MISSISSIPPI STATE DEPARTMENT OF HEALTH DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT FEBRUARY 15, 2021

CON REVIEW NUMBER: HG-PET-1220-010

BAPTIST MEMORIAL HOSPITAL – UNION COUNTY, INC.

OFFERING OF MOBILE POSITRON EMISSION TOMOGRAPHY (PET) SERVICES

CAPITAL EXPENDITURE: \$0.00

LOCATION: NEW ALBANY, UNION COUNTY, MISSISSIPPI

STAFF ANALYSIS

I. PROJECT SUMMARY

A. <u>Applicant Information</u>

Baptist Memorial Hospital – Union County, Inc. is a not-for-profit acute care hospital whose parent company is Baptist Memorial Health Care Corporation of Memphis, Tennessee. The facility is licensed for 153 beds with eighty-five (85) set up and staffed, including twelve (12) swing-beds. Baptist Memorial Hospital – Union County, Inc. is governed by a board of six (6) officers and directors. On October 28, 2020, the Mississippi Office of the Secretary of State issued a Certificate of Good Standing for the facility certifying that Baptist Memorial Hospital – Union County, Inc. is in good standing to do business in Mississippi.

B. Project Description

Baptist Memorial Hospital-Union County, Inc. ("BMHUC") requests Certificate of Need ("CON") authority to offer Positron Emission Tomography (PET) services for residents in General Hospital Service Area 2. The applicant proposes that PET/CT scanning services will be implemented utilizing mobile equipment at the hospital. BMHUC certifies that no construction, renovation, or capital cost will be necessary as a dock complete with utilities for the mobile van is in place. The applicant states Alliance HealthCare Services, Inc., formerly Alliance Imaging, Inc. ("Alliance") will own and operate a GE Discovery St 8 on an Oshkosh Specialty Trailer VIN: 1S9FS482871183175. The application contains documenting evidence of Alliance's approval to operate such equipment.

The applicant states PET scanning services are not available in the community and patients must travel to other cities for services. The applicant further states mobile technology will cost-effectively provide access to diagnostic PET without additional capital investment. Furthermore, the scanning modality may reduce unnecessary or more invasive techniques. BMHUC asserts no increase in staff composition is necessary for the implementation of the project.

The applicant anticipates the project will be completed by March 2021. No capital expenditure is requested for the project.

The application contains a letter dated December 16, 2020, documenting the Mississippi State Department of Health (MSDH) