

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.*

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.

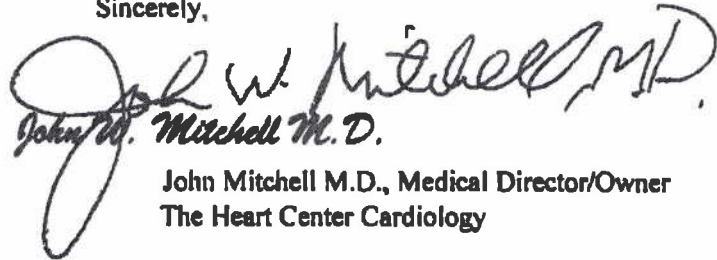
An electronic payment of \$1,000.00 for the filing fee with respect to a request for a reviewability determination will be sent today via the SHPDA online payment portal.

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,

A handwritten signature in black ink that reads "John W. Mitchell M.D.". The signature is written in a cursive style with a large, looping initial "J".

*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 29<sup>th</sup> day of October 2020.

Notary Public Samantha Rowley

My commission expires 4/7/2022