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RV2023-005  
**RECEIVED**  
**Nov 17 2022**

STATE HEALTH PLANNING AND  
DEVELOPMENT AGENCY

November 17, 2022

Via email to [shpda.online@shpda.alabama.gov](mailto:shpda.online@shpda.alabama.gov)  
And U.S. First Class Mail

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

Re: *Request for Non-Reviewability Determination for Heart Group of the Eastern Shore, P.C.*

Dear Emily:

Attached please find a Request for Non-Reviewability Determination we are filing on behalf of Heart Group of the Eastern Shore, P.C.. The filing fee for this request is being paid this date through the SHPDA Electronic Payment Portal. Please let me know if you have any questions or need any additional information.

Thank you for your consideration.

Respectfully,

HAND ARENDALL HARRISON SALE, LLC

A handwritten signature in blue ink, appearing to read 'Mark T. Waggoner', written over a blue ink stamp of the same name.

Mark T. Waggoner

MTW/vb  
Enclosure

CC: Christopher S. Williams (*Of the Firm*)



RV2023-005

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Nov 17 2022

STATE HEALTH PLANNING AND  
DEVELOPMENT AGENCY

150 S. Ingleside St., Building 4  
Fairhope, AL 36532  
(251) 990-1920  
(251) 990-1921 Fax

**Cardiology Specialties:**

Adult Cardiology • Echocardiography • Nuclear Cardiology  
Pacemaker • Peripheral Cardiology

**Michael S. Pursley, M.D., F.A.C.C.**  
**Glenn Harris, M.D., F.A.C.C.**  
**Elizabeth Key, PA-C**  
**Michael S. Charles, CRNP**

November 17, 2022

Hon. Emily T. Marsal  
Executive Director  
State Health Planning and Development Agency  
RSA Union Building  
100 N. Union Street, Suite 870  
Montgomery, Alabama 36104  
[Shpda.online@shpda.alabama.gov](mailto:Shpda.online@shpda.alabama.gov)

Re: Request for Non-Reviewability Determination for Heart Group of the Eastern Shore, P.C.

Dear Ms. Marsal:

Heart Group of the Eastern Shore P.C. ("HGES") seeks to acquire a GE cardiac PET/CT system to better serve our patients in need of evaluation for coronary artery disease. We seek to establish a Cardiac PET/CT MPI program with CardioGen-82® (Rubidium Rb 82 Generator) for use in positron emission tomography (PET) myocardial perfusion imaging (MPI). Rubidium Rb 82 chloride injection is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the myocardium under rest or pharmacologic stress conditions to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary artery disease.

Cardiac PET/CT MPI has been shown to outperform SPECT MPI for determination of coronary artery disease. This modality will support our organization by providing an accurate and cost-effective means of diagnosing and managing patients with coronary artery disease.

Adopting this technology will assist our facility in meeting the American Society of Nuclear Cardiology (ASNC) Recommendations for Reducing Radiation Exposure in Myocardial Perfusion Imaging and the ASNC and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET.

Our current diagnostic offerings with SPECT imaging contribute to lower sensitivity and specificity, diagnostic accuracy, and interpretive confidence when compared to the capabilities of PET imaging. As a result, some patients may receive inappropriate downstream testing, which increases cost of care and inconvenience to the patient. Additional benefits of PET/CT MPI include decreased patient staff exposure to radiation, increased departmental efficiencies and higher rates of patient satisfaction.

Pursuant to Ala. Admin. Code r. 410-1-7-.02, HGES hereby requests 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 for this new office-based equipment that will be located at 150 Ingleside Street Suite 4, Fairhope, Alabama 36532. HGES is a physician practice owned solely by Dr. Michael S. Pursley, M.D. Dr. Glenn Harris also works for HGES and may use the equipment for HGES patients. No other healthcare facility has a financial interest in HGES. The scanner shall be acquired and owned by HGES. The service area for this request is Baldwin County, Alabama.

Our goal is to demonstrate that this request falls within the criteria of a Physician Office Exemption outside of the thresholds established for CON review. Offices of private physicians are not "health care facilities" pursuant to Alabama 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" pursuant to Alabama Code § 22-21-260(8).

This equipment will be used as part of the HGES's private medical practice and consistently with the Physician Office Exception standards set forth in Alabama Code § 22-21-260(6) and further defined by the Alabama Supreme Court in *Ex parte Sacred Heart Health Systems, Inc.*, 155 So. 3d 980, 988 (Ala. 2012). Specifically:

1. The proposed services and related equipment shall be used exclusively by physicians of the HGES for the care and treatment of its patients.
2. The proposed services and related equipment shall be performed and used exclusively at the HGES's office in Fairhope.
3. All patient billings related to such services will be done through or expressly on behalf of HGES.
4. At no time will the equipment and services identified for these office-based procedures be used for inpatient care nor by, through, or on behalf of any healthcare facility or any other practice other than HGES.

In addition, the following information is being provided as required by SHPDA Rule 410-1-7-.02:

1. Name of company seeking the reviewability determination: **Heart Group of the Eastern Shore, P.C.**
2. Address and contact information for the authorized company representative seeking the determination: **Michael S. Pursley, M.D. 150 Ingleside Street Suite 4, Fairhope, Alabama 36532**
3. Service area for the proposed service/equipment: **Baldwin County, Alabama**
4. Any new/additional services to be provided under the proposed project: **Cardiac PET/CT MPI Program**


5. Approximated costs of the proposed project are:
  - a. Total cost of new medical equipment purchased or leased for the office-based procedures: **\$1,282,000**, including GE PET Scanner, Bracco generator and Infusion System
  - b. Estimated annual first year operating cost: **\$152,000** including:
    - Stress system, monitor, case, supplies: \$16,000
    - Employee wages: \$136,000
  - c. Capital costs: Renovation/Construction costs: **\$262,000**
6. Disclosure of financial interests in the entity requesting the reviewability determination held by any other healthcare facilities or groups. **None**
7. Attestation by an officer, partner or authorized agent of the company having knowledge of the facts disclosed in the request: **See below.**

I believe our request meets the criteria established by the Alabama Supreme Court for the Physician Office Exemption. I also confirm that this addition of services and equipment within the HGES private medical practice will not exceed any of the CON expenditure thresholds, nor do I believe it will constitute a "new institutional health service" under Ala. Code § 22-21-263.

Payment of the \$1,000 filing fee for this request of non-reviewability determination will be submitted through the SHPDA Electronic Payment Portal in accordance with Ala. Admin. r. 410-1-3-.09.

Affirmation of Requesting Party:

The undersigned, Michael S. Pursley, M.D., being first duly sworn, hereby makes oath and affirms that he is the owner of the Heart Group of the Eastern Shore, P.C., 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

Sworn to and subscribed before me this 17 day of November, 2022.



  
 \_\_\_\_\_  
 NOTARY PUBLIC  
 My commission expires: 5/23/23