitchell to itemize the basis for the estimate under the rule. It is simply an estimated figure. EAMC and Mr. Williams are grasping in making this misleading argument. The financial disclosures satisfy the Agency requirements and the factual disclosures are undisputed.

Mr. Williams' letter completely misconstrues the position of Dr. Mitchell and the THC by declaring that we have argued that patient "safety has no place" in consideration of whether a letter of non-reviewability should be granted in any case, or in this one. Unfortunately, his assertion in that regard is inaccurate and misleading. No such statement has ever been made. Please refer to my letter dated February 5, 2021 at pages 4 and 5, which outlines our discussion on that issue. As stated Dr. Mitchell is a board certified cardiologist fully capable of exercising his clinical judgment in the best interests of his patients. Moreover, the standard of care recognizes, as does SHPDA, that office based cath labs are operated safely and efficiently.

To the extent that EAMC and Mr. Williams continue to assert that the hospital is the only appropriate environment for performance of cath lab procedures (as opposed to an office based practice), SHPDA has previously determined otherwise, having granted several non-reviewable determinations for other office based cath labs. Surely, in making those determinations, SHPDA has not failed in its duty under Ala. Code § 22-21-261, which Mr. Williams cites for the proposition that patient safety (risk stratification) is an important consideration. Again, that issue is directly addressed in our February 5, 2021 correspondence. Mr. Williams has offered nothing to refute that discussion.

That EAMC chose to relocate the cath lab that it had previously operated at 2375 Champions Blvd in 2011 is likewise irrelevant. The 8/18/2011 SHPDA letter to Mr. Terry Andrus, who was then President of EAMC, does not raise any issue for consideration as to RV2021-003. It certainly does not imply that there is any basis for concern regarding the operation of an office based cath lab, at that location or at any other office location that has ever been approved by SHPDA. If anything, it underscores the inconsistency of the position that EAMC takes now in opposing RV2021-003. It would certainly be inconsistent for SHPDA to deny RV2021-003, having heretofore issued non-review determinations for many prior office based cath lab applications, based on the arguments that EAMC is now making and in consideration of the fact that EAMC previously operated its own cath lab at the same address. How it may have chosen to staff or operate its office based lab there does not in any way imply that anything set forth by Dr. Mitchell and THC in RV2021-003 (or as set out in any other application heretofore approved by SHPDA), is in any way deficient or below the standard of care.

In conclusion, there is a distinction to be made under these circumstances between merely "opposing," on the one hand, and "contesting/disputing," on the other. It may sound like semantics, and in some way it probably is, but under these circumstances, the latter requires submission of some substantive evidence that would support the dispute. To oppose or disagree, with nothing more, is meaningless. Dr. Mitchell and THC have satisfied the POE criteria. EAMC has offered nothing substantive to dispute that. Instead, EAMC simply asserts an "opposition" without substance.

February 12, 2021
Page -4-

Respectfully, RV2021-003 is due to be determined allowed and non-reviewable.

Yours very truly,

STARNES DAVIS FLORIE LLP



Michael K. Wright

MKW/jm

cc: Dr. John W. Mitchell
James E. Williams, Esq.

February 12, 2021

Page -5-

bc: Catherine G. Kirkland, Esq.
Allen C. King, Esq.
Dr. Yoe
Dr. Townsend
Jeff Welch
MKC

Exhibit A-11

LAW OFFICES
MELTON, ESPY & WILLIAMS, P.C.
255 DEXTER AVENUE
MONTGOMERY, AL 36104

JOSEPH C. ESPY, III
JAMES E. WILLIAMS
J. FLYNN MOZINGO
C. MARK BAIN
BENJAMIN J. ESPY*
WILLIAM M. ESPY

OAKLEY W. MELTON, JR.
(1927-2013)

MAILING ADDRESS:
P.O. DRAWER 5130
MONTGOMERY, AL 36103-5130
TELEPHONE (334) 263-6821
FAX (334) 269-9515

February 17, 2021

Via Electronic Filing
(shpda.online@shpda.alabama.gov)

* ALSO ADMITTED IN MISSISSIPPI

Emily T. Marsal, Executive Director
State Health Planning & Development Agency
100 North Union St., Suite 870
Montgomery AL 36104

RE: RV2021-003, The Heart Center Cardiology

Dear Ms. Marsal:

On behalf of EAMC, this is *hopefully* my last response regarding The Heart Center Cardiology's request for a letter of non-reviewability from SHPDA.

Prior to this letter, I have never quoted Shakespeare in writing or otherwise. But there is a first time for everything, and Mr. Wright's correspondence to SHPDA, dated February 12, 2021, on behalf of The Heart Center, presents the opportunity because: "[Mr. Wright] doth protest too much, methinks." Hamlet, Act III, Scene II.

To set the stage, recall that in Dr. John Mitchell's letter to SHPDA, dated January 14, 2021, on behalf of The Heart Center, Dr. Mitchell made the following representations:

The Heart Center and I no longer have any plans to affiliate with Leg Health in the Auburn/Opelika area, and the previously proposed relationship with Leg Health has been terminated. In speaking with a representative for Leg Health, we mutually agreed that the previous request, RV2020-021, should be formally withdrawn. Again, while there was never a written affiliation between The Heart Center or myself and Leg Health, The Heart Center and I have completely disassociated from Leg Health. As reflected in the RV2021-003 request, Leg Health will have no role in providing cardiac services at The Heart Center under the valid proposal set forth in RV2021-003.

(Correspondence from J. Mitchell to SHPDA, p. 2, Jan. 14, 2021).

As mentioned above, it is not identical. RV2021-003 shows that Leg Health is not and will not be involved with the proposed services.

...

Exhibit

A-11

exhibitsticker.com

Again, The Heart Center and I are completely dissociated from Leg Health.

...

As mentioned previously, Leg Health will play no role in regard to the proposed services sought in RV2021-003. RV2021-003 should be considered as a standalone request.

...

I further attest to the Agency that Leg Health is not a party to RV2021-003 and Leg Health will not be involved in the provision of the proposed services in any way. I sincerely request the Agency review RV2021-003 as it was filed—i.e. as a separate, standalone request.

(Id. at 4).

To give Dr. Mitchell's representations credibility, Mr. Wright, by separate letter to SHPDA also dated January 14, 2021, stated as follows:

As described in further factual detail in Dr. Mitchell's response letter, Dr. Mitchell and/or The Heart Center Cardiology no longer have any relationship with Leg Health Vascular Centers. Further, Dr. Mitchell is of the understanding that Leg Health Vascular Centers has issued a letter to the Agency to formally withdraw RV2020-021.

...

It is clear based on the different parties, different facts, and even the termination of the RV2020-021 request from Leg Health and complete dissociation of any relationship between The Heart Center Cardiology and Leg Health that RV2021-003 is a standalone request offered solely on behalf of Dr. Mitchell's private practice, The Heart Center Cardiology.

...

In fact, Leg Health is completely irrelevant to the Agency's determination of the reviewability issue posed by RV2021-003—especially after the clarifications submitted since the hospital's objections. In view of the numerous clarifications provided, any injection or reference to a party (Leg Health) that has no interest in the request should not be considered by the Agency in connection with the standalone RV2021-003 request.

(Id. at p. 6).

To further dramatize the point, Mr. Wright wrote as follows in his letter to SHPDA, dated February 5, 2021, on pages 8 through 9:

EAMC's letter improperly and repeatedly continues to inject Leg Health into the consideration process for RV2021-003. In fact, the basis of the hospital's objection appears to truly center around the previous relationship between Dr. Mitchell and Leg Health, and it argues that the "confusion" created by the RV2020-021 request has not been resolved. This is simply a false assertion. The record is clear that there is no relationship between Dr. Mitchell and Leg Health, and there are no contradictions within RV2021-003.

...

As described in the previous submissions, Dr. Mitchell and/or The Heart Center Cardiology no longer have any relationship with Leg Health Vascular Centers. Further, RV2020-021 has been formally withdrawn. There is nothing "contradictory" within the RV2021-003 request, and there are no "competing factual and legal assertions of [The Heart Center Cardiology,] Leg Health and EAMC" as the hospital continues to argue. In fact, Leg Health is completely irrelevant to the Agency's determination of the reviewability issue posed by RV2021-003—especially after the clarifications submitted since the hospital's objections.

The simple issue presented for the Agency is whether RV2021-003, a standalone request made solely on behalf of The Heart Center Cardiology/Dr. Mitchell, satisfies the POE criteria under Alabama law.

Finally, in his most recent letter to SHPDA, dated February 12, 2021, Mr. Wright attempts to address, for the first time, EAMC's argument repeatedly made in its rebuttal letters to SHPDA, that the costs for Dr. Mitchell's "stand-alone" project are identical to the project involving Leg Health and Drs. Yoe and Townsend, which is highly suspicious for two separate, independent requests. According to Mr. Wright:

We have confirmed in previous correspondence and submissions that Leg Health has no relationship to THC, Dr. Mitchell nor to RV2021-003. There is no application pending on behalf of Leg Health. We understand that the Leg Health application has been withdrawn. There are no competing factual and legal assertions nor contradictory sworn statements relating to RV2021-003. Any suggestion to the contrary, at this point, is inaccurate and misleading. RV2021-003 stands on its own, completely independent of Leg Health. This has been stated clearly in the past, yet Mr. Williams continues to insinuate otherwise, without basis.

...
Mr. Williams' letter places emphasis on the financial disclosures submitted in RV2021-003 as being the same estimates that were submitted for the now withdrawn application of Leg Health. The Agency simply requires a statement of the "approximate cost of the proposed project....." (See SHPDA Rule 410-1-7-0.2)[sic]. Otherwise, Dr. Mitchell has attested that only he and THC will operate the lab. The cost estimate for the equipment and operations of the same cath lab at the same location being the same as that stated in the previous submission on behalf of Leg Health does not imply or contradict the separate factual disclosure of who would own and operate the lab. If Mr. Williams is implying that physicians other than Dr. Mitchell will be performing the procedures, that has been directly addressed, explained and eliminated from consideration by Dr. Mitchell.

Inasmuch as the costs are estimated, it is logical that estimates would be the same for the same lab, location, etc. It is not incumbent on THC or Dr. Mitchell to itemize the basis for the estimate under the rule. It is simply an estimated figure. EAMC and Mr. Williams are grasping in making this misleading argument. The financial disclosures satisfy the Agency requirements and the factual disclosures are undisputed.

(Correspondence from M. Wright to SHPDA, p. 2, Feb. 12, 2021).

To my surprise and the surprise of EAMC, in protesting so much The Heart Center has revealed what it denied exists - - the continued involvement of Leg Health and Drs. Yoe and Townsend in The Heart Center's request. On page 5 of Mr. Wright's letter dated February 12, 2021, Mr. Wright publicly disclosed who is blind-copied on his letter, and the persons receiving a blind copy are as follows:

bc: Catherine G. Kirkland, Esq.
Allen C. King, Esq.
Dr. Yoe
Dr. Townsend
Jeff Welch
MKC

(Emphasis added).

As you may recall, Jeff Welch is a principal in Leg Health and is the author and signor of Leg Health's request for a letter of non-reviewability dated August 3, 2020. Of course, now that The Heart Center has disclosed that Leg Health, Dr. Yoe, and Dr. Townsend, obviously have sufficient interest in The Heart Center's request to be blind-copied on letters submitted to SHPDA, it makes

perfect sense why the cost estimates for both projects are identical, and that's because it's the exact same project but with different lipstick.

As you are aware ALA. CODE § 22-21-265.2 (1975), expressly provides that SHPDA may not "forgive, ratify, or confirm any illegal actions or presentation known to be false on the part of applicants" Although the Heart Center is requesting a letter of non-reviewability, which is a ***non-binding opinion*** from SHPDA and is not subject to the rules for review of an administrative agency per the Administrative Procedures Act, the same principal applies and SHPDA cannot forgive, ratify or confirm The Heart Center's misrepresentations. To the extent The Heart Center will once again claim that there has been a mistake or it has inadvertently caused confusion, like it has done in its prior letters, EAMC reminds SHPDA of its response to Leg Health's request for a letter of non-reviewability:

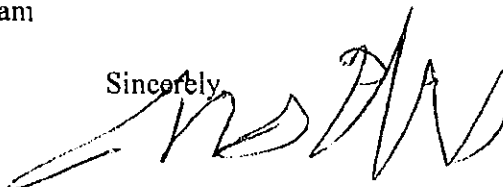
Here, the Agency has received contradictory sworn statements regarding the operation of the project, which, among other things, raises doubt as to whether the new services and equipment are limited to Dr. Mitchell's office-based medical practice. ***The LNR process is not well suited to resolve the competing factual and legal assertions of Leg Health and EAMC. Accordingly, the Agency is unable to determine that this project qualifies for the POE.***

Leg Health Vascular Centers, Inc., RV2020-021, October 26, 2020 (emphasis added).

Accordingly, EAMC respectfully requests that The Heart Center's request be denied.

With kindest personal regards, I am

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Williams", written over the word "Sincerely,".

James E. Williams

JW/FM/I

cc: Michael K. Wright, Esq.
(mwright@starneslaw.com)

Exhibit A-12

From: Mike Wright
To: shpda.online@shpda.alabama.gov
Cc: [Jim Williams](#); [Flynn Mozingo](#)
Subject: Re: RV2021-003, The Heart Center Cardiology
Date: Wednesday, February 17, 2021 6:05:57 PM

Dear Ms. Marsal,

While the blind cc's for my letter were inadvertently disclosed on the submission, the purpose in blind copying Dr. Yoe, Dr. Townsend and Mr. Welch was, quite obviously I think, informational & simply to show that we confirmed for SHPDA:

1. The absence of any relationship between Leg Health and The Heart Center; and
2. That Drs. Yoe and Townsend were not performing procedures there,

matters which we had previously confirmed directly with each of those individuals. If anything is to be taken from that revelation, it is just that.

We certainly felt that it was necessary to inform them of exactly what we were reporting to SHPDA, being as precise as we could be, in view of the fact that the Leg Health issue was being constantly pressed by Mr. Williams/EAMC, despite our previous reporting of there being no existing relationship between LH and Dr. Mitchell/THC.

If Mr. Williams is now insinuating that the clerical error that disclosed the bcc's implies that there has been a misrepresentation, or that a false statement has been made, or anything other than confirmation with those very individuals of the accuracy of information provided to us and submitted to SHPDA, he is, again, flat wrong.

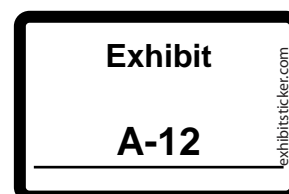
Shakespeare also said: "The first thing we do, let's kill all the lawyers,...". This was stated by the character Dick the Butcher in Henry VI, Part II, Act IV, Scene II, Line 73 and, in context, was simply a reference to the corrupt, unethical lawyers. I certainly hope that Mr. Williams is not putting me in that category. (Incidentally, Shakespeare meant to compliment attorneys and judges who instill justice in society.)

One should well observe that opposition, without substantive basis, and this continued innuendo (of raising a question that has been answered directly and without dispute) in an effort to influence the SHPDA decision, does not serve a just purpose.

The fact remains, there are no contradictory or competing factual or legal assertions. The questions initially raised by SHPDA have been answered directly. SHPDA has not been presented with any evidence from EAMC that would warrant denial of the application for the letter of non review. RV2021-003 is due to be granted.

Sincerely,

Michael K. Wright



This communication is made by way of voice to text transcription technology. Technology limitations may result in speech recognition/transcription errors in text.

STARNES DAVIS
FLORIE LLP

Michael Wright - Attorney
100 Brookwood Place, 7th Floor, Birmingham, 35209
(205) 868-6062 - Fax: (205) 868-6099
www.starneslaw.com

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On Feb 17, 2021, at 4:26 PM, LaRita McGee <LMcGee@mewlegal.com> wrote:

Dear Ms. Marsal:

I have attached correspondence from Jim Williams to be filed regarding the referenced Letter of Non-Reviewability. By copy of this email, I am also providing this correspondence to Michael K. Wright.

If you have any problems accessing the attachment, please let me know.

Warmest regards,

LaRita

LaRita A. McGee
Melton, Espy & Williams, P.C.
Post Office Drawer 5130
Montgomery, AL 36103-5130

Office: (334) 263-6621

Fax: (334) 269-9515

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lmcgee@mewlegal.com

www.mewlegal.com

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<2021-02-21 EAMC Response to Wright letter.pdf>

Exhibit A-13



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

100 NORTH UNION STREET, SUITE 870

MONTGOMERY, ALABAMA 36104

February 19, 2021

John Mitchell, M.D., Medical Director/Owner
The Heart Center Cardiology
2375 Champions Boulevard, Suite 100
Auburn, Alabama 36830

RE: RV2021-003
The Heart Center Cardiology

Dear Dr. Mitchell:

This letter is in response to the above referenced Request for Reviewability Determination received on October 30, 2020, on behalf of The Heart Center Cardiology ("The Heart Center"), with additional information received on January 15, 2021, February 5, 2021 and February 18, 2021 (collectively, the "Request"). East Alabama Medical Center ("EAMC") filed letters opposing the request on December 16, 2020, and January 28, 2021, February 12, 2021 and February 17, 2021. The Request was submitted following the Agency's October 26, 2020 denial of a reviewability request submitted by Leg Health Vascular Centers, Inc. (RV2020-021) related to the same location at 2375 Champions Boulevard, Suite 100, Auburn, Alabama 36830.

As described, The Heart Center seeks to perform low risk peripheral angiography and interventional procedures, left and right diagnostic heart catheterizations-coronary angiography, elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk internal cardiac defibrillator (ICD) and pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, infusaport placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures to patients within the private medical practice located at the Champions Boulevard facility. You state that the procedures are low risk, minimally invasive, and general anesthesia will not be required nor administered, although "moderate and deep sedation" will be utilized. In response to objections raised by EAMC, you have not identified those personnel who will be involved in the administration of anesthesia, but assert that you will abide by the requirements of the Board of Medical Examiners, specifically ALA. ADMIN. CODE r. 540-X-10-.01, *et seq.*

You assert that the proposal is exempt from Certificate of Need ("CON") review under the so-called Physician's Office Exemption ("POE") found in ALA. CODE § 22-21-260(6) (1975 as amended). Alabama law requires the issuance of a CON as a prerequisite to the offering or

MAILING ADDRESS: P.O. BOX 303025, MONTGOMERY, ALABAMA 36130-3025
PHONE: (334) 242-4103 WWW.SHPDA.ALABAMA.GOV

Exhibit

A-13

exhibitsicker.com

operation of any "new institutional health service." ALA. CODE §§ 22-21-263, -265(a) and -266 (1975 as amended). The CON statutes define "institutional health services" as "health services provided in or through health care facilities . . . including the entities in or through which such services are provided." ALA. CODE § 22-21-260(9) (emphasis added). The statute further specifies that "new institutional health services" subject to CON review encompass four distinct circumstances: (1) the construction or operation of a new health care facility; (2) any expenditure by or on behalf of a health care facility exceeding certain thresholds; (3) a change in bed capacity of a health care facility; and (4) health services proposed to be offered in or through a health care facility or health maintenance organization, and which were not offered on a regular basis in or through such health care facility or health maintenance organization within the twelve (12) month period prior to the time such services would be offered.

A health care facility is defined in ALA. CODE § 22-21-260(6) as including, among other things, "facilities for surgical treatment of patients not requiring hospitalization"; but excludes the "offices of private physicians or dentists, whether for individual or group practices and regardless of ownership..." ALA. CODE § 22-21-260(8) similarly excludes from the definition of health services "the lawful practice of any profession or vocation conducted independently of a health care facility and in accordance with applicable licensing laws of this state." ALA. CODE § 22-21-260(8).

In 2012, the Alabama Supreme Court modified criteria used by SHPDA to determine whether a project qualifies for the POE, finding that a qualifying project must meet each of four criteria set out below. *Ex parte Sacred Heart Health Sys., Inc.*, 155 So. 3d 980, 988 (Ala. 2012). Your response to the *Sacred Heart* criteria is set forth in italics:

- 1) The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physicians' practice for the care of their patients;

You state that Dr. Mitchell, the owner and sole physician at The Heart Center, will be exclusively providing all services and utilizing the related equipment at his practice for the care of his patients, and you have represented and affirmed that Dr. Robert Yoe, Dr. Jacob Townsend and Leg Health Vascular Centers, Inc., who were listed in RV2020-021, are not involved in this project.

- 2) The proposed services are to be provided, and related equipment used, at an office of such physicians;

You state that the proposed services will be provided, and related equipment used at Dr. Mitchell's office, The Heart Center, located at 2375 Champions Boulevard, Suite 100, Auburn, Alabama.

- 3) All patient billings related to such services are through, or expressly on behalf of, the physicians' practice;

You state that all patient billings relating to services performed will be done through and on behalf of Dr. Mitchell's physician practice, The Heart Center.

- 4) The equipment shall not be used for inpatient care, nor by, through, or on behalf of a health care facility.

You state that the equipment used for the performance of office-based procedures shall not be used for inpatient care, nor by, through, or on behalf of any other health care facility.

Based on the facts and representations identified above, the proposal as described in the Request is not subject to Certificate of Need (CON) review.

In reaching this conclusion, we have taken into account your representations that you will not perform acute emergency cardiac interventions, nor invasive coronary artery angioplasty procedures. Such services, along with any related equipment and facilities, are beyond the scope of this letter.

In the absence of a CON, physicians other than owners/employees are prohibited from using this facility, and this facility may not be used for any services or equipment billed by or on behalf of any entity other than the physicians' practice. This would include, without limitation, any outside personnel or other entities who are engaged to meet the requirements of ALA. ADMIN. CODE r. 540-X-10-.01(d). In addition, this facility may not be used for inpatient care, which for purposes of this letter shall mean patients may not stay at this facility overnight or for more than twenty-four (24) hours under any circumstances. Services where such a stay might become necessary for patient safety should not be provided.

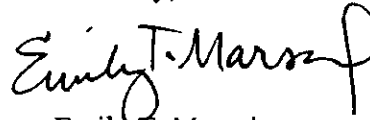
This letter deals solely with the applicability of the POE as interpreted in *Ex parte Sacred Heart Health Sys., Inc.*, and thus does not address the risks, responsibilities and best practices associated with performing these services in an office setting or elsewhere. The section of the Alabama State Health Plan pertaining to Fixed-Based Cardiac Catheterization, found at ALA. ADMIN. CODE r. 410-2-3-.03 (1)(a), contains numerous provisions related to patient safety and informed consent. Based on the information provided, your office arrangement would appear not to meet the requirements of this section if it was classified as a health care facility. While the State Health Plan is not applicable to entities that qualify for the POE, I wanted to bring this to your attention.

Pursuant to ALA. ADMIN. CODE r. 410-1-7-.02, this opinion is for informational purposes only and is based on circumstances as they currently exist. This letter is also specifically conditioned upon the continuing accuracy of the representations contained in this request and assumes that all pertinent information relative to this request has been disclosed. Should there be any deviations from the facts and premises provided to this Agency, this letter shall become null and void.

RE: RV2021-003
February 19, 2021
Page 4 of 4

You may seek a declaratory order from the CON Review Board to obtain a more definitive ruling on this issue pursuant to ALA. ADMIN. CODE r. 410-1-9-.01. Should you have any questions, please contact the Agency at (334) 242-4103.

Sincerely,

A handwritten signature in cursive script, reading "Emily T. Marsal". The signature is written in dark ink and is positioned above the printed name and title.

Emily T. Marsal
Executive Director

ETM:mst

cc: Michael K. Wright, Esquire
James E. Williams, Esquire

Exhibit B-1

RV2020-021
RECEIVED
Aug 06 2020

LEG HEALTH VASCULAR CENTERS, INC.

Administrative Offices: 2525 Bell Rd – Montgomery, AL 36117

August 3, 2020

**Hon. Emily T Marsal
Executive Director
State Health Planning and Development Agency
100 North Union Street
RSA Union Building, Suite 870
Montgomery, AL 36130-3025**

Re: Non – Reviewability Determination Request for Leg Health Vascular Centers Inc.

Dear Ms. Marsal:

On behalf of Leg Health Vascular Centers, Inc., I am writing pursuant to CON r. 410-1-7-.02 to submit a reviewability determination request in accordance with the Alabama State Health Planning and Development Agency's certificate of need program rules and regulation. Specifically, we respectfully request a determination of non- reviewability with respect to the addition of an office-based lab. Our physicians intend to perform low risk peripheral angiography and interventional procedures, left and right diagnostic heart catheterizations- coronary angiography ,elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk ICD and pacemaker implantation, Implantable loop recorder insertion, direct current cardioversion, infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures within our private practice. No novel procedures will be performed, and all of the procedures requested are standard, commonly performed in both inpatient and outpatient settings. The procedures are low risk, minimally invasive and general anesthesia is not required, nor will it be used in the office lab setting. Leg Health Vascular Centers has an established care plan including the identification of involved personnel and equipment, to deal with any issues related to unexpected changes in a patient's status. This includes oxygen and masks for ventilation, medications for arrhythmias and reversal of sedation, defibrillation and pacing as well as a pathway to transfer to a higher level of care as needed. Our physicians have personally verified that every procedure requested above has been previously approved for other office-based labs in our state.

Our goal with this letter is to demonstrate that our request falls within the criteria of the Physician Office Exemption and outside of the thresholds established for CON review. See Ala. Code 22-21-260(6) offices of private physicians are not "health care facilities" and 22-21-2(8) "health services" do not include " the lawful practice of any profession or vocation conducted independently of a health care facility and in accordance with applicable licensing laws of this state"). The private practice office location for Leg Health Vascular Centers; Dr. Robert Yoe, Dr. John Mitchell and Dr. Jacob Townsend is 2375 Suite 100 Champions Blvd. Auburn, AL 36830. The service area for this request is Auburn

Leg Health Vascular Centers Inc. 2375 Champions Blvd. Auburn, AL 36830

Exhibit

B-1

exhibitsticker.com

Alabama and surrounding counties. The physician owners and or employees of Leg Health Vascular Centers; Dr. Robert Yoe, Dr. John Mitchell, and Dr. Jacob Townsend, are each licensed in the state of Alabama and certified to perform the procedures listed above. The physicians will not perform any acute emergency cardiac interventions nor any coronary angioplasty in the private practice setting. In addition, the private practice facility will not be used for inpatient care.

The criteria as adopted by the Supreme Court for the Physician Office Exemption are as follows:

1. The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physician's practice for the care of their patients.
2. The proposed services are to be provided, and related equipment used, at any office of such physicians.
3. All patients' billings related to such services are through, or expressly on behalf of, the physician's practice.
4. The equipment shall not be used for inpatient care, nor by, through or on behalf of a healthcare facility.

Leg Health Vascular Centers, Inc. will meet the four requirements set forth by the Alabama Supreme Court, respectfully as follows:

1. Procedures will be performed only by physician owners or physicians employed by Leg Health Vascular Centers, Inc. and the related equipment shall be used exclusively by the physicians identified as owners or employees.
2. All procedures will be performed in the private physician office of Leg Health Vascular Centers, Inc., currently located at the address provided in the letter head of this document. All equipment necessary for the performance of the procedures will be used only in the office of Leg Health Vascular Centers, Inc.
3. The patient billing related to such services are through, or expressly on behalf of the private physician offices of Leg Health Vascular Centers, Inc.
4. At no time will the equipment identified for the performance of the office-based procedures provided in this letter be used for inpatient care, nor by, through or on behalf of a health care facility.

For the purpose of this request, we would like to provide the following Financial Disclosure:

Total Major Medical Equipment estimated cost for the office-based procedures = \$350,000.00

- a) To include: Diagnostic X-Ray System, patient monitoring equipment, patient recovery equipment, defibrillator and IVUS for arterial and venous procedures. All other equipment is already owned by the private practice.

Estimated annual first year operating cost: Total = \$618,000

- a) Building Lease \$48,000.00/annual
- b) Equipment Lease \$120,000.00/annual
- c) Supplies – \$200,000.00

- d) Employee Wages – 250,000.00
- e) Land Cost – None
- f) Renovation/Construction Cost- None

In light of the foregoing analysis, our request should meet the criteria adopted by the Alabama Supreme Court for application of the Private Office Exemption. As noted above, we can also affirm that this addition of services within our private physician practice will not exceed any of the certificate of need expenditure thresholds, nor will it constitute a "new institutional health service" under Alabama Code 22-21-263 and the Rules due to the following:

- a) No new health care facility or health maintenance organization will be constructed, developed or acquired;
- b) No major medical equipment will be acquired by or on behalf of a health care facility that exceeds the statutory purchase price or operating expense thresholds;
- c) No new health care facility beds or stations will be added;
- d) No new health service that is currently offered by Leg Health Vascular Centers, Inc. will be provided with the implementation of the procedures described in the document; and
- e) No other event reviewable under the CON law or Rules will occur as a result of our implementation of the procedures described in this document.

With the support of this document we respectfully request that the Alabama State Health Planning and Development Agency grant a determination of non-reviewability to Leg Health Vascular Centers, Inc. for the proposed procedures as described above.

No other healthcare facilities have any financial interests in Leg Health Vascular Centers Inc.

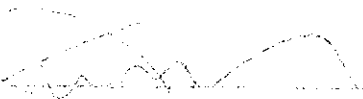
An electronic payment of \$1,000.00 for the filing fee with respect to a request for a reviewability determination will be sent today via the SHPDA online payment portal.

Please do not hesitate to call or contact me; Jeff Welch (205) 563-5082 - jeffwelch@myhealthscan.com with any questions.

Leg Health Vascular Centers Inc. Management/Administrative Offices for correspondence – 2525 Bell Rd. Montgomery, AL 36117 Attn: Jeff Welch

We appreciate your time and consideration in this matter.

Kind Regards,



Jeff Welch
Partner, Managing Member
Leg Health Vascular Centers, Inc.

Request Summary:

Name of Company/Private Practice applying: Leg Health Vascular Centers Inc.

Manager/ Practice Administrator — Jeff Welch 2525 Bell Rd Montgomery, AL 36117

Physicians: Dr. Robert Yoe, Dr. John Mitchell and Dr. Jacob Townsend

Private Practice address- 2375 Suite 100 Champions Blvd. Auburn, AL 36830

Service Area- Auburn and surrounding counties

Services Provided- low risk peripheral angiography and Interventional procedures, left and right diagnostic heart catheterizations- coronary anglography ,elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk ICD and pacemaker implantation, Implantable loop recorder insertion, direct current cardioversion, Infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures

*General anesthesia not needed or used for these services.

*Established care plan, to include a transfer to higher level of care, is included in the request

*Services provided are within the physicians scope of practice and all procedures have been approved in other private practice OBL's in the state of Alabama.

Financial breakdown: Total Major Medical Equipment estimated cost for the office-based procedures = \$350,000.00

- b) To Include: Diagnostic X-Ray System, patient monitoring equipment, patient recovery equipment, defibrillator and IVUS for arterial and venous procedures. All other equipment is already owned by the private practice.

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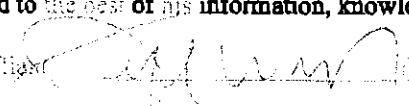
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- h) Equipment Lease \$120,000.00/annual
- i) Supplies – \$200,000.00
- j) Employee Wages – 250,000.00
- k) Land Cost – None
- l) Renovation/Construction Cost- None

Financial interest by other health care facilities or groups- NONE

Check or Money Order: Paid via SHPDA online portal 8/5/2020


Affirmation of Requesting Party:

The undersigned, Jeff Welch, being first duly sworn, hereby make oath or affirm that he, a **Partner and Managing Member of, Leg Health Vascular Centers Inc.**, has knowledge of the facts in the request, and to the best of his information, knowledge and belief, such facts are true and correct.

ATTEST:  (SEAL)

Subscribed and Sworn to me before this 3rd day of August 2020.

Notary Public


Fred Johnson


My commission expires 10/25/2022

Exhibit B-2

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

100 NORTH UNION STREET, SUITE 870
MONTGOMERY, ALABAMA 36104

MEMORANDUM

DATE : August 11, 2020
TO: All Interested Parties
FROM: Emily T. Marsal 
Executive Director
SUBJECT: Reviewability Determination Request (RV2020-021)

The attached request for a reviewability determination has been received. Any affected person may file written comments regarding this request, per 410-1-7-.02 of the *Alabama Certificate of Need Program Rules and Regulations*, by September 22, 2020.

Pursuant to ALA. ADMIN. CODE r 410-1-3-.09, all documents to be filed with the Agency must be submitted to shpda.online@shpda.alabama.gov in PDF, text searchable format.

Enclosure: see attached

Exhibit

B-2

exhibitstickers.com

Aug 06 2020

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY**LEG HEALTH VASCULAR CENTERS, INC.****Administrative Offices: 2525 Bell Rd – Montgomery, AL 36117**

August 3, 2020

Hon. Emily T Marsal
Executive Director
State Health Planning and Development Agency
100 North Union Street
RSA Union Building, Suite 870
Montgomery, AL 36130-3025

Re: Non – Reviewability Determination Request for Leg Health Vascular Centers Inc.

Dear Ms. Marsal:

On behalf of Leg Health Vascular Centers, Inc., I am writing pursuant to CON r. 410-1-7-.02 to submit a reviewability determination request in accordance with the Alabama State Health Planning and Development Agency's certificate of need program rules and regulation. Specifically, we respectfully request a determination of non-reviewability with respect to the addition of an office-based lab. Our physicians intend to perform low risk peripheral angiography and interventional procedures, left and right diagnostic heart catheterizations- coronary angiography, elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk ICD and pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures within our private practice. No novel procedures will be performed, and all of the procedures requested are standard, commonly performed in both inpatient and outpatient settings. The procedures are low risk, minimally invasive and general anesthesia is not required, nor will it be used in the office lab setting. Leg Health Vascular Centers has an established care plan including the identification of involved personnel and equipment, to deal with any issues related to unexpected changes in a patient's status. This includes oxygen and masks for ventilation, medications for arrhythmias and reversal of sedation, defibrillation and pacing as well as a pathway to transfer to a higher level of care as needed. Our physicians have personally verified that every procedure requested above has been previously approved for other office-based labs in our state.

Our goal with this letter is to demonstrate that our request falls within the criteria of the Physician Office Exemption and outside of the thresholds established for CON review. See Ala. Code 22-21-260(6) offices of private physicians are not "health care facilities" and 22-21-2(8) "health services" do not include "the lawful practice of any profession or vocation conducted independently of a health care facility and in accordance with applicable licensing laws of this state"). The private practice office location for Leg Health Vascular Centers; Dr. Robert Yoe, Dr. John Mitchell and Dr. Jacob Townsend is 2375 Suite 100 Champions Blvd. Auburn, AL 36830. The service area for this request is Auburn

Leg Health Vascular Centers Inc. 2375 Champions Blvd. Auburn, AL 36830

Alabama and surrounding counties. The physician owners and or employees of Leg Health Vascular Centers; Dr. Robert Yoe, Dr. John Mitchell, and Dr. Jacob Townsend, are each licensed in the state of Alabama and certified to perform the procedures listed above. The physicians will not perform any acute emergency cardiac interventions nor any coronary angioplasty in the private practice setting. In addition, the private practice facility will not be used for inpatient care.

The criteria as adopted by the Supreme Court for the Physician Office Exemption are as follows:

1. The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physician's practice for the care of their patients.
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Leg Health Vascular Centers, Inc. will meet the four requirements set forth by the Alabama Supreme Court, respectfully as follows:

1. Procedures will be performed only by physician owners or physicians employed by Leg Health Vascular Centers, Inc. and the related equipment shall be used exclusively by the physicians identified as owners or employees.
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Leg Health Vascular Centers Inc. 2375 Champions Blvd. Auburn, AL 36830

- d) Employee Wages – 250,000.00
- e) Land Cost – None
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In light of the foregoing analysis, our request should meet the criteria adopted by the Alabama Supreme Court for application of the Private Office Exemption. As noted above, we can also affirm that this addition of services within our private physician practice will not exceed any of the certificate of need expenditure thresholds, nor will it constitute a "new Institutional health service" under Alabama Code 22-21-263 and the Rules due to the following:

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No other healthcare facilities have any financial interests in Leg Health Vascular Centers Inc.

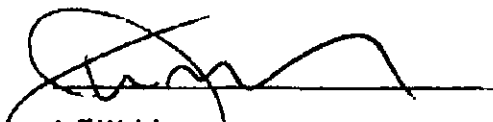
An electronic payment of \$1,000.00 for the filing fee with respect to a request for a reviewability determination will be sent today via the SHPDA online payment portal.

Please do not hesitate to call or contact me; Jeff Welch (205) 563-5082 - jeffwelch@myhealthscan.com with any questions.

Leg Health Vascular Centers Inc. Management/Administrative Offices for correspondence – 2525 Bell Rd. Montgomery, AL 36117 Attn: Jeff Welch

We appreciate your time and consideration in this matter.

Kind Regards,



Jeff Welch
Partner, Managing Member
Leg Health Vascular Centers, Inc.

Request Summary:

Name of Company/Private Practice applying: Leg Health Vascular Centers Inc.

Manager/ Practice Administrator – Jeff Welch 2525 Bell Rd Montgomery, AL 36117

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- j) Employee Wages – 250,000.00
- k) Lend Cost – None
- l) Renovation/Construction Cost- None

Financial Interest by other health care facilities or groups- NONE

Check or Money Order: Paid via SHPDA online portal 8/5/2020

Affirmation of Requesting Party:

The undersigned, Jeff Welch, being first duly sworn, hereby make oath or affirm that he, a Partner and Managing Member of, Leg Health Vascular Centers Inc., has knowledge of the facts in the request, and to the best of his information, knowledge and belief, such facts are true and correct.

Affiant  (SEAL)

Subscribed and Sworn to me before this 3rd day of August 2020.

Notary Public 

Fred Johnson

My commission expires 10/25/2022

Exhibit B-3

LAW OFFICES
MELTON, ESPY & WILLIAMS, P.C.
255 DEXTER AVENUE
MONTGOMERY, AL 36104

JOSEPH C. ESPY, III
JAMES E. WILLIAMS
J. FLYNN MOZINGO
C. MARK BAIN
BENJAMIN J. ESPY*
WILLIAM M. ESPY

* ALSO ADMITTED IN MISSISSIPPI

September 21, 2020

RV2020-021
RECEIVED
Sep 21 2020

OAKLEY W. MELTON, JR.
(1927-2013)

MAILING ADDRESS:
P.O. DRAWER 5130
MONTGOMERY, AL 36103-5130
TELEPHONE (334) 263-0821
FAX (334) 268-9515

Emily T. Marsal, Esq.
Executive Director
Alabama State Health Planning & Development Agency
100 North Union Street
RSA Union Building - Suite 870
Montgomery, Alabama 36104
Email: Emily.Marsal@shpda.alabama.gov

**Re: Reviewability Determination Request (RV2020-021)
Leg Health Vascular Centers, Inc.**

Dear Ms. Marsal,

I represent East Alabama Medical Center ("EAMC") in Opelika. EAMC is the only full-service acute care provider in Lee County and, with 340 licensed beds, is the leading tertiary referral center for the six-county area comprising east-central Alabama. EAMC is presently developing at Auburn Research Park the first free-standing ambulatory surgery center and free-standing emergency department in Lee County. EAMC is the primary cardiovascular care provider in east-central Alabama, and provides the full spectrum of inpatient and outpatient cardiovascular services including cardiovascular and thoracic surgery, cardiac rehabilitation, and cardiac catheterization laboratory.

EAMC has received and reviewed the reviewability determination request by Leg Health Vascular Centers. Leg Health's request is governed by ALA. ADMIN. CODE r. 410-1-7-.02, which has been promulgated by SHPDA in the Alabama Certificate of Need Program Rules and Regulations. The duty to administer the Rules and Regulations is vested in the CON Review Board. As CON Review Board Chairman, Dr. Swaid Swaid, stated in Project AL2020-021:

The CON Board is charged with administering the CON program in a manner that is consistent with the State Health Plan and to assure that "that only those healthcare services and facilities found to be in the public interest shall be offered or developed in the state." ALA. CODE § 22-21-261 (1975). . . .

Paramount among these criteria is patient safety. Our rules require us to determine "the ability of the person, directly or indirectly, to render adequate service

Exhibit

B-3

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to the public..." and the "[p]rofessional capability of the facility". Ala. Admin. Code 410-1-6-.09....

Leg Health's reviewability determination request in which it asks SHPDA to apply the physician's office exemption to its project that will involve the development of an "office-based lab" for Drs. John Mitchell, Jacob Townsend, and Robert Yoe, must be denied. For the reasons discussed herein, (1) Leg Health's project involves the development of a healthcare facility; (2) the physician's office exemption does not apply to Leg Health's request for the same reasons expressed by the CON Review Board in denying the application of the physician's office exemption in DR110 and DR112; (3) Leg Health does not have standing to request the physician's office exemption for Drs. Mitchell, Townsend, and Yoe; and (4) Leg Health has not fully disclosed all factual information for its project required by r. 410-1-7-.02, especially all probing factual information involving procedural risks and patient safety, which will be compromised by its project. Accordingly, EAMC respectfully states as follows in response and opposition to Leg Health reviewability determination request.

(1) The "Office-Based Lab" Described in Leg Health's Request is a Health Care Facility and Will Provide New Institutional Health Services.

Leg Health's reviewability determination request proposes the development of a project in Auburn, Alabama that is very much like the project proposed in DR110 and DR112, which concerned the construction of multi-story facility in Auburn, Alabama, to be equipped with a CT scan and heart catheterization laboratory, and to be operated by The Institute for Advanced Cardiovascular Care. The CON Review Board held in DR110 and DR112 that the project involved the development of a healthcare facility, that Advanced Cardiovascular Care was not a physician's office, and the project was not exempt from CON review. Coincidentally, the multi-story building where Leg Health will be located is the exact same building involved in DR 110 and DR112; the proposed cardiovascular services are also similar; and Dr. John Mitchell, who will practice at Leg Health, was also going to practice at Advanced Cardiovascular Care.

In considering whether the physician's office exemption applied to The Institute for Advanced Cardiovascular Care, the CON Review Board stated as follows:

A determination regarding the reviewability of a project thus requires a two-fold analysis: first, does the project fit the general definition of a "health care facility" offering a "new institutional health service", and, if so, is it otherwise exempt under the Physicians' Office Exemption?

Using the same analysis here, Leg Health's proposed office-based laboratory is a healthcare facility and will provide new institutional health services like the project involving the Institute for Advanced Cardiovascular Care. Leg Health states that it will develop an office-based laboratory at 2375 Champions Boulevard in Auburn, Alabama, that will provide the following services:

peripheral angiography and interventional procedures, left and right diagnostic heart catheterizations - coronary angiography, elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk ICD and pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures

Leg Health does not use the words "catheterization laboratory" in describing its project, but all of the services Leg Health plans to provide are already provided by EAMC in its hospital-based catheterization laboratory. Accordingly, Leg Health is proposing to develop a catheterization laboratory that is similar or identical to the project in DR110 and DR112 in which the CON Review Board held the laboratory was a health care facility.

As observed by the CON Review Board in DR110, the definition of "health care facility" in ALA. CODE § 22-21-260(6) (1975) includes hospitals and related facilities such as laboratories and outpatient clinics. Leg Health's project involves the development of a catheterization laboratory which will provide outpatient clinical services. Therefore, Leg Health is proposing to develop a "health care facility" as defined by ALA. CODE § 22-21-260(6).

(2) The "Office-Based Lab" Does Not Meet the Physician's Office Exemption.

Leg Health's "office-based lab" fails to satisfy the physician's office exemption for many of the same reasons The Institute for Advanced Cardiovascular Care failed to satisfy the physician's office exemption. Leg Health represents that it will be the "private practice office" of Drs. John Mitchell, Jacob Townsend, and Robert Yoe. However, Drs. Yoe and Townsend presently do not practice medicine with Dr. Mitchell; they do not practice medicine in Lee County (neither has staff privileges at EAMC); and they do not live in Lee County.

Drs. Yoe and Townsend both practice medicine as interventional cardiologist with Birmingham Heart Clinic located at 100 Pilot Medical Drive, Suite 300, Birmingham, Alabama. See <https://www.birminghamheart.com/index.php/physicians/> (last accessed September 21, 2020). Birmingham Heart Clinic is 120 miles (or more than a two hour drive) from Champions Boulevard in Auburn. Dr. Yoe resides at 1003 Euclid Avenue, Mountain Brook, Alabama. Dr. Townsend resides at 13 Spring Street, Mountain Brook, Alabama. There are no public records showing either doctor owns property in Lee County, and there is no record of either doctor having a connection to Lee County - Dr. Yoe attended Birmingham Southern College and Dr. Townsend attended the University of Georgia.

In addition, Birmingham Heart Clinic's other office locations are limited to Birmingham and its metropolitan area, in Pell City, Gardendale, and Oneonta. Birmingham Heart Clinic does not have an office or presence in Lee County or in the six county area served by EAMC.

Dr. John Mitchell practices medicine separately from Drs. Yoe and Townsend, at The Heart Center located at 2375 Champions Boulevard. According to The Heart Center's website, Dr. Mitchell is a solo-practitioner. See <https://www.theheartcentercardiology.com/about-us.html> (last accessed September 21, 2020). Unlike Drs. Yoe and Townsend, Dr. Mitchell resides in Lee County at 2700 Mimms Trail, Auburn.

There is no evidence - - only Leg Health's unsubstantiated representations - - that Leg Health is an existing medical practice or that Drs. Yoe, Townsend and Mitchell practice medicine in the same physicians' group. In fact, Leg Health's representations are undeniably false because Leg Health was not incorporated until July 14, 2020, just two weeks before it submitted its reviewability determination request, and Leg Health did not obtain a national provider identifier ("NPI") from the Centers for Medicare and Medicaid until August 25, 2020, three weeks after it submitted its reviewability determination request.¹ In contrast, Drs. Townsend and Yoe have practiced medicine with Birmingham Heart Clinic since 2012 and 2015 respectively, and Dr. Mitchell has been practicing medicine in the Auburn-Opelika area for 30 years.

The physician's office exemption is broader today than when applied in DR110 and DR112 due to the Alabama Supreme Court's holding in Ex parte Sacred Heart Health System, Inc., 155 So. 3d 90 (Ala. 2012). However, the basis for the CON Review Board's ruling in DR110 and DR112 was not effected by Ex parte Sacred Heart, and therefore DR110 and DR112 still apply. Initially, in DR110 the CON Review Board determined that there was no actual physician's practice to which the physician's office exemption could apply, stating:

[I]t is the "current intention" of Dr. Davis and his practice, Cardiovascular Associates, and Dr. Mitchell and his current practice, HCC, to move to the POB and to "lease certain medical office space and equipment from CMD." They also state that they anticipate that Cardiovascular Associates and HCC "will merge and form a single professional corporation known as the Institute for Advanced Cardiovascular Care", and that thereafter Dr. Davis, Dr. Mitchell and other physician members of the two merged entities will practice medicine through the Institute. . . . However, the Respondents failed, despite ample opportunity, to provide documentary evidence to support their claims regarding the changes to the cardiology practice's organization structure and the manner in which the equipment will be owned and operated.

(DR110 at 2). Likewise, in reconsidering the same project in DR112, the CON Review Board held: "The record also reflects that the physicians are not actually practicing medicine as one group," and "the Application of the Physician's Office Exemption to such a large facility operated by a group of loosely connected physicians providing a multitude of services ordinarily

¹ Given the recent issuance of Leg Health's NIP, it is possible that Leg Health does not have a provider billing number with Blue Cross Blue Shield Alabama, Medicare or Medicaid.

provided in a health care facility would create an exception that swallows the rule.” (DR112 at 3-4).

In this review as well, the record reflects that the physicians are not actually practicing medicine as one group. Therefore, the physician’s office exemption does not apply to Leg Health’s project despite its representations. Leg Health represents that “The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physician’s practice for the case of their patients.” (Emphasis added). Drs. Yoe and Townsend practice with Birmingham Heart Clinic, and Dr. Mitchell practices with The Heart Center. Therefore, any billing by Leg Health on their behalf will be outside of their physician’s practice.

Leg Health represents that “No new health service that is currently offered by Leg Health Vascular Centers, Inc., will be provided with the implementation of the procedures described in the document[.]” Leg Health is a newly formed entity, however, and it has never provided any medical services. Therefore, this representation cannot be true.

Leg Health represents that “All patients’ billings related to such service are through, or expressly on behalf of, the physician’s practice.” However, Leg Health cannot bill for services provided by Drs. Yoe and Townsend with Birmingham Heart Clinic or by Dr. Mitchell with The Heart Center. Therefore, any billing by Vascular Health for procedures performed by Drs. Yoe, Townsend and Mitchell will be as a healthcare facility, and not a physician’s office.

Leg Health represents “The equipment shall not be used for inpatient care, nor by, through or on behalf of a healthcare facility.” However, Leg Health is a health care facility and is not a physician’s office. Therefore, all billing by Leg Health will be by, through, and on behalf of a healthcare facility.

Accordingly, SHPDA should deny Leg Health’s request for a determination that its project is exempt from CON review under the physician’s office exemption. SHPDA should respond that the project involves the development of a healthcare facility for which a CON is required.

(3) Leg Health Does Not Have Standing to Request a Reviewability Determination Involving Drs. Yoe, Townsend, and Mitchell.

A reviewability determination request must “be attested by an officer, partner or authorized agent of the company having knowledge of the facts contained therein.” ALA. ADMIN. CODE r. 410-1-7-.02(1). The individual who signed the reviewability determination request is Jeffery Welch. Jeffrey Welch identifies himself as Leg Health’s “Partner, Managing Member.” However, as discussed above, there is no evidence that Leg Health is an actual physician’s office. There is no representation that Jeffrey Welch is an employee or agent of Birmingham Heart Clinic or The Heart Center. There is no evidence that Jeffrey Welch is a physician with knowledge of the procedures Leg Health will perform and there is no attestation, or even an

acknowledgment, from Drs. Yoe, Townsend, and Mitchell, the physicians who allegedly will comprise the physician's office.

Jeffrey Welch does not have standing to make a reviewability determination request for Drs. Yoe, Townsend, and Mitchell. As a layperson, Jeffrey Welch obviously cannot represent the types of procedures the doctors will perform nor can he represent whether the procedures are low risk, non-novel, minimally invasive, etc. Jeffrey Welch also cannot represent that Leg Health has a care plan for dealing with unexpected changes in a patient's status. Jeffrey Welch states the Leg Health has a "pathway to transfer to a higher level of care as needed." (Request at 1). However, EAMC is the only higher level of care located in Lee County and it has no pathway to receive transfers from Leg Health.

In fact, Jeffrey Welch is co-CEO of HealthScan Imaging, LLC, located at 2525 Bell Road in Montgomery - the same address given for Leg Health's managerial/administrative office. The CFO for HealthScan is Fred Johnson, who also is the incorporator for Leg Health. HealthScan Imaging's website, <http://myhealthscan.com/> (last accessed September 21, 2020), represents that it provides echocardiography, ultrasound, and nuclear cardiology services, but it does not identify any employed or associated physicians. Furthermore, upon information and belief, the office of HealthScan Imaging at 2525 Bell Road is not a physician's office or clinical office, and the website does not identify other practice locations.

In a company marketing video, Jeffrey Welch describes Healthscan Imaging offerings – "At Healthscan, we're not just a service provider. We're truly partnering with that practice to come in and make sure from the schedule to the billing and collections, to the reporting is all done for the best of the patient and the practice. We're partnering physicians and helping them save lives, helping them identify disease and conditions they could not have otherwise done in their practices." Jeffrey Welch's brother, Brian, who is the co-CEO of HealthScan Imaging, adds – "There is no upfront cost for HealthScan services. After our team does its analysis, we come in and work with your office manager, your administrator, and your billing company to help to provide these services in a way that you have plenty of time to perform the test, bill for the test, collect the money before anything is due to Healthscan. It's a program that offers patient convenience, physician control, practice profitability, with no risk to you."

A HealthScan Imaging advertisement on Facebook states that the company provides "solutions for all your cardiac nuclear imaging and ultrasound needs," and lists the following benefits available with HealthScan Imaging: complimentary nuclear laboratory analysis; guaranteed lowest price for isotopes and Lexiscan; all staffing needs, cardiac nuclear testing & ultrasounds for satellite locations; etc. According to Jeffrey Welch's LinkedIn profile, the company is "actively seeking cardiologists who are expanding in new markets, opening new clinics or wanting to evaluate their current imaging program."

Leg Health is apparently a marketing, office management, or cardiac services program, or a combination thereof, for HealthScan Imaging. Whatever Leg Health may actually be, it is not a physician's office and it is not the "physician's practice" for Drs. Yoe, Townsend, and Mitchell.

Therefore, Jeffrey Welch does not have standing to request a reviewability determination that the physician's office exemption applies to Leg Health's proposed clinic in Auburn.

(4) Leg Health Has Not Disclosed the Required Full Factual Information For its "Office-Based Lab," And SHPDA Therefore Cannot Issue a Letter of Non-Reviewability.

Rule 410-1-7-.02(1) provides that a party making a reviewability determination request "shall . . . disclos[e] full factual information." As discussed above, Leg Health's request is unsubstantiated and erroneous in light of publicly available information, and EAMC's own familiarity with the physician practices in Lee County. Furthermore, Leg Health does not provide meaningful factual information regarding patient safety and project costs which must be carefully considered when applying the physician's office exemption.

Most of the procedures Leg Health will perform are traditionally performed in a catheterization laboratory.² A catheterization laboratory is an examination room that contains diagnostic imaging equipment useful in visualizing the arteries of the heart and heart chambers, and to treat arterial stenosis or abnormalities. A catheterization laboratory is staffed by a multidisciplinary team, or a multidisciplinary team is readily accessible. Some of the procedures Leg Health says it will perform are, contrary to Leg Health's representation, not "minimally invasive." Attached hereto as Exhibit A is a chart which identifies the nature of each procedure Leg Health represents it will perform; the level of anesthesia involved; and the equipment needed. Nearly all of the procedures involve conscious sedation up to general anesthesia; nearly all require a multidisciplinary team; and all involve risks ranging from bleeding, allergic reaction, and infection; to blood clots, perforation, blood vessel damage, collapsed lung, and pulmonary artery rupture. Many of the procedures have the potential of requiring immediate intervention and surgery.

In fact, cardiac patients are by definition a higher risk group due to age, prevalence of comorbidities, and baseline reduced cardiac reserve. Any procedure on a high-risk population becomes high-risk itself.

A catheterization laboratory is equipped with a defibrillator, medications, other equipment, and trained staff to respond to such risks. In addition, a hospital-based catheterization laboratory, like the one at EAMC, has all the resources and professionals associated with a tertiary care facility immediately available. Leg Health's reviewability determination request does not disclose any of the complexities and risks associated with the procedures it will perform, and it fails to give any factual information regarding how the risks will be contained or addressed; what healthcare professionals will be involved; whether a multidisciplinary team will be used; and what equipment and staff will be available in the event of

² A transesophageal echocardiogram ("TEE") is usually performed in a echocardiography laboratory instead of a catheterization laboratory.

morbidity or mortality. In summary, Leg Health fails to provide any factual information that assures SHPDA that patient safety is a priority and will be assured in its physician's office.

Leg Health's reviewability determination request does not disclose the equipment that will be available for the procedures it will perform. Leg Health represents that its equipment costs will be \$350,000, and its annual operating cost will be \$618,000. However, a cath lab by itself costs \$950,000, and it costs approximately \$1.8 million to construct and fully equip a cath lab, broken down as follows:

Cath Lab	\$950,000
Construction	\$250,000
Echo Machine	\$204,000
TEE Probe	\$32,553
Defibrillator - Cardioversion	\$16,670
EP Mapping System	\$150,000
Nuclear Medicine Camera	\$200,000

In summary, Leg Health has failed to provide full factual information required by r. 410-1-7-.02(1). For this reason, and the other reasons previously discussed, SHPDA must deny Leg Health's reviewability determination request.

In addition, SHPDA should not allow Leg Health to supplement its reviewability determination request. In the alternative, no supplemental information should be accepted or considered by SHPDA unless Leg Health makes the required disclosure discussed above and, in addition, makes a full factual disclosure responsive to the following questions.

1. What is the ownership structure of Leg Health, who all has an ownership interest, and what is the nature and extent of each interest?
2. Will Drs. Yoc and Townsend continue to practice medicine with Birmingham Heart Clinic and/or in the Birmingham area?
3. Will Dr. Mitchell continue to practice medicine as The Heart Center?
4. Will Drs. Mitchell, Yoc, and Townsend cease to use the provider numbers they currently use with their existing physician practices for any future medical services they provide?
5. Will Drs. Mitchell, Yoc, and Townsend, all together, exclusively use the Provider Number obtained for Leg Health going forward for any and all medical services they provide regardless of the location and in which the services are provided?
6. Do Drs. Yoe and Townsend intend to relocate their homes and families from Birmingham to Lee County?

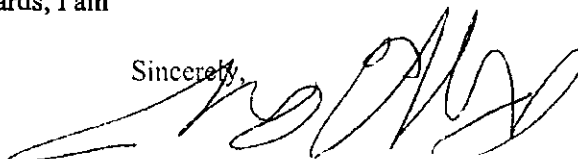
7. Will Drs. Yoe and Townsend seek to obtain staff privileges at EAMC?
8. What is Leg Health's pathway to transfer patients needing a higher level of care?
9. Concerning Leg Health's representation in the "Financial breakdown" in its reviewability request, what equipment is already owned by the practice, and who in fact is the owner of the equipment?
10. What equipment will Leg Health purchase or lease, and what equipment is each physician contributing?
11. What is the square footage of the area in the building that will be leased by Leg Health?
12. How many employees with Leg Health have, what is or will be their qualifications, and what expertise will they provide?
13. What involvement will HealthScan Imaging have with Leg Health, what persons employed by or associated with HealthScan Imaging will be involved, and what will be the nature and extent of their involvement?
14. What involvement will Fred Johnson have with Leg Health?
15. What management and administrative services will be provided by Jeffery Welch and/or from the office located at 2525 Bell Road, Montgomery, AL 36117?
16. What equipment, medications, and staff will be available to handle any and all risks to the patients associated with the procedures Leg Health will perform?
17. What procedures will Leg Health perform outside of those represented in its reviewability determination request?
18. Will Leg Health perform procedures that are more invasive than those represented in its request and, if so, what are the procedures?
19. Does Leg Health have a clear and defined robust QA and PI protocol to insure quality and, if so, what is the protocol?

On behalf of EAMC, we appreciate the opportunity to respond to Leg Health's request for a reviewability determination.

Emily T. Marsal, Esq., Executive Director
Alabama State Health Planning & Development Agency
September 21, 2020
Page 10

With kindest personal regards, I am

Sincerely,

A handwritten signature in black ink, appearing to read 'James E. Williams', written over the word 'Sincerely,'.

James E. Williams

JW/JFM/I

cc: Jeff Welch, Partner, Managing Member
Leg Health Vascular Centers, Inc.

Leg Health "Office Lab"	Brief description	Typically performed (office/hospital)	Safe in office setting	Level of Anesthesia	Equipment needed	Immediate higher level of care for complications
Peripheral angiography and interventional procedures (angioplasty, atherectomy)	Invasive imaging (uses catheters threaded through arterial system, usually through a groin or radial site) to find arterial blockages in arteries other than coronary arteries. Angioplasty is performed to open the blocked arteries.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	-Cath Lab -Documentation system -Image archival system (PACS) -Cardiology monitoring system -Patient monitoring equip -O2 monitoring -defibrillator	Yes. These procedures carry a real and finite risk of vessel or organ damage and perforation which often require urgent open surgical repair. Also, risk of anaphylaxis reactions to contrast agents.
L&R diagnostic heart cath	Invasive imaging (catheter inserted into blood vessel and passed through to the coronary arteries) to evaluate presence of coronary artery, valve or aortic disease.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	-Cath Lab -Documentation system -Image archival system (PACS) -Cardiology monitoring system -Patient monitoring equip -O2 monitoring -balloon pump -defibrillator	Yes. These procedures carry a real and finite risk of vessel or organ damage and perforation which often require urgent open surgical repair. Also, risk of anaphylaxis reactions to contrast agents.
Coronary angiography	Same as peripheral procedure, but detects blockages in coronary arteries.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	-Cath Lab -Documentation system -Image archival system (PACS) -Cardiology monitoring system -Patient monitoring equip -O2 monitoring -balloon pump -defibrillator	Yes. These procedures carry a real and finite risk of vessel or organ damage and perforation which often require urgent open surgical repair. Also, risk of anaphylaxis reactions to contrast agents.
ICD	(Implantable device that monitors heart rhythm for patients at high risk of having lethal heart arrhythmia (Vtach, Vfib). Small incisions are made in the chest where the lead(s) and device are inserted. The lead is inserted through the incision and into a vein, then guided to the heart with the aid of the fluoroscopy machine. The tip of the lead is attached to the heart muscle, while the other end is attached to the pulse generator. The generator is placed in a pocket created under the skin in the upper chest.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	Fluoroscopy gantry -Patient monitoring equip -O2 monitoring -defibrillator	Yes. Bleeding, infection, allergic reaction, damage to blood vessel, or collapsed lung. *All patients who require defibrillator implantation of any kind are at higher risk and should have their procedure performed under the safest conditions available.

EXHIBIT A

Leg Health "Office Lab"	Brief description	Typically performed (office/hospital)	Safe in office setting	Level of Anesthesia	Equipment needed	Immediate higher level of care for complications
PM generator changes	Same as ICD and pacemaker implantation- just changes the battery.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Local or conscious sedation	Fluoroscopy gantry -Patient monitoring equip -O2 monitoring -defibrillator	Yes. bleeding, infection, allergic reaction, damage to blood vessel, or collapsed lung
pacemaker implantation	A local anesthetic is given to numb the area. An incision is made in the chest where the leads and pacemaker are inserted. The lead(s) is inserted through the incision and into a vein, then guided to the heart with the aid of the fluoroscopy machine. The lead tip attaches to the heart muscle, while the other end of the lead (attached to the pulse generator) is placed in a pocket created under the skin in the upper chest.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Local or conscious sedation	Fluoroscopy gantry -Patient monitoring equip -O2 monitoring -defibrillator	Yes. bleeding, infection, allergic reaction, or collapsed lung All patients who require pacemaker insertions or battery changes of any kind are at higher risk and should have their procedure performed under the safest conditions available. These patients are almost always elderly with multiple co- morbidities.
Implantable loop recorder insertion	device implanted just under the skin of a patient's chest to record the heart's electrical activity.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Local or conscious sedation	-Patient monitoring equip -O2 monitoring -defibrillator	Yes. bleeding, infection, allergic reaction
Cardioversion	electrical shocks are delivered to the heart to convert an irregular or fast heart rhythm (arrhythmia) to a normal heart rhythm.	Hospital Cath Lab (not infrequently require overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	-Patient monitoring equip -O2 monitoring -defibrillator	Yes. Stroke, blood clots, life- threatening arrhythmia. Requires deep sedation and exposes the patient to the need for emergent airway support in addition to requiring significant nursing and physician oversight that should be documented and approved by credentialed anesthesiologists.
Infusaport placement	a small device which is utilized to deliver medications directly into the patient's bloodstream. a small catheter attached to a reservoir is placed under the skin with the soft catheter placed inside one of the chest veins. This allows the administration of medications or withdrawal of blood for	Hospital (not infrequently require overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	-Performed in OR -Patient monitoring equip -O2 monitoring -defibrillator -instrumentation -sterilizing equipment -appropriate air exchanges	Yes Venous malpositioning of catheter and perforation with arterial injury, pneumothorax, hemothorax, thoracic duct injury, cardiac tamponade.

Leg Health "Office Lab"	Brief description	Typically performed (office/hospital)	Safe in office setting	Level of Anesthesia	Equipment needed	Immediate higher level of care for complications
	testing without repeatedly having to stick the arm veins. <i>This procedure is done in the operating room, under sedation or a general anesthetic.</i>					
TEE	A transesophageal echocardiogram (TEE) is a type of <u>ultrasound</u> test. Involves placing a tube down your <u>esophagus</u> with an ultrasound device that takes a series of moving pictures of your <u>heart</u> . It can show if it makes clots when it pumps <u>blood</u> .	Hospital- Echo Lab (not infrequently require overnight admission)	No Possible risks of transesophageal echocardiograms include bleeding, breathing issues, or heart rhythm problems	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	-echo machine -TEE probe -Instrumentation -TEE scope -Sterilizing equipment	Yes. Bleeding or tearing of the esophagus, allergic reaction. Requires deep sedation and exposes the patient to the need for emergent airway support in addition to requiring significant nursing and physician oversight that should be documented and approved by credentialed anesthesiologists. In addition, acute methemoglobinemia is a known complication of aerosolized numbing agents for TEE and requires urgent administration of therapy to avoid life-threatening issues.
Pulmonary artery pressure recording devices	A sensor is implanted into pulmonary artery through right heart catheterization	Hospital - Cath Lab (not infrequently require overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	Cath Lab CardioMems or similar device Documentation system -Image archival system (PACS) -Cardiology monitoring system -Patient monitoring equip -O2 monitoring -defibrillator	Yes. Abnormal or life-threatening heart arrhythmias, right bundle branch block, (the heart is unable to conduct electrical signals), knotting of the catheter, rupture of the pulmonary artery, severely reduced blood flow to part of the lung, blood clots causing a stroke, endocarditis (infection of the heart valves), infections of the catheter, bleeding at the insertion site
Atrial, ventricular and nodal ablation	Treatment for cardiac arrhythmias (AVNRT, Afib, A flutter, Vtach) A catheter is inserted into the heart. A special machine delivers energy through the catheter to tiny areas of the heart muscle that cause the abnormal heart rhythm.	Hospital. Cath Lab 4 hr procedure Majority stay overnight	No	Deep sedation or general anesthesia based on ASA classification	-Fluoroscopy gantry -Intracardiac ultrasound -Mapping system -Patient monitoring equip -O2 monitoring -defibrillator	Yes. Damage to the blood vessel, bleeding, formation of a blood clot or blood collection (hematoma) Dislodging of the pacemaker lead,

Leg Health "Office Lab"	Brief description	Typically performed (office/hospital)	Safe in office setting	Level of Anesthesia	Equipment needed	Immediate higher level of care for complications
	<p>This energy disconnects the pathway of the abnormal rhythm.</p> <p>Ablation can also be used to disconnect the electrical pathway between the upper chambers (atria) and lower chambers (ventricles) of the heart. The type of ablation performed depends upon the type of arrhythmia.</p> <p>Involves insertion of several catheters through a small incision into a large blood vessel, and it may be necessary to use both an artery and a vein. A transducer is inserted through one of the catheters so an intracardiac (inside your heart) ultrasound can be performed during the procedure. The ultrasound allows the doctor to view the structures of the heart.</p>					<p>puncture in the heart wall.</p> <p>EP ablation procedures often require trans-septal puncture for completeness. This fact may not be known until the procedure is underway. Significant operator and imaging skill is required for successful completion and complications can be quickly life-threatening.</p> <p>VT ablation almost exclusively involves patients with severely reduced cardiac function and are at risk for severe compromise during the procedure.</p>

*Note: Cardiac patients are inherently at higher risk due to age, high prevalence of comorbidities and baseline reduced cardiac reserve. Any procedure on a high-risk population becomes high-risk. These procedures, when performed in an office setting vs. a hospital further increase the risk and compromise safety of the patient, with no obvious patient benefit. All procedures should have a clear and defined robust QA and PI protocol in place to insure quality.

Exhibit B-4

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

100 NORTH UNION STREET, SUITE 870
MONTGOMERY, ALABAMA 36104

September 23, 2020

Mr. Jeff Welch, Managing Member
Leg Health Vascular Centers, Inc.
2525 Bell Road
Montgomery, Alabama 36117

RE: RV2020-021
Leg Health Vascular Centers, Inc.

Dear Mr. Welch:

This is written in response to the Reviewability Determination Request received August 6, 2020 regarding a proposal by Leg Health Vascular Centers, Inc. for the addition of an office-based lab to provide low risk peripheral angiography and interventional procedures, left and right diagnostic heart catheterizations-coronary angiography, elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk internal cardiac defibrillator (ICD) and pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures within the private practice to patients through the Physician Office Exemption.

On September 21, 2020, the Agency received comments in opposition to this request filed by East Alabama Medical Center (EAMC). A copy of the comments is enclosed. Please provide responses to the concerns outlined by EAMC as you deem appropriate.

ALA. ADMIN. CODE r. 410-1-7-.02(4) allows the Executive Director additional time to evaluate all comments received on behalf of a request prior to rendering a response. In an effort to provide Leg Health Vascular Centers, Inc. an opportunity to respond to these comments and concerns, the Agency is executing its authority to extend the response time.

By October 7, 2020, it is requested that the Agency be provided with the following information:

1. Please clarify the relationship between HealthScan Imaging, LLC, located at 2525 Bell Road, Montgomery, Alabama and Leg Health Vascular Centers, Inc., located at 2375 Champions Boulevard, Suite 100, Auburn, Alabama.
2. On page two of the Reviewability Determination Request, it states all procedures will be performed in the private physician office of Leg Health Vascular Centers, Inc., "*currently located at the address provided in the letterhead of this document.*" However, the address referenced on the letterhead is for Leg Health Vascular Centers, Inc., Administrative Offices, 2525 Bell Road, Montgomery, Alabama. The request also reports the service area as Auburn, Alabama.

MAILING ADDRESS: P.O. BOX 303025, MONTGOMERY, ALABAMA 36130-3025
PHONE: (334) 242-4103 FAX: (334) 242-4113

Exhibit

B-4

exhibitsticker.com

RE: RV2020-021
September 23, 2020
Page Two

Please confirm the correct address for the proposal as well as the applicable service area for this application.

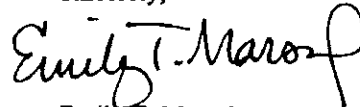
3. Provide clarification regarding whether patients are currently being served at Leg Health Vascular Centers, Inc., located at 2375 Champions Boulevard, Suite 100, Auburn, Alabama.
4. Please advise of the primary practice locations of Drs. Robert Yoe, Jacob Townsend, and John Mitchell, as well as locations of all satellite practices of each physician.
5. Provide the current billing structures, i.e. the name and provider number, of each physician for all practice locations, and provide the proposed billing structure of this request on behalf of Leg Health Vascular Centers, Inc.

Upon receipt of verifications, due consideration will be given to all comments, and a finding issued in accordance with Statute and the *Alabama Certificate of Need Program Rules and Regulations*.

Pursuant to ALA. ADMIN. CODE r. 410-1-3-.09, all documents to be filed must be submitted electronically to shpda.online@shpda.alabama.gov in text searchable, PDF format.

Should you have any questions, please contact the Agency at (334) 242-4103.

Sincerely,



Emily T. Marsal
Executive Director

ETM:mst

cc: James E. Williams, Esquire

Exhibit B-5

LEG HEALTH VASCULAR CENTERS, INC.

Administrative Offices: 2525 Bell Rd – Montgomery, AL 36117

Practice Location: 2375 Champions Blvd. Auburn, AL 36830

RV2020-021

RECEIVED

Sep 30 2020

ALABAMA STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

September 28, 2020

Emily T. Marsal, Esq.
Executive Director
Alabama State Health Planning & Development Agency
100 North Union Street
RSA Union Building – Suite 870
Montgomery, Alabama 36104

RE: RV2020-021

Leg Health Vascular Centers, Inc

Dear Ms. Marsal,

This letter is in response to yours dated September 23, 2020 seeking comment in response to questions raised by East Alabama Medical Center (EAMC) regarding our Reviewability Determination Request. We appreciate the opportunity to provide answers to your questions:

1. **Please clarify the relationship between HealthScan Imaging, LLC, located at 2525 Bell Road, Montgomery, Alabama and Leg Health Vascular Centers, Inc, located at 2375 Champions Boulevard, Suite 100, Auburn, Alabama.**

HealthScan imaging is an employee staffing and diagnostic equipment financing/leasing company developed and managed by Jeff and Brian Welch, helping physicians provide diagnostic imaging for their patients within their private offices for more than 14 years. Leg Health Vascular Centers, Inc, is a private physician medical practice. This practice was formed for the sole purpose of managing Dr. John Mitchell's office based procedural lab, allowing the clinical and in-office procedural portions of his practice to have individual attention as separate business entities under the same private practice umbrella. From a patient perspective, Leg Health Vascular Centers, Inc, is an invisible entity, completely encompassed within Dr. Mitchell's practice, The Heart Center Cardiology, located on Champions Drive. The only links between HealthScan and Leg Health are the involvement of Jeff and Brian Welch, using their knowledge of in-office imaging and staffing resources to help Dr. Mitchell's office-based surgery lab achieve success. Using Leg Health's administrative office of 2525 Bell Rd, Jeff Welch and Brian Welch will provide Dr. Mitchell with administrative duties such as, but not limited to, HR, staffing, medical billing, collections, equipment, maintenance, compliance, and accreditation support.

Exhibit

B-5

exhibitsticker.com

2. On page two of the Reviewability Determination Request, it states all procedures will be performed in the private physician office of Leg Health Vascular Centers, Inc., '*currently located at the address provided in the letterhead of this document*'. However, the address referenced on the letterhead is for Leg Health Vascular Centers, Inc., Administrative Offices, 2525 Bell Road, Montgomery, Alabama. The request also reports the service area as Auburn, Alabama. Please confirm the correct address for the proposal as well as the applicable service area for the application.

Our apologies for any confusion created with the response. All procedures will be performed in the private physician office of Leg Health Vascular Centers, Inc, at 2375 Champions Boulevard, Auburn, AL, which is also the physical location of Dr Mitchell's private practice, The Heart Center Cardiology. This allows for individual focus on the management and business aspects of his clinical practice (The Heart Center Cardiology), and the in-office procedural side of his practice (Leg Health Vascular Centers). The service area is Auburn, AL. Dr Mitchell is the only physician credentialed in Leg Health Vascular Centers to provide office-based surgery, and the office-based lab is solely an extension of his private practice.

3. **Provide clarification regarding whether patients are currently being served at Leg Health Vascular Centers, Inc., located at 2375 Champions Boulevard, Suite 100, Auburn, Alabama.**

Dr Mitchell's patients are currently being served at the above-mentioned address, but not by Leg Health Vascular Centers Inc. Leg Health, like the Heart Center Cardiology, is Dr Mitchell's private practice, and the office-based lab is therefore an extension of his practice – however because Leg Health was created to house the procedural side of his practice, it will not function to serve patients until the Reviewability Determination has been approved.

4. **Please advise of the primary practice locations of Drs. Robert Yoe, Jacob Townsend, and John Mitchell, as well as locations of all satellite practices of each physician.**

Drs. Robert Yoe and Jacob Townsend maintain a primary practice with the Birmingham Heart Clinic at 100 Pilot Medical Drive Suite 300, Birmingham, Alabama. Dr Yoe also has a satellite practice at 150 Gilbreath Drive, Oneonta, Alabama. Dr Townsend has a satellite practice at 74 Plaza Medical Drive, Suite 2B, Pell City, Alabama. Neither Drs. Yoe or Townsend will be practicing in the Auburn area, nor are they credentialed with any insurers outside of their work with the Birmingham Heart Clinic. Their involvement in Leg Health Vascular Centers, Inc., is in an advisory role, leveraging prior experience in office-based surgery to assist Dr. Mitchell in providing the highest quality care and best patient outcomes.

Dr Mitchell's primary practice is The Heart Center Cardiology, located at 2375 Champions Boulevard, Suite 100, Auburn, Alabama. In addition, Dr. Mitchell proposed to practice in the private practice of Leg Health Vascular Centers, Inc located at the same address as The Heart Center Cardiology, 2375 Champions Boulevard, Suite 100, Auburn, Alabama.

5. **Provide the current billing structures, i.e. the name and provider number, of each physician for all practice locations, and provide the proposed billing structure of this request on behalf of Leg Health Vascular Centers, Inc.**

Using the physician office exemption, Dr. John Mitchell is the only physician being credentialed to bill for procedures in the private office location of Leg Health Vascular Centers, Inc. As mentioned, Leg Health is the practice entity developed with the sole purpose of operating Dr. Mitchell's in-office surgery lab, serving as the extension of his clinical practice. Leg Health was formed exclusively for Dr. Mitchell's private practice and the patients he serves. Dr. Mitchell's NPI #1417975186. Leg Health NPI # 1518570068.

Dr. Mitchell will continue to offer clinical services within the private medical practice of The Heart Center Cardiology.

In considering whether the Physician's Office Exemption applies to Leg Health's request, and for the committee's benefit in granting Leg Health a letter of non-reviewability, we would like to offer the summary of facts outlined below.

As stated in our initial request, the proposed services are to be provided, and related equipment used, exclusively by the physician(s) identified as owners or employees of the physician's practice, for the case of their patients.

With guidance from the Alabama State Board of Medical Examiners, Dr. Mitchell successfully completed the ADPH survey and is approved to perform Office Based Surgery at 2375 Champions Blvd Auburn, AL. This information is documented on his 2020 Alabama Medical License. Dr. Mitchell will continue providing clinical services to his patients within his private practice, The Heart Center Cardiology, located at 2375 Champions Blvd. Auburn, AL, however, he is requesting The Board's approval to utilize the newly formed private practice of Leg Health Vascular Centers, Inc as his secondary private medical practice, existing within his current private practice, (The Heart Center Cardiology). Leg Health was formed for the sole purpose of managing Dr. John Mitchell's office based procedural lab, allowing the clinical and in-office procedural portions of his practice to have individual attention as separate business entities under the same private practice umbrella. From Leg Health's administrative offices at 2525 Bell Rd, Jeff Welch, Leg Health's Authorized Official, and Brian Welch will provide Dr. Mitchell support functions such as, but not limited to, HR, staffing, payroll, medical billing, collections, equipment, maintenance, compliance and accreditation support. Neither Dr. Yoe nor Dr. Townsend will be practicing in the Auburn area, nor are they credentialed with any insurers outside of their work with the Birmingham Heart Clinic. Their involvement in Leg Health Vascular Centers, Inc., is solely an advisory role, leveraging prior experience in office-based surgery to assist Dr. Mitchell in providing the highest quality care and best patient outcomes. To ensure the safety of each patient receiving OBS and to achieve compliance with Alabama guidelines, Leg health and Dr. Mitchell have adopted Alabama's Board of Medical Examiner's Administrative Code 540-x-10 as well as other best practices for Office Based Surgery. The existing layout of Dr. Mitchell/Leg Health office currently meets or exceeds the required specifications to perform each of the procedures requested. Therefore, no construction will be needed.

Legal authority for determining what types of facilities and services are subject to review is found in the CON statute, Ala. Code § 22-21-260, et seq., and under the regulations

promulgated by SHPDA, Ala. Admin. Code § 410-1-1, et seq. Under the statute and regulations, four types of "new institutional health services" are subject to CON review:

1. The construction, development, acquisition or other establishment of a new healthcare facility or health maintenance organization (HMO);
2. A capital expenditure by a healthcare facility for major medical equipment, new annual operating costs, or "other expenditures" which exceed certain monetary thresholds;
3. A change in the existing bed capacity of a healthcare facility or HMO; or
4. The offering of a "new health service" by a healthcare facility not previously offered within the prior 12 month period.

Leg Health Vascular Centers Inc. is a private physicians office. Dr. Mitchell and the private medical practice of Leg Health is not proposing to develop a healthcare facility. It's our understanding that healthcare facilities include hospitals, rehabilitation centers, nursing homes, ambulatory surgery centers, kidney disease treatment centers, home health agencies, alcohol and drug abuse facilities and other statutorily defined types of facilities. **The term "healthcare facility" does not include "the offices of private physicians or dentists, whether for individual or group practices and regardless of ownership."** In addition, Dr. Mitchell does not propose to build or construct a new building, nor is there a need for construction within the private office of Leg Health/The Heart Center Cardiology. The offices of Leg Health and The Heart Center Cardiology are both private physician practice locations, used exclusively by Dr. Mitchell, located at the above-mentioned address of 2375 Champion Blvd.

The capital expenditure thresholds over which a CON is needed are much higher than the estimated budget provided below.

Total Major Medical Equipment estimated cost for the office-based procedures = \$350,000.00

To include: Diagnostic X-Ray System, patient monitoring equipment, patient recovery equipment, defibrillator and IVUS for arterial and venous procedures. All other equipment is already owned by the private practice.

Estimated annual first year operating cost: Total = \$618,000

- Building Lease \$48,000.00/annual
- Equipment Lease \$120,000.00/annual
- Supplies – \$200,000.00
- Employee Wages – \$250,000.00
- Land Cost – None
- Renovation/Construction Cost- None

On behalf of Dr. Mitchell and the patients he serves in his private medical practice, located at 2375 Champions Blvd. Auburn, AL, we respectfully request your approval of Leg Health Vascular Centers request for a letter of non-reviewability determinization.

Thank you again for the opportunity to address your questions. We look forward to your response.

Sincerely,

Jeff Welch Electronic Signature 9/28/2020

Jeff Welch, Authorized Official/Managing Member
Leg Health Vascular Centers, Inc.

John W. Mitchell M.D. Electronic Signature 9/28/2020

John Mitchell M.D., Medical Director/Owner
Leg Health Vascular Centers, Inc.

Exhibit B-6



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

100 NORTH UNION STREET, SUITE 870
MONTGOMERY, ALABAMA 36104

October 6, 2020

Mr. Jeff Welch, Managing Member
Leg Health Vascular Centers, Inc.
2525 Bell Road
Montgomery, Alabama 36117

RE: RV2020-021
Leg Health Vascular Centers, Inc.

Dear Mr. Welch:

This is written in response to your letter dated September 28, 2020, providing the additional information requested by this Agency on September 23, 2020, regarding the Reviewability Determination Request filed on behalf of Leg Health Vascular Centers, Inc. for the addition of an office-based lab to provide low risk peripheral angiography and interventional procedures, left and right diagnostic heart catheterizations-coronary angiography, elective internal cardiac defibrillator (ICD) and planned pacemaker generator changes, low risk internal cardiac defibrillator (ICD) and pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures to patients within a private physician medical practice located in Auburn, Alabama through the Physician Office Exemption.

Based on the facts presented to date, the Agency is unable to conclude that the proposed project meets the requirements for the Physician Office Exemption or any other Certificate of Need exemption. It is requested that the following additional information be provided in support of your request:

Supplemental information was provided to the Agency regarding the relationship between HealthScan Imaging, LLC, Leg Health Vascular Centers, Inc., and The Heart Center Cardiology. In your letter you stated *"This practice was formed for the sole purpose of managing Dr. John Mitchell's office based procedural lab, allowing the clinical and in-office procedural portions of his practice to have individual attention as separate business entities under the same private practice umbrella. From a patient perspective, Leg Health Vascular Centers, Inc. is an invisible entity, completely encompassed within Dr. Mitchell's practice, The Heart Center Cardiology, located on Champions Drive."* Please provide clarification and any relevant documentation as to whether Leg Health Vascular Centers, Inc. is a sub part of a global entity or an entirely separate entity.

In the original Reviewability Determination Request received August 6, 2020, you stated *"The private practice office location for Leg Health Vascular Centers; Dr. Robert Yoe, Dr. John Mitchell, and Dr. Jacob Townsend is 2375 Suite 100 Champions Blvd. Auburn, AL 36830...The physician owners*

MAILING ADDRESS: P.O. BOX 303025, MONTGOMERY, ALABAMA 36130-3025
PHONE: (334) 242-4103 FAX: (334) 242-4113

Exhibit

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RE: RV2020-021
October 6, 2020
Page Two

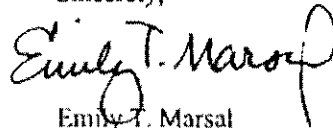
and or employees of Leg Health Vascular Centers; Dr. Robert Yoe, Dr. John Mitchell, and Dr. Jacob Townsend, are each licensed in the state of Alabama and certified to perform the procedures listed above. The physicians will not perform any acute emergency cardiac interventions nor any coronary angioplasty in the private practice setting." However, in correspondence dated September 28, 2020, it stated "*Dr. Mitchell is the only physician credentialed in Leg Health Vascular Centers to provide office-based surgery, and the office-based lab is solely an extension of his private practice.*" It also stated that "*neither Drs. Yoe or Townsend will be practicing in the Auburn area, nor are they credentialed with any insurers outside of their work with the Birmingham Heart Clinic. Their involvement in Leg Health Vascular Centers, Inc. is in an advisory role.*" Please provide the Agency with a detailed explanation regarding the relationship of the three referenced doctors, and the roles of Dr. Robert Yoe and Dr. Jacob Townsend at Leg Health Vascular Centers, Inc., to include their reimbursement for services provided, and specifics as to the financial involvement of Drs. Yoe or Townsend in the proposed project. Please also provide the names of all physicians identified as owners or employees of the practice who will be providing the proposed services and utilizing the related equipment.

Upon receipt of verifications, due consideration will be given to all comments, and a finding issued in accordance with Statute and the *Alabama Certificate of Need Program Rules and Regulations*.

Pursuant to ALA. ADMIN. CODE r. 410-1-3-.09, all documents to be filed must be submitted electronically to shpda.online@shpda.alabama.gov in text searchable, PDF format.

Should you have any questions, please contact the Agency at (334) 242-4103.

Sincerely,



Emily T. Marsal
Executive Director

ETM:mst

Exhibit B-7

RV2020-021
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Oct 09 2020

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

LEG HEALTH VASCULAR CENTERS, INC.

Administrative Offices: 2525 Bell Rd – Montgomery, AL 36117

Practice Location: 2375 Champions Blvd. Auburn, AL 36830

October 07, 2020

Emily T. Marsal, Esq.
Executive Director
Alabama State Health Planning & Development Agency
100 North Union Street
RSA Union Building – Suite 870
Montgomery, Alabama 36104

RE: RV2020-021

Leg Health Vascular Centers, Inc

Dear Ms. Marsal,

This letter is in response to yours dated October 6, 2020 seeking comment in response to questions raised regarding our *Reviewability Determination Request* pursuant to the exemption from Certificate of Need ("CON") review provided to the "offices of private physicians" under Ala. Code 22-21-260(6) (1975 as amended) (the "Physician's Office Exemption" or "POE"). *Ex parte Sacred Heart Health Sys., 155 So. 3d 980, 988 (Ala. 2012)*

Please provide clarification and any relevant documentation as to whether Leg Health Vascular Centers Inc. is part of a global entity or an entirely separate entity.

Leg Health Vascular Centers Inc. is a standalone entity and is not part of, nor affiliated with any other entity. Leg Health Vascular Centers, Inc. is organized and officially recognized as a private medical practice in the state of Alabama and is not part of a Healthcare facility or HMO. Dr. John Mitchell is the only physician provider credentialed to perform the approved office-based procedures. The NPI # is 1518570068.

Please provide the agency with a detailed explanation regarding the relationship of the three referenced doctors, and the roles of Dr. Robert Yoe and Dr. Jacob Townsend at Leg Health Vascular Centers, Inc. to include their reimbursement for services provided, and specifics as to the financial involvement of Drs. Yoe or Townsend in the proposed project. Please also provide the names of all the physicians identified as owners or employees of the practice who will be providing the proposed services and utilizing the related equipment.

Exhibit

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Drs. Yoe and Townsend are acting in an advisory and business consulting role for the benefit of Dr. Mitchell's private practice patients. Dr. Mitchell is the sole provider for office based procedures utilizing the private practice of Leg Health. The owner or employee of Leg health providing the proposed services and utilizing the related equipment will be Dr. John Mitchell. Dr. Mitchell will perform approved office-based procedures exclusively for and on behalf of his private practice patients. Dr. Mitchell, Dr. Townsend, Dr. Yoe, Jeff Welch and Brian Welch organized the formation of Leg Health Vascular Centers, Inc. as a private physician office for the purpose of separately managing administrative and billing functions for Dr. Mitchell (i.e. Providing best practices, compliance with SHPDA OBS guidelines, revenue cycle management, equipment financing, accreditation) as well as other back office responsibilities for the approved office-based procedures. We felt separating the clinical and procedural functions into separate private medical practices would reduce the administrative impact on The Heart Center Cardiology. Drs. Yoe and Townsend are not credentialed with any insurance providers outside of their affiliation with Birmingham Heart and their involvement with Dr. Mitchell and Leg Health Vascular Centers is in an advisory role. Drs. Yoe and Townsend will not practice medicine or perform clinical services for Leg Health, nor will they be reimbursed for any clinical procedures performed at Leg Health or The Heart Center Cardiology. Any financial involvement regarding Drs. Yoe and Townsend will be entirely related to their role as an advisor and oversight to the office lab and staff.

Summary of request:

The POE provides an exemption from CON review process under Alabama Code 221-21-260(6) for the "offices of private physicians..., whether for individual or group practices and regardless of ownership." We feel strongly that our request meets the four-part test adopted by the Alabama Supreme Court and used to determine whether a proposed project qualifies for the POE:

Dr. Mitchell is the only physician performing office-based surgery for Leg Health Vascular Centers and, in effect, on behalf of the patients within his private practice, The Heart Center Cardiology. Dr. Mitchell will only offer low risk procedures, such as peripheral angiography and interventions, where chances of having complications is exceedingly low. All procedures will be performed in the private physician office of Leg Health Vascular Centers, Inc, at 2375 Champions Boulevard, Auburn, AL, which is also the physical location of Dr Mitchell's private practice, The Heart Center Cardiology. The separation of private practices allows for individual focus on the management and business aspects of his clinical practice (The Heart Center Cardiology), and the in-office procedural side of his practice (Leg Health Vascular Centers). The service area is Auburn, AL. Dr Mitchell is the only physician credentialed in Leg Health Vascular Centers to provide office-based surgery, and the office-based lab is solely intended as an extension of his private practice. The related equipment will be used exclusively by the physicians identified as owners or employees of Leg Health, which in this case, will be Dr. John Mitchell. Dr. Mitchell successfully completed the ADPH survey and is approved to perform Office Based Surgery at 2375 Champions Blvd Auburn, AL. Leg Health and Dr. Mitchell have adopted Alabama's Board of Medical Examiner's Administrative Code 540-x-10 as well as other local best practices for Office Based Surgery. The existing layout of

Dr. Mitchell/Leg Health currently meets or exceeds the required specifications to perform each of the procedures requested. Therefore, no construction will be needed. Total Major Medical Equipment estimated cost for the office-based procedures = \$350,000.00.

Dr. Mitchell is not proposing to develop a healthcare facility or HMO. It's our understanding that healthcare facilities include hospitals, rehabilitation centers, nursing homes, ambulatory surgery centers, kidney disease treatment centers, home health agencies, alcohol and drug abuse facilities and other statutorily defined types of facilities. The term "healthcare facility" does not include "the offices of private physicians or dentists, whether for individual or group practices and regardless of ownership." In addition, Dr. Mitchell does not propose to build or construct a new building, nor is there a need for construction within the private office of Leg Health/The Heart Center Cardiology. The offices of Leg Health and The Heart Center Cardiology are both established private practice locations, used by Dr. Mitchell, located at the above-mentioned address of 2375 Champion Blvd.

Dr. Mitchell and Leg Health Vascular Centers Inc. will abide by the foregoing criteria and will not exceed any of the CON expenditure thresholds or constitute "new institutional health services" under ALA. Code 221-21-263(a)(1)-(4) (1975 as amended).

On behalf of Leg Health and Dr. Mitchell, we respectfully request for the agency to grant the LNR by applying the "physician's office exemption".

Thanks again for the opportunity to address your questions. We look forward to your response.

Sincerely,

Jeff Welch Electronic Signature 10/6/2020

Jeff Welch, Authorized Official/Managing Member

Leg Health Vascular Centers, Inc

Exhibit B-8

LAW OFFICES
MELTON, ESPY & WILLIAMS, P.C.
255 DEXTER AVENUE
MONTGOMERY, AL 36104

JOSEPH C. ESPY, III
JAMES E. WILLIAMS
J. FLYNN MOZINGO
C. MARK BAIN
BENJAMIN J. ESPY*
WILLIAM M. ESPY

* ALSO ADMITTED IN MISSISSIPPI

October 20, 2020

RV2020-021
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Oct 20 2020

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

OAKLEY W. MELTON, JR.
(1927-2013)

MAILING ADDRESS:
P.O. DRAWER 5130
MONTGOMERY, AL 36103-5130
TELEPHONE (334) 263-6521
FAX (334) 269-9516

Via E-mail to shpda.online@shpda.alabama.gov

Emily T. Marsal, Esq.
Executive Director
Alabama State Health Planning & Development Agency
100 North Union Street
RSA Union Building - Suite 870
Montgomery, Alabama 36104
Email: Emily.Marsal@shpda.alabama.gov

**Re: Reviewability Determination Request (RV2020-021)
Leg Health Vascular Centers, Inc.**

Dear Ms. Marsal,

On behalf of East Alabama Medical Center ("EAMC"), which previously submitted its response in opposition to Leg Health Vascular Center's reviewability determination request, I'm writing to address Leg Health's correspondences to SHPDA dated September 28, 2020, and October 7, 2020, in which Leg Health gives supplemental information regarding its project. EAMC would have responded sooner, but Leg Health did not copy EAMC or me with its correspondences; and we only recently obtained copies after directly requesting them from SHPDA.

Given the newly-disclosed information, Leg Health cannot obtain a reviewability determination pursuant to ALA. ADMIN. CODE r. 410-1-7-.02 because it has failed to comply with the rule's sworn-full-factual-disclosure requirement. As stated in EAMC's initial response, the duty to administer the Rules and Regulations is vested in the CON Review Board; and, as CON Review Board Chairman, Dr. Swaid Swaid, stated in Project AL2020-021:

The CON Board is charged with administering the CON program in a manner that is consistent with the State Health Plan and to assure that "only those healthcare services and facilities found to be in the public interest shall be offered or developed in the state." ALA. CODE § 22-21-261 (1975). . . .

