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

April 4, 2019



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

RV2019-037

St. Vincent's Blount 150 Gilbreath Drive Oneonta, AL 35121 RECEIVED
Jun 04 2019

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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

St. Vincent's One Nineteen 7191 Cahaba Valley Road, Suite 101A Birminaham, AL 35242

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:

- 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

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

St. Vincent's One Nineteen 7191 Cahaba Valley Road, Suite 101A Birmingham, AL 35242

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.
- 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

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 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,

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

July 26, 2019



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

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> 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 Marsai:

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.

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 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

	SUBSCRIBED AND SWORN to before me this day of August, 2019
	Panela Drynn
9	Notary Public My commission expires: (30) 20 2 3 **********************************
	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, MD - Secretary
	SUBSCRIBED AND SWORN to before me this day of
	Notary Public My commission expires: 4 30 20 23 ***********************************
	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, MD - Treasurer
A STATE OF THE PARTY OF THE PAR	SUBSCRIBED AND SWORN to before me this day of August, 2019 Panela Duyna Notary Public 41 30120 32
	My commission expires:
	Wynin Notary Public, Alabama State At Large My Commission Expires 4 3012023

Robert E. Foster, M.D. President