SHPDA and the CON Review Board cannot fulfill their statutory obligations unless they receive full and truthful disclosure regarding a CON application or reviewability determination

Exhibit

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Emily T. Marsal, Esq.
Executive Director
Alabama State Health Planning & Development Agency
October 20, 2020
Page 2

request. The duty to provide honest and truthful information in seeking a reviewability determination is expressly imposed by r. 410-1-7-.02, which states in part:

Such request shall be submitted pursuant to Rule 410-1-3-.09 ***disclosing full factual information*** as may be more specifically identified on the SHPDA website, supplemented by any additional information or documentation which the Executive Director may deem necessary. ***Such request shall be attested by an officer, partner or authorized agent of the company having knowledge of the facts contained therein, utilizing the following form:***

(a) Affirmation of Requesting Party: The undersigned, being first duly sworn, hereby make oath or affirm that he/she is [include position with entity requesting the determination], has knowledge of the facts in this request, and to the best of his/her/their information, knowledge and belief, such facts are true and correct.

Affiant _____ (SEAL)
SUBSCRIBED AND SWORN to before me this ____ day of _____.
Notary Public
My commission expires:

(emphasis added). A CON licensed healthcare facility can even have its license revoked for committing fraud in obtaining, or exceeding the scope of, its CON license. See ALA. ADMIN. CODE r. 410-1-1-.04(4).

Leg Health has undeniably failed to provide truthful factual information and fully disclose the project underlying its initial reviewability determination request. Therefore, Leg Health's request is deceptive, at least, or deliberately fraudulent.

On the first page of the Reviewability Determination Request dated August 3, 2020, Leg Health represents that it is the private practice office for Dr. Robert Yoe, Dr. John Mitchell, and Dr. Jacob Townsend:

Our goal with this letter is to demonstrate the our request falls within the criteria of the Physician Office Exemption and outside of the thresholds established for CON review. . . . The private practice office location for Leg Health Vascular Centers; Dr. Robert Yoe, Dr. John Mitchell and Dr. Jacob Townsend is 2375 Suite 100 Champions Blvd. Auburn, Alabama 36830.

Emily T. Marsal, Esq.
Executive Director
Alabama State Health Planning & Development Agency
October 20, 2020
Page 3

In fact, all representations by Leg Health in its reviewability determination request are in the plural form. For example, Leg Health states:

- “***Our physicians*** intend to perform low risk peripheral angiography interventional procedures,” etc. Id.
- “***Our physicians*** have personally verified that every procedure requested above has been previously approved for other office-based labs in our state.” Id.
- “***Our*** goal with this letter is to demonstrate that ***our*** request falls within the criteria of the Physicians Office Exemption” Id.
- “The ***physician owners*** and/or employees of Leg Health Vascular Centers, ***Dr. Robert Yoe, Dr. John Mitchell, and Dr. Jacob Townsend***, are all licensed in the state of Alabama and certified to perform the procedures listed above.” Id. at 2.
- “Procedures will be performed only by ***physician owners*** or ***physicians employed*** by Leg Health Vascular Centers, Inc.” Id.
- “***Our*** request should meet the criteria adopted by the Alabama Supreme Court for application of the Private Office Exemption.” Id. at 3.
- “***We*** can also affirm that this addition of services within ***our*** private physician practice will not exceed any of the Certificate of Need expenditure thresholds” Id.
- “With the support of this document, ***we*** respectfully request that the Alabama State Health Planning and Development Agency grant a Determination of Non-Reviewability to Leg Health Vascular Centers, Inc.” Id.

Furthermore, Leg Health’s “Request Summary” identifies the medical practice and the physicians involved in the practice as follows:

Name of Company/Private Practice Applying: Leg Health Vascular Centers, Inc.

Manager/Practice Administrator - Jeff Wekh 2525 Bell Rd Montgomery, AL 36117

Physicians: Dr. Robert Yoe, Dr. John Mitchell and Dr. Jacob Townsend

Private Practice address - 2375 Suite 100 Champions Blvd. Auburn, AL 36830

Emily T. Marsal, Esq.
Executive Director
Alabama State Health Planning & Development Agency
October 20, 2020
Page 4

Leg Health's request also contains the obligatory sworn statement that the information contained in the request is "true and correct":

The undersigned, Jeff Welch, being first duly sworn, hereby make oath or affirm that he, a Partner and Managing Member of, Leg Health Vascular Centers, Inc., has knowledge of the facts in the request, and to the best of his information, knowledge, and belief, such facts are true and correct.

Affiant: */s/ Jeff Welch (SEAL)*

Subscribed and sworn to me this 3rd day of August, 2020.

Notary Public: */s/ Fred Johnson*

However, in response to SHPDA's request for additional information, Leg Health now represents that it "was formed for the sole purposes of managing Dr. John Mitchell's office-based procedural lab." (Leg Health letter to SHPDA, Sept. 28, 2020, p. 1). The letter also contradicts Leg Health's earlier representations to SHPDA, as follows:

- "Dr. Mitchell is the only physician credentialed in Leg Health Vascular Centers to provide office-based surgery, and the office-based lab is solely an extension of his private practice." Id. at 2;
- "Neither Doctors Yoc or Townsend will be practicing in the Auburn area, nor are they credentialed with any insurers outside of their work with the Birmingham Heart Clinic. Their involvement in Leg Health Vascular Centers, Inc., is in an advisory role. . . ." Id. at 2;
- "Dr. Mitchell will continue providing clinical services to his patients within his private practice, The Heart Center Cardiology, located at 2375 Champions Blvd. [sic.] Auburn, Alabama, however, he is requesting The Board's approval to utilize the newly formed private practice of Leg Health Vascular Centers, Inc as his secondary private medical practice, existing within his current private practice (Heart Center Cardiology)." Id. at 3;
- "Leg Health was formed for the sole purpose of managing Dr. Mitchell's office based procedural lab . . ." Id.

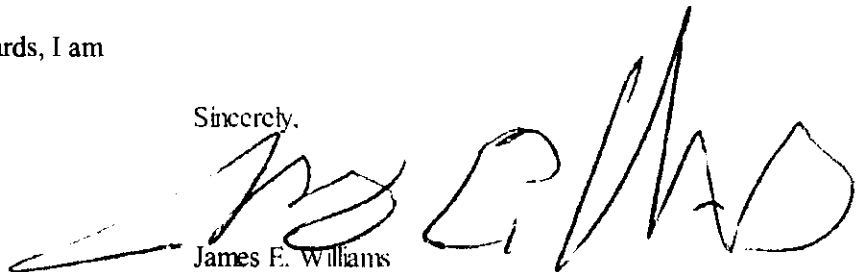
Emily T. Marsal, Esq.
Executive Director
Alabama State Health Planning & Development Agency
October 20, 2020
Page 5

In fact, Leg Health's supplemental communications are themselves self-contradictory. In its correspondence dated September 28, 2020, Leg Health states: "Leg Health Vascular Centers, Inc., is an invisible entity, completely encompassed within Dr. Mitchell's practice, the Heart Center Cardiology, located on Champions Drive." Id. at 1. However, approximately a week later, in its correspondence dated October 7, 2020, it states: "Leg Health Vascular Centers, Inc., is a standalone entity, and is not part of nor affiliated with any other entity." (Leg Health letter to SHPDA, Oct. 7, 2020, p. 1). Obviously, Leg Health cannot be encompassed within The Heart Center, a separate entity, and simultaneously unaffiliated with any other entity.

In summary, the differences between the project described in Leg Health's reviewability determination request and that described in Leg Health's supplemental communications to SHPDA, which were only made in response to probing questions posed by SHPDA, are significant and material, and describe two very different health care facilities. Therefore, Leg Health's certification under ALA. ADMIN. CODE R. 410-1-7-.02 is false and deceptive; and the project described in the reviewability determination request is not the project Leg Health intends to develop. Accordingly, Leg Health's reviewability determination request cannot be approved by SHPDA and must be rejected.

With kindest personal regards, I am

Sincerely,



James E. Williams

JW/JFM/1

cc: Jeff Welch, Partner, Managing Member
Leg Health Vascular Centers, Inc.

Exhibit B-9

LEG HEALTH VASCULAR CENTERS, INC.

Administrative Offices: 2525 Bell Rd – Montgomery, AL 36117

Practice Location: 2375 Champions Blvd. Auburn, AL 36830

RV2020-021

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Oct 21 2020

ALABAMA HEALTH PLANNING AND
DEVELOPMENT AGENCY

October 20, 2020

Emily T. Marsal, Esq.
Executive Director
Alabama State Health Planning & Development Agency
100 North Union Street
RSA Union Building – Suite 870
Montgomery, Alabama 36104

RE: RV2020-021

Leg Health Vascular Centers, Inc

Dear Ms. Marsal,

This letter is in response to East Alabama Medical Center "EAMC" and Mr. James Williams latest objection to Leg Health Vascular Centers reviewability determination. In their attempts to dissect the reviewability request submitted by Leg health Vascular Centers, it appears that Mr. Williams and EAMC have unfortunately conclude that Leg Health's request was not accurately portrayed to the agency. We strongly disagree and would like to offer the following response to the agency, Mr. Williams and to our friends at EAMC.

In a letter dated October 20, 2020, Mr. Williams describes Leg Health's reviewability determination request as "deceptive, at least, or deliberately fraudulent" and he goes on to attack Leg Health's use of the plural form used in describing the collaborative nature of Drs. Yoe, Townsend and Mitchel's relationship.

As a representative of Leg Health Vascular Centers, I would like to say that we take Mr. Williams and EAMC's comments very seriously. Everyone involved in this process was taken aback by the accusations expressed by Mr. Williams and we hope our response today will relieve any confusion regarding Leg Health's reviewability request.

When drafting the initial request, we offered a full and truthful depiction of our intent to perform office-based surgery in the private offices of Leg Health Vascular Centers, located at 2375 Champions Blvd. Auburn, AL 36830. We believed it was important to list all parties involved in Leg Health, Dr. Yoe, Dr. Townsend and Dr Mitchell. After reviewing the request, we felt strongly that our description met the guidelines set forth by SHPDA and the CON Board. In subsequent responses to the Agency, we further described the nature of Dr. Yoe and Dr. Townsend's involvement as advisors and administrators for Leg Health and clarified the fact

Exhibit

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that Dr. Mitchell would be the physician providing office-based surgery on his private practice patients. We clarified that Drs. Yoe and Townsend would not perform clinical services or perform office-based surgery in Auburn. Every effort has been made to meet the SHPDA requirements to perform office-based surgery as outlined in our initial request, including Dr. Mitchell amending his Alabama Medical License to reflect his intent of performing "office-based surgery".

We hope the above clarification helps the Agency and our friends at EAMC have a better understanding of our request, as a private physician's office.

Leg Health Vascular Centers Inc. is a private physicians office. Dr. Mitchell and the private medical practice of Leg Health is not proposing to develop a healthcare facility. It's our understanding that healthcare facilities include hospitals, rehabilitation centers, nursing homes, ambulatory surgery centers, kidney disease treatment centers, home health agencies, alcohol and drug abuse facilities and other statutorily defined types of facilities. **The term "healthcare facility" does not include "the offices of private physicians or dentists, whether for individual or group practices and regardless of ownership."** In addition, Dr. Mitchell does not propose to build or construct a new building, nor is there a need for construction within the private office of Leg Health/The Heart Center Cardiology. The offices of Leg Health and The Heart Center Cardiology are both private physician practice locations, used exclusively by Dr. Mitchell, located at the above-mentioned address of 2375 Champion Blvd. The involvement, management and advisory roles of Dr. Yoe, Dr Townsend, Jeff Welch and Brian Welch allows Dr. Mitchell to provide exceptional office based surgery care to his patients.

The capital expenditure thresholds over which a CON is needed are much higher than the estimated budget provided below.

Total Major Medical Equipment estimated cost for the office-based procedures = \$350,000.00

To include: Diagnostic X-Ray System, patient monitoring equipment, patient recovery equipment, defibrillator and IVUS for arterial and venous procedures. All other equipment is already owned by the private practice.

Estimated annual first year operating cost: Total = \$618,000

- **Building Lease \$48,000.00/annual**
- **Equipment Lease \$120,000.00/annual**
- **Supplies – \$200,000.00**
- **Employee Wages – \$250,000.00**
- **Land Cost – None**
- **Renovation/Construction Cost- None**

The undersigned, Jeff Welch, being first duly sworn, hereby make oath or affirm that he, a Partner and Managing Member of, Leg Health Vascular Centers, Inc., has knowledge of the facts in the request, and to the best of his information, knowledge, and belief, such facts are true and correct.

Affiant: /s/ *Jeff Welch* (SEAL)

Subscribed and sworn to me this 3rd day of August 2020.

Notary Public: /s/ *Fred Johnson*

On behalf of Leg Health and Dr. Mitchell, we respectfully request for the agency to grant the LNR by applying the "physician's office exemption".

We look forward to your response.

Sincerely,

Jeff Welch Electronic Signature 10/20/2020

Jeff Welch, Authorized Official/Managing Member

Leg Health Vascular Centers, Inc

Exhibit B-10

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

100 NORTH UNION STREET, SUITE 870
MONTGOMERY, ALABAMA 36104

October 26, 2020

Leg Health Vascular Centers, Inc.
Jeff Welch, Authorized Partner, Managing Member
2525 Bell Road
Montgomery, Alabama 36117

RE: Leg Health Vascular Centers, Inc.
RV2020-021

Dear Mr. Welch:

This is in response to your request for a reviewability determination dated August 3, 2020 on behalf of Leg Health Vascular Centers, Inc. ("Leg Health"), and additional information dated September 28, 2020, October 7, 2020, and October 20, 2020, regarding Leg Health's proposal to establish and operate an "office based lab". East Alabama Medical Center ("EAMC") filed letters opposing the request on September 21, 2020 and October 20, 2020.

As described in your correspondence, Leg Health is proposing to perform peripheral angiography and interventional procedures, to include left and right diagnostic heart catheterizations - coronary angiography, elective internal cardiac defibrillator ("ICD"), planned pacemaker generator changes, low risk ICD, pacemaker implantation, implantable loop recorder insertion, direct current cardioversion, infusa port placement, transesophageal echocardiography, pulmonary artery pressure recording devices and low risk atrial, ventricular and nodal ablation procedures, in Auburn, Alabama. You assert that the proposal is exempt from Certificate of Need ("CON") review under the so-called Physician's Office Exemption ("POE") found in ALA. CODE § 22-21-260(6) (1975 as amended).

ALA. CODE § 22-21-263(a)(1) (1975 as amended) includes in the definition of new institutional health services subject to CON review: "the construction, development, acquisition through lease or purchase, or other establishment of a new health care facility or health maintenance organization." Under ALA. CODE § 22-21-260(6) (1975 as amended), the definition of a health care facility includes among other things, "facilities for surgical treatment of patients not requiring hospitalization", "laboratories" and "out-patient clinics". Specifically excluded from this definition are "the offices of private physicians or dentists, whether for individual or group practices and regardless of ownership..." *Id.*

MAILING ADDRESS: P.O. BOX 303025, MONTGOMERY, ALABAMA 36130-3025
PHONE: (334) 242-4103 FAX: (334) 242-4113

Exhibit

B-10

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The definition of new institutional health services also includes any new health services offered through a health care facility. ALA. CODE § 22-21-263(a)(4) (1975 as amended). However, a "the lawful practice of any profession or vocation conducted independently of a health care facility and in accordance with applicable licensing laws of this state" is excluded from the health services definition. ALA. CODE § 22-21-260(8) (1975 as amended).

The Alabama Supreme Court most recently interpreted the POE in *Ex parte Sacred Heart Health Sys., Inc.*, 155 So. 3d 980, 988 (Ala. 2012), when it found a facility is exempt from CON review if:

- (1) The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physicians' practice for the care of their patients.
- (2) The proposed services are to be provided, and related equipment used, at any office of such physicians.
- (3) All patient billings related to such services are through, or expressly on behalf of, the physicians' practice.
- (4) The equipment shall not be used for inpatient care, nor by, through, or on behalf of a health-care facility.

In your August 3, 2020 letter, you represented that Leg Health meets each of the requirements of the POE and that the private office location for Leg Health, Dr. Robert Yoe, Dr. John Mitchell and Dr. Jacob Townsend is 2375 Suite 100 Champions Blvd. Auburn, AL 36830. Leg Health further represented that "[t]he physician owners and/or employees of Leg Health Vascular Centers, Dr. Robert Yoe, Dr. John Mitchell, and Dr. Jacob Townsend, are all licensed in the state of Alabama and certified to perform the procedures listed above" and the "proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physician's practice for the care of their patients."

In EAMC's September 21, 2020 response, it alleged that, contrary to the above representations, Drs. Yoe and Townsend are interventionalist cardiologists that practice in Birmingham and "presently do not practice medicine with Dr. Mitchell; they do not practice medicine in Lee County (neither has staff privileges at EAMC); and they do not live in Lee County."

In your September 28, 2020 letter, you represented that Dr. Mitchell is the only physician credentialed in Leg Health to provide office-based surgery, and the office-based lab is solely an extension of his private practice, and that Drs. Yoe and Townsend will be involved in an "advisory" role in the project. Further, you state, "Leg Health Vascular Centers, Inc., is an invisible entity, completely encompassed within Dr. Mitchell's practice, the Heart Center Cardiology, located on Champions Drive."

RV2020-021
October 26, 2020
Page Three

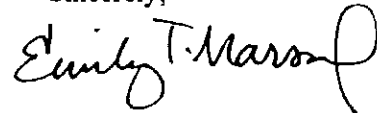
Finally, in your October 7, 2020 supplemental letter, you state "Leg Health Vascular Centers, Inc., is a standalone entity, and is not part of nor affiliated with any other entity." You reiterate that Dr. Mitchell will be the sole provider for office-based procedures for Leg Health.

Rule 410-1-9-.01 was amended in 2016 to require that a responsible official of the requesting entity attest to the accuracy of the information contained in the reviewability request. Here, the Agency has received contradictory sworn statements regarding the operation of the project, which, among other things, raises doubt as to whether the new services and equipment are limited to Dr. Mitchell's office-based medical practice. The LNR process is not well suited to resolve the competing factual and legal assertions of Leg Health and EAMC. Accordingly, the Agency is unable to determine that this project qualifies for the POE.

If desired, you may file a petition to seek a declaratory order from the CON Review Board to obtain a definitive ruling on this issue pursuant to ALA. ADMIN. CODE r. 410-1-9-.01 (2007).

Should you have any questions regarding this letter, please do not hesitate to contact the Agency at (334) 242-4103.

Sincerely,

A handwritten signature in cursive script, reading "Emily T. Marsal". The signature is written in dark ink and is positioned above the printed name and title.

Emily T. Marsal
Executive Director

Exhibit C

**Ruling of the Certificate of Need Review Board
East Alabama Health Care Authority d/b/a East Alabama Medical Center's Petition
for Declaratory Ruling Regarding The Institute for Advanced Cardiovascular Care and
Community Medical Development, LLC
DR110**

By petition filed on January 9, 2007, East Alabama Health Care Authority d/b/a East Alabama Medical Center ("EAMC"), seeks a declaratory ruling that the project it describes as "The Institute for Advanced Cardiovascular Care" in Auburn, Alabama (the "Institute") is a "health care facility" under Alabama's Certificate of Need ("CON") statutes. EAMC's petition is opposed by the developer of the project, Community Medical Development, LLC ("CMD") and the following entities: East Alabama Cardiovascular Associates, P.C. ("Cardiovascular Associates"), CathLab Partners, LLC ("CathLab"), The Heart Center Cardiology, P.C. ("HCC"), Advanced Cardiovascular Development, LLC, ("ACD"), as well as Dr. Ross Davis, the President of Cardiovascular Associates, and John Mitchell, M.D., the President of HCC (collectively, the "Respondents").

A hearing was held on February 21, 2007, in which representatives of EAMC and the Respondent participated. With consent of the parties, the Board carried the matter over to the April 18, 2007 CON Board meeting to allow the Respondents to provide additional information regarding the nature of the project. At the April 18, 2007 meeting, each party was given an opportunity to present additional testimony and evidence and to respond to questions from Board members.

FACTS

CMD is constructing a \$9.5 million, three-story, 58,000 square foot facility in Auburn, Alabama, which is projected to be completed by August of 2007. Located in the building will be a CT scan and heart catheterization laboratory, among other equipment, as well as available tenant

Exhibit

C

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space for "allied medical practices" other than the primary cardiovascular group, or groups, that will occupy the site.¹ CMD is owned by CathLab and Cardiovascular Associates. Cardiovascular Associates' sole member is Ross Davis, M.D. CathLab's members include John Mitchell, M.D., and Kevin Ryan, M.D. Dr. Mitchell is also a member of HCC.

According to CMD, no formal legal documents have been executed regarding the use of the POB and the heart catheterization lab; however, it is the "current intention" of Dr. Davis and his practice, Cardiovascular Associates, and Dr. Mitchell and his current practice, HCC, to move to the POB and to "lease certain medical office space and equipment from CMD." They also state that they anticipate that Cardiovascular Associates and HCC "will merge and form a single professional corporation known as the Institute for Advanced Cardiovascular Care", and that thereafter Dr. Davis, Dr. Mitchell and other physician members of the two merged entities will practice medicine through the Institute.² According to the Respondents, the Institute will lease from CMD the space and equipment necessary for its physicians to perform outpatient cardiac catheterization services for their patients. CMD disputes EAMC's allegations that CathLab will separately own and operate the catheterization lab and testified that only members of its practice will use the heart catheterization and CT equipment and that the Institute will constitute the "primary" office of the physicians using such equipment and providing such services. However, the Respondents failed, despite ample opportunity, to provide documentary evidence to support their claims regarding the changes to the cardiology practice's organizational structure and the manner in which the equipment will be owned and operated.

¹ALA. CODE § 22-21-263(d) (1975 as amended) removed extracorporeal shock wave lithotripters, magnetic resonance imaging and positron emission tomography from the definition of "new institutional health service" subject to review, including the definitional provisions of ALA. CODE § 22-21-263(b) (2) (1975 as amended) dealing with expenditure thresholds. See *Auburn Medical Center v. East Alabama Health Care Authority*, 908 So. 2d 243 (Ala. Civ. App. 2003).

² See Correspondence to Alva M. Lambert from David M. Hunt dated February 7, 2007, *Re: Declaratory Ruling Request 110* at 3.

DISCUSSION

A "health care facility" is statutorily defined, in pertinent part, as:

General and specialized hospitals, including ... psychiatric, long-term care, and other types of hospitals, and related facilities such as, laboratories, out-patient clinics, ... facilities for surgical treatment of patients not requiring hospitalization.... The term health care facility shall not include the offices of private physicians or dentists, whether for individual or group practices and regardless of ownership...

ALA. CODE § 22-21-260(9) (1975 as amended). The CON statute requires the issuance of a CON as a pre-requisite to the offering or operation of any "new institutional health service", which is defined as "health services provided in or through health care facilities...including the entities in or through which such services are provided." ALA. CODE § 22-21-260(6) (1975 as amended). The statute further defines new institutional health services to encompass four distinct circumstances:

- (1) the construction, development, acquisition through lease or purchase, or other establishment of a new health care facility ...;
- (2) a capital expenditure by or on behalf of a defined health care facility for major medical equipment, new annual operating costs, or "other expenditures" which exceed certain monetary thresholds;
- (3) a change in the existing bed capacity of a health care facility or health maintenance organization through the addition of new beds, the relocation of one or more beds from one physical facility to another, a change in the bed capacity of a health care facility...; or
- (4) the offering of health services "in or through a health care facility," not previously offered within the prior twelve month period.

ALA. CODE §§ 22-21-263(a) (1)-(4) (1975 as amended).

A determination regarding the reviewability of a project thus requires a two-fold analysis: first, does the project fit the general definition of a "health care facility" offering a "new institutional health service", and, if so, is it otherwise exempt under the Physicians' Office

Exemption?

DEFINITION OF HEALTH CARE FACILITY

In *Heart-Lung Associates of America, P.C.*, Order on Petition for a Declaratory Ruling DR-100 (August 15, 2001) at 3-4 ("*Heart-Lung*"), the CON Board stated the following in regard to the definition of a health care facility:

12. The record also supports a finding that the proposed operation falls under the definition of a "health care facility" under ALA. CODE § 22-21-260(6) (1975 as amended).(footnote omitted). This statute defines a "health care facility," in part, as "general and specialized hospitals, including tuberculosis, psychiatric, long-term care, and other types of hospitals, and related facilities such as, laboratories, out-patient clinics, and central service facilities operated in connection with hospitals" The statute does not limit this definition of a health care facility to inpatient facilities, indeed, it clearly contemplates that other out-patient facilities can constitute a "health care facility". The Board finds that the proposed Heart-Lung facility shares the essential characteristics of both a "hospital" and a "related facility" as defined in the statute.

13. The term "hospital" is not defined in the CON statute or its regulations. Black's Law Dictionary defines a "hospital" as "an institution for the treatment and care of sick, wounded, infirm, or aged persons." Black's Law Dictionary, page 737 (6th Ed. 1991). Stedman's Medical Dictionary defines a "hospital" as "an institution that provides medical, surgical or psychiatric care and treatment for the sick or injured." Stedman's Medical Dictionary, page 379 (1995). Webster's Dictionary defines a "hospital" as "an institution providing medical or surgical care and treatment for the sick and injured." Webster's II New College Dictionary, page 534 (1995). The Board finds that the proposed facility falls within plain, ordinary, and commonly understood definitions found above. The Board notes that such a definition is also consistent with the definition used by the Alabama Legislature in regard to a statute applicable to health care institutions subject to licensure requirements, which defines a "hospital" as including:

HOSPITALS. General and specialized hospitals, including ancillary services; independent clinical laboratories; rehabilitation centers; ambulatory surgical treatment facilities for patients not requiring hospitalization; end stage renal disease treatment and transplant centers, including free-standing hemodialysis units; abortion or reproductive health centers; hospices; health maintenance organizations; and other related health care institutions when such institution is primarily engaged in offering to the public generally, facilities and services for the diagnosis and/or treatment of injury, deformity, disease, surgical or obstetrical care. ...

ALA. CODE § 22-21-20 (1975 as amended).

14. In conclusion, Heart-Lung's proposal, which calls for multiple, otherwise unaffiliated physicians to utilize Heart-Lung's facility, equipment and support services, on a fractional basis, in order to treat a variety of patients and ailments constitutes a "hospital" or "related facility" as defined in the under ALA. CODE § 22-21-260(6) (1975 as amended).

In the present case, the Respondents assert that the heart catheterization and CT equipment will be used solely by those employees of the Institute and that there will be no formal relationship between the Institute and the other physician practices in the building. EAMC asserts and presented evidence that the design and plans for the facility reflect a different intent, one where multiple physicians use the facility and the on-site equipment for medical procedures in a fashion that is functionally indistinguishable from the services performed in a hospital.

As was the case with *Heart-Lung*, the record here supports a finding that the project would normally constitute a "hospital" or "related facility", as defined under ALA. CODE § 22-21-260(6) (1975 as amended), and its construction would thus constitute a "new institutional health service" under ALA. CODE § 22-21-263(a) (1975 as amended), unless otherwise qualifying for the Physicians' Office Exemption.

PHYSICIANS' OFFICE EXEMPTION

As shown above, the definition of a health care facility excludes the "offices of private physicians...whether for individual or group practices and regardless of ownership". The statute does not otherwise define the term "offices of private physicians." However, in *Heart-Lung*, the CON Board focused on the inapplicability of the Physicians' Office Exemption in certain situations involving multiple practices in the same building. *Heart-Lung Associates of America, P.C.*, Order on Petition for a Declaratory Ruling DR-100 (August 15, 2001). In *Heart-Lung*, the

Board applied a common sense definition to what constitutes a "physician's office" through the application of four basic requirements. According to the Board, a project would qualify for the exception if:

1. That the proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physicians' practice for the care of their patients.
2. That the proposed services are to be provided, and related equipment used, at the primary office of such physicians.
3. That all patient billings related to such services are through, or expressly on behalf of, the physicians' practice, and not on behalf of a third party.
4. That the equipment shall not be used for inpatient care, nor by, through or on behalf of a health care facility.

See *Heart-Lung* at 3, ¶ 11 n.3. The Board also stated the following:

9. The Physicians' Office Exemption provides an exemption from the CON review process for the "offices of private physicians ... whether for individual or group practices and regardless of ownership", the statute provides no further definition of the phrase "offices of private physicians." Words in a statute should be given their plain, ordinary, and commonly understood meaning unless there is a specific statutory definition." State Dept. of Revenue v. Sonat, Inc., 690 So. 2d 412, 417 (Ala. Civ. App. 1997). Among the definitions of "office" found in Webster's Dictionary is the following: "A place in which business, professional, or clerical activities are conducted." Webster's II New College Dictionary, page 760 (1995). This definition is difficult to apply to the health care industry, because physicians who maintain an office often also regularly treat patients in a variety of other settings, including hospitals and ambulatory surgical centers owned, operated and/or controlled by third parties. These facilities typically purchase expensive diagnostic and other equipment whose cost would not be justified in a typical private physician office.(footnote omitted). While in one sense a physician may be temporarily "conducting business" at such location by engaging in patient care, it is not a reasonable construction of the statute to consider all such locations the physician's "office" and, therefore, exempt from the CON review process.

10. There are several reasons why the Physicians' Office Exception should not be interpreted to apply to a physician's fractional use (by lease or other third party agreement) of an independent facility (not otherwise associated the physician's practice) that is built, equipped and/or staffed to provide services, such as MRI service, that are otherwise subject to the CON statutes. Such an

application would eviscerate the CON statutes, by allowing health care facilities to purchase expensive diagnostic equipment and to avoid application of the CON statute by simply "leasing" a portion of a treatment facility to a physician for the limited period of time such facility is used by a treating physician.

11. In a written submission, the petitioners offered to obtain assurances from the leasing physicians that its facility would constitute the "primary" office of such physicians. In prior non-reviewability determinations, one of several factors the Agency has examined is whether the proposed location of a facility claiming the Physicians' Office Exception will be the primary "office" of the physician seeking the exemption. Such information is relevant to a determination of whether the location is, in fact, the physicians' actual "office" or just a location, such as a hospital, where a physician occasionally provides medical treatment. In the present case, however, the proposed arrangements, providing for a "lease" of the facility containing expensive diagnostic equipment, by numerous unaffiliated individual physicians for as little as a few hours a week, requires a finding that the proposed facility, as a whole, is not an "office" of a private physician as contemplated by the Physicians' Office Exception. The provision of support services by Heart-Lung, when combined with the other factors, also supports a finding that the proposal is subject to CON Review. (Footnote omitted).

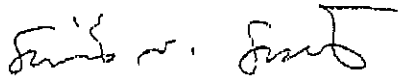
Id. at 2-3.

In the present case, after considerable review of the evidence and examination by Board members, the Board has concluded that the design and structure of this large multi-floor facility reflects an intent to share and use facilities and equipment for the treatment of patients other than just those of the treating physicians whose primary offices are located at the facility. The Board further concludes that, based on the available evidence, the project involves the provision of a new institutional health service, does not qualify for the Physicians' Office Exemption, and is thus reviewable.

CONCLUSION

For the reasons stated above, the Board finds that EAMC's Petition for declaratory relief is due to be granted. This finding does not foreclose a different conclusion in the future based on

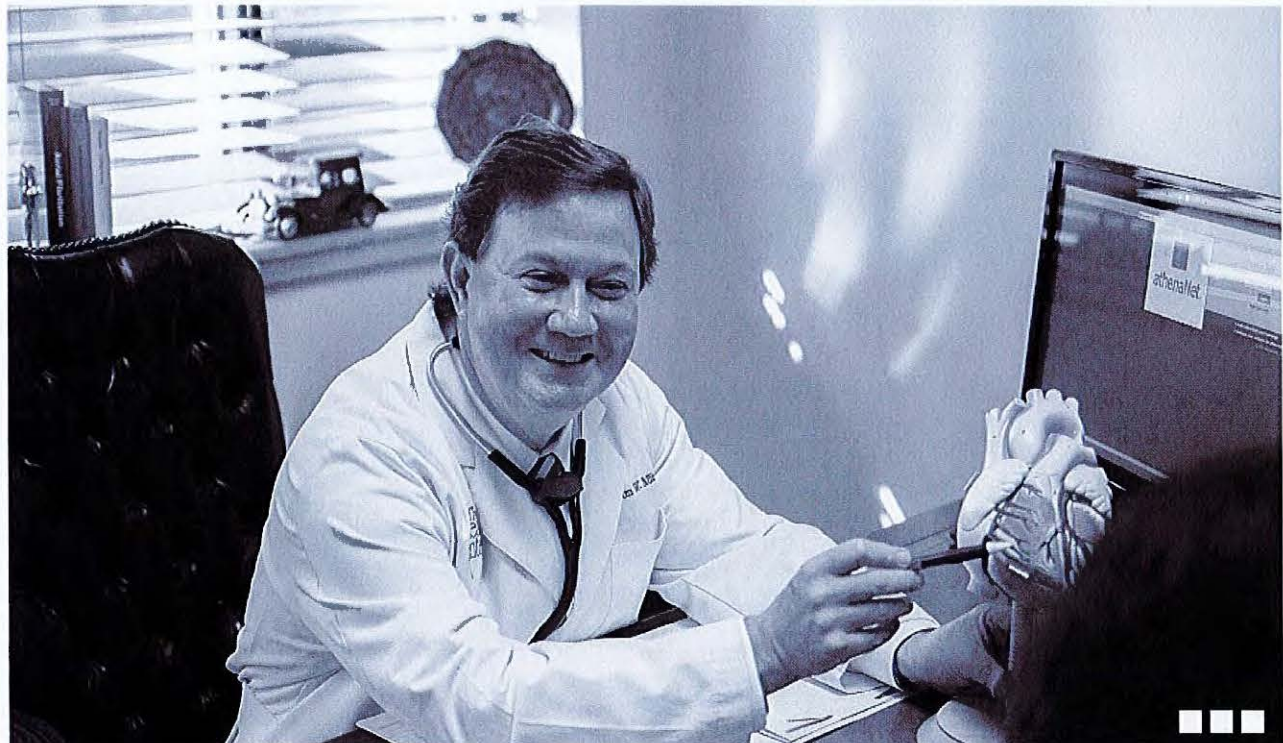
a restructuring of the project designed to clearly fall within the Physicians' Office Exemption, as historically interpreted and applied by the Agency.



Swaid N. Swaid, M.D., Chairman
Certificate of Need Review Board

5/3/07
Date

Exhibit D

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TREATING YOUR HEART. TREATING YOU LIKE FAMILY.

Auburn Cardiologist, Dr. John Mitchell, and The Heart Center Cardiology are widely recognized for providing high quality, state-of-the-art heart disease diagnosis and treatment. We invest in the latest technology that only two percent of patients nationwide receive. We also use a team approach and compassionate care to give you the right options for the best possible outcomes.

Our commitment is preventing and treating the #1 killer of men and women in America—heart disease.

In the rapidly changing field of medicine, The Heart Center Cardiology stands out as a group committed to providing the very best in personal and individualized care while incorporating the very latest in technology and innovation. As one of the most recognized cardiologists in Auburn, AL, Dr. Mitchell and his team also serve patients in the Valley, Alabama and Wedowee, Alabama areas with compassionate treatment and prevention of heart disease.

**Exhibit****D**

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The Heart Center Cardiology

2375 Champions Blvd

Auburn, AL 36830

Phone: (334) 321-3700 Fax: (334) 887-7475

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TECHNOLOGY SETS OUR CLINIC APART. OUR PEOPLE MAKE THE DIFFERENCE.

Our technology sets our clinic apart from most, but it's our people that really make the difference for our patients. Our caring staff always puts the patient's needs first. Compassionate care is our top priority. So when you are deciding where to turn for your cardiac care, consider Dr. John Mitchell and the Heart Center Cardiology.

Dr. John W. Mitchell, MD

Dr. John Mitchell has been practicing cardiology in the Auburn-Opelika area for 30 years. He started the cardiac care program in the area in 1985. Ever since, his highest priority has been to provide the best medical care possible to his patients.

He graduated summa cum laude and was inducted into Phi Beta Kappa at Birmingham-Southern College, where he earned a degree in chemistry in 1976.

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He performed an internship in Internal Medicine at the University of South Florida from 1980-1981 and served his residency in Internal Medicine at the University of South Florida from 1981-1983, where he was chief resident and recipient of the prestigious Marcus



Award. He then served his Fellowship in Cardiovascular Medicine from 1983-1985, after which time he started the Cardiac Program at EAMC.

Licenses and Associations

Alabama State Medical License #11981

Diplomate, American Board of Internal Medicine

Diplomate, American Board of Cardiology

Associate, American College of Physicians

Associate, American College of Cardiology

Member, American Board of Internal Medicine

Instructor, University of South Florida School of Nursing (Pharmacology), 1980-1985

Instructor, Physical diagnosis, University of South Florida College of Medicine, 1982-1985

Certified, Advanced Cardiac Life Support

Instructor, Basic Cardiac Life Support

David Pate, CRNP

David Pate has been a Certified Registered Nurse Practitioner at The Heart Center Cardiology since 2000. He earned his Associates Degree in Nursing from Wallace State Community College (Cum Laude) in 1983, his Bachelor of Science in Nursing from Auburn University School of Nursing in 1998 and his Masters of Science in Nursing from UAB School of Nursing in 2000.



Licensure & Certifications

Family Nurse Practitioner, American Academy of Nurse Practitioners, Certified

Family Nurse Practitioner, American Nurses Credentialing Center, Certified

Certified Registered Nurse Practitioner, Alabama

Registered Nurse, Alabama

Registered Nurse, Georgia

Advanced Life Support Provider

Basic Trauma Life Support Provider

Certified Autotransfusionist

Sigma Theta Tau International Nursing Honor Society

American Association of Critical Care Nurses

Alabama Nurse Practitioner Council

OUR MISSION.

Our mission at the The Heart Center Cardiology, P.C. is to provide the highest-quality cardiac care available. We work to achieve excellence and exceed expectations at every level while treating all of our patients like family.



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The caring and compassionate staff at The Heart Center Cardiology strives to make every patient as comfortable as possible on every visit to our office. We work hard to ensure a smooth visit, insurance processing and paperwork.

To make each visit more efficient, new patients should print and fill out our new patient forms shown to the right. Simply click the form to view it, print and complete each section. Bring these with you when you arrive for your first visit.

The Heart Center Cardiology Office Hours:

Monday - Thursday 8:30am - 4:30pm

Friday 8:30am-3:00pm

Lab Test Hours (effective September 1, 2014)

Monday, Thursday, Friday 8:30am - 10:30am

By appointment only

Patients requiring assistance with appointments, medications, insurance or

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other needs please call:

(334) 321-3700

Directions from the north (Atlanta):

- Take I-85 South to Exit 57
- Go left at the light at the top of the ramp and back over the interstate
- Go through the next light
- Take the next right onto Champions Blvd.
- The Heart Center Cardiology is 1/2 mile on the right

Directions from the south (Montgomery):

- Take I-85 North to Exit 57
- Go right at the light at the top of the ramp
- Take the first right onto Champions Blvd.
- The Heart Center Cardiology is 1/2 mile on the right



Receipt of Privacy Notice



Privacy Notice



Disclosure of Health Information



Medical Records Release Form

The Heart Center Cardiology

2375 Champions Blvd

Auburn, AL 36830

Phone: (334) 321-3700 Fax: (334) 487-7475

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The Heart Center Cardiology

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Auburn, AL 36830
(334) 321-3700

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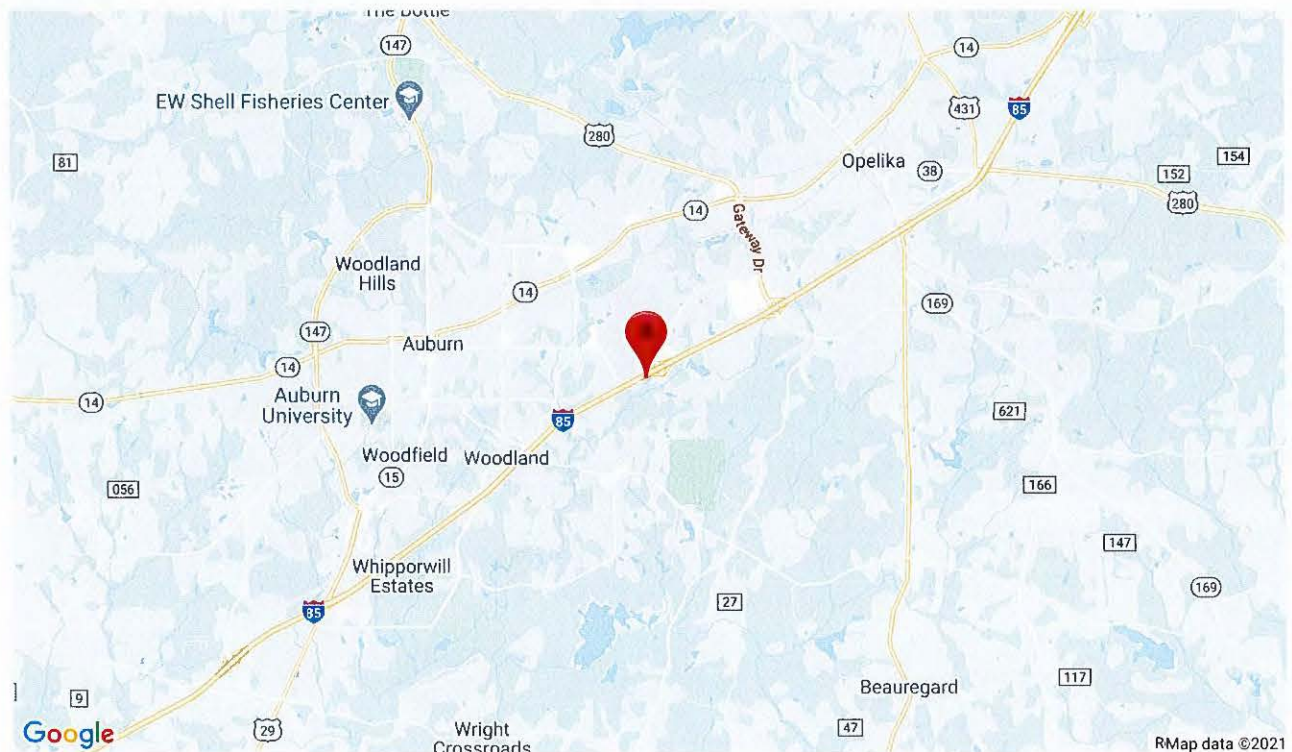
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Wedowee Clinic

(Tuesdays Only)
209 Main Street
Wedowee, AL 36278

Valley Clinic

(Tuesday & Every Other Thursday Only)
7 Medical Park N
Valley, AL 36854



The Heart Center Cardiology is located just off of I-85 at Bent Creek Road (Exit 57) in Auburn, Alabama.

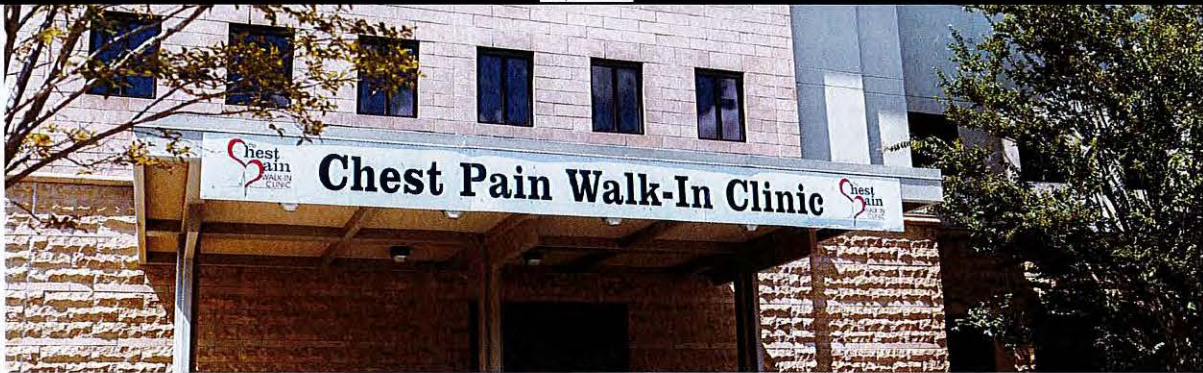
Exhibit E

1278 Champions Drive
Albany, NY 12243

Tel: (518) 321-1278



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Friday: 8:00 am - 2:00 pm

Exhibit

E

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LONG WAITS AT THE ER FOR CHEST PAIN ARE A THING OF THE PAST

ABOUT US

We are a walk-in clinic for individuals experiencing chest pain or discomfort. Upon your arrival, you will be promptly evaluated, including an EKG, labs, and stress test. If you are experiencing a cardiac event, transport will be arranged for immediate transport to EAMC, bypassing the long wait in the emergency department. For non-emergent scenarios, a treatment plan will be developed and discussed with the patient. When it comes to your heart, seconds can be the difference between life and death. You can skip the wait at the emergency room by visiting The Walk-In Chest Pain Clinic.

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Auburn, AL 36830
Tel: (334) 821-3760

Operating Hours

Monday - Thursday 8:00am - 4:00pm
Friday 8:00am - 4:00pm

© 2014 The Chest Pain Walk-In Clinic

 Español



 Dial 911 in the case of a medical emergency

Welcome to the The Heart Center Cardiology, PC Patient Portal

Make a One-Time Payment

QuickPay Code, Statement ID, or
Access Code



[Where can I find my code?](#)



By clicking **Make a Payment**, you
represent that you are authorized to
address the patient's billing matters.

Make a Payment

Sign in to Your Portal Account

We're using alternate ways to help you access
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offices with just one email and password.

Start by clicking the button below and
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ADDRESS

2375 Chancellors Walk
Arlington, VA 22202
Tel: (304) 221-0700

Operating Hours

Monday - Thursday 9am - 4pm
Friday 8:00 am - 12:00 pm



Our Team



Dr. John W. Mitchell



David Pate, CRNP



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- Diplomate, American Board of Cardiology
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- Associate, American College of Cardiology
- Member, American Board of Internal Medicine
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- Certified Registered Nurse Practitioner, Alabama
- Registered Nurse, Alabama
- Registered Nurse, Georgia
- Advanced Life Support Provider
- Basic Trauma Life Support Provider
- Certified Autotransfusionist
- Sigma Theta Tau International Nursing Honor Society
- American Association of Critical Care Nurses
- Alabama Nurse Practitioner Council



Tracy C. Williams, CRNP

Tracy Williams began her nursing career in 2006 after graduating from Auburn University with her Bachelor of Science degree in Nursing.

She spent the next five years at Mission Hospital, Asheville, NC where she worked as a Registered Nurse in various cardiac specialty units. During this time, she earned her Master's Degree in Nursing from Western Carolina University and graduated with honors in 2010.

Before joining The Heart Center's team in August 2019, she practiced for eight years as a Family Nurse Practitioner in a primary care rural health clinic in Union Springs, AL. She also spent an additional year in family medicine in Asheville, NC.

Licensure and Certifications

- Family Nurse Practitioner, American Academy of Nurse Practitioners, Certified
- Certified Registered Nurse, Alabama
- Certified Medical Examiner for the Federal Motor Carrier Safety Administration (DOT)
- American Association of Nurse Practitioners
- Advanced Practitioners for the River Region
- Nurse Practitioner Alliance of Alabama
- Sigma Theta Tau International Honor Society
- American Nurses Association

Exhibit F

Leg Health "Office Lab"	Brief description	Typically performed (office/hospital)	Safe in office setting	Level of Anesthesia	Equipment needed	Immediate higher level of care for complications
Peripheral angiography and interventional procedures (angioplasty, atherectomy)	Invasive imaging (uses catheters threaded through arterial system, usually through a groin or radial site) to find arterial blockages in arteries other than coronary arteries. Angioplasty is performed to open the blocked arteries.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	-Cath Lab -Documentation system -Image archival system (PACS) -Cardiology monitoring system -Patient monitoring equip -O2 monitoring -defibrillator	Yes. These procedures carry a real and finite risk of vessel or organ damage and perforation which often require urgent open surgical repair. Also, risk of anaphylaxis reactions to contrast agents.
L&R diagnostic heart cath	Invasive imaging (catheter inserted into blood vessel and passed through to the coronary arteries) to evaluate presence of coronary artery, valve or aortic disease.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	-Cath Lab -Documentation system -Image archival system (PACS) -Cardiology monitoring system -Patient monitoring equip -O2 monitoring -balloon pump -defibrillator	Yes. These procedures carry a real and finite risk of vessel or organ damage and perforation which often require urgent open surgical repair. Also, risk of anaphylaxis reactions to contrast agents.
Coronary angiography	Same as peripheral procedure, but detects blockages in coronary arteries.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	-Cath Lab -Documentation system -Image archival system (PACS) -Cardiology monitoring system -Patient monitoring equip -O2 monitoring -balloon pump -defibrillator	Yes. These procedures carry a real and finite risk of vessel or organ damage and perforation which often require urgent open surgical repair. Also, risk of anaphylaxis reactions to contrast agents.
ICD	Implantable device that monitors heart rhythm for patients at high risk of having lethal heart arrhythmia (Vtach, Vfib). Small incisions are made in the chest where the lead(s) and device are inserted. The lead is inserted through the incision and into a vein, then guided to the heart with the aid of the fluoroscopy machine. The tip of the lead is attached to the heart muscle, while the other end is attached to the pulse generator. The generator is placed in a pocket created under the skin in the upper chest.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	Fluoroscopy gantry -Patient monitoring equip -O2 monitoring -defibrillator	Yes. Bleeding, infection, allergic reaction, damage to blood vessel, or collapsed lung. *All patients who require defibrillator implantation of any kind are at higher risk and should have their procedure performed under the safest conditions available.

Exhibit

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Leg Health "Office Lab"	Brief description	Typically performed (office/hospital)	Safe in office setting	Level of Anesthesia	Equipment needed	Immediate higher level of care for complications
PM generator changes	Same as ICD and pacemaker implantation- just changes the battery.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Local or conscious sedation	Fluoroscopy gantry -Patient monitoring equip -O2 monitoring -defibrillator	Yes. bleeding, infection, allergic reaction, damage to blood vessel, or collapsed lung
pacemaker implantation	A local anesthetic is given to numb the area. An incision is made in the chest where the leads and pacemaker are inserted. The lead(s) is inserted through the incision and into a vein, then guided to the heart with the aid of the fluoroscopy machine. The lead tip attaches to the heart muscle, while the other end of the lead (attached to the pulse generator) is placed in a pocket created under the skin in the upper chest.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Local or conscious sedation	Fluoroscopy gantry -Patient monitoring equip -O2 monitoring -defibrillator	Yes. bleeding, infection, allergic reaction, or collapsed lung All patients who require pacemaker insertions or battery changes of any kind are at higher risk and should have their procedure performed under the safest conditions available. These patients are almost always elderly with multiple co- morbidities.
Implantable loop recorder insertion	device implanted just under the skin of a patient's chest to record the heart's electrical activity.	Hospital Cath Lab (not infrequently requires overnight admission)	No	Local or conscious sedation	-Patient monitoring equip -O2 monitoring -defibrillator	Yes. bleeding, infection, allergic reaction
Cardioversion	electrical shocks are delivered to the heart to convert an irregular or fast heart rhythm (arrhythmia) to a normal heart rhythm.	Hospital Cath Lab (not infrequently require overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	-Patient monitoring equip -O2 monitoring -defibrillator	Yes. Stroke, blood clots, life- threatening arrhythmia. Requires deep sedation and exposes the patient to the need for emergent airway support in addition to requiring significant nursing and physician oversight that should be documented and approved by credentialed anesthesiologists.
Infusaport placement	a small device which is utilized to deliver medications directly into the patient's bloodstream. a small catheter attached to a reservoir is placed under the skin with the soft catheter placed inside one of the chest veins. This allows the administration of medications or withdrawal of blood for	Hospital (not infrequently require overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	-Performed in OR -Patient monitoring equip -O2 monitoring -defibrillator -Instrumentation -Sterilizing equipment -appropriate air exchanges	Yes. Venous malpositioning of catheter and perforation with arterial injury, pneumothorax, hemothorax, thoracic duct injury, cardiac tamponade.

Leg Health "Office Lab"	Brief description	Typically performed (office/hospital)	Safe in office setting	Level of Anesthesia	Equipment needed	Immediate higher level of care for complications
	testing without repeatedly having to stick the arm veins. <i>This procedure is done in the operating room, under sedation or a general anesthetic.</i>					
TEE	A transesophageal echocardiogram (TEE) is a type of <u>ultrasound</u> test. Involves placing a tube down your <u>esophagus</u> with an ultrasound device that takes a series of moving pictures of your <u>heart</u> . It can show if it makes clots when it pumps <u>blood</u> .	Hospital- Echo Lab (not infrequently require overnight admission)	No Possible risks of transesophageal echocardiograms include <u>bleeding</u> , <u>breathing</u> issues, or heart rhythm problems	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	-echo machine -TEE probe -Instrumentation -TEE scope -Sterilizing equipment	Yes. Bleeding or tearing of the esophagus, allergic reaction. Requires deep sedation and exposes the patient to the need for emergent airway support in addition to requiring significant nursing and physician oversight that should be documented and approved by credentialed anesthesiologists. In addition, acute methemoglobinemia is a known complication of aerosolized numbing agents for TEE and requires urgent administration of therapy to avoid life-threatening issues.
Pulmonary artery pressure recording devices	A sensor is implanted into pulmonary artery through right heart catheterization	Hospital - Cath Lab (not infrequently require overnight admission)	No	Conscious sedation up to deep sedation or general anesthesia based on ASA classification	Cath Lab CardioMems or similar device Documentation system -Image archival system (PACS) -Cardiology monitoring system -Patient monitoring equip -O2 monitoring -defibrillator	Yes. Abnormal or life-threatening heart arrhythmias, right bundle branch block, (the heart is unable to conduct electrical signals), knotting of the catheter, rupture of the pulmonary artery, severely reduced blood flow to part of the lung, <u>blood clots</u> causing a <u>stroke</u> , <u>endocarditis</u> (infection of the heart valves), infections of the catheter, bleeding at the insertion site
Atrial, ventricular and nodal ablation	Treatment for cardiac arrhythmias (AVNRT, Afib, A flutter, Vtach) A catheter is inserted into the heart. A special machine delivers energy through the catheter to tiny areas of the heart muscle that cause the abnormal heart rhythm.	Hospital. Cath Lab 4 hr procedure Majority stay overnight	No	Deep sedation or general anesthesia based on ASA classification	-Fluoroscopy gantry -Intracardiac ultrasound -Mapping system -Patient monitoring equip -O2 monitoring -defibrillator	Yes. Damage to the blood vessel, bleeding, formation of a blood clot or blood collection (hematoma) Dislodging of the pacemaker lead,

Leg Health "Office Lab"	Brief description	Typically performed (office/hospital)	Safe in office setting	Level of Anesthesia	Equipment needed	Immediate higher level of care for complications
	<p>This energy disconnects the pathway of the abnormal rhythm.</p> <p>Ablation can also be used to disconnect the electrical pathway between the upper chambers (atria) and lower chambers (ventricles) of the heart. The type of ablation performed depends upon the type of arrhythmia.</p> <p>Involves insertion of several catheters through a small incision into a large blood vessel, and it may be necessary to use both an artery and a vein. A transducer is inserted through one of the catheters so an intracardiac (inside your heart) ultrasound can be performed during the procedure. The ultrasound allows the doctor to view the structures of the heart.</p>					<p>puncture in the heart wall.</p> <p>EP ablation procedures often require trans-septal puncture for completeness. This fact may not be known until the procedure is underway. Significant operator and imaging skill is required for successful completion and complications can be quickly life-threatening.</p> <p>VT ablation almost exclusively involves patients with severely reduced cardiac function and are at risk for severe compromise during the procedure.</p>

***Note:** Cardiac patients are inherently at higher risk due to age, high prevalence of comorbidities and baseline reduced cardiac reserve. Any procedure on a high-risk population becomes high-risk. These procedures, when performed in an office setting vs. a hospital further increase the risk and compromise safety of the patient, with no obvious patient benefit. All procedures should have a clear and defined robust QA and PI protocol in place to insure quality.

Exhibit G



Exhibit

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 Chest Pain Walk-In Clinic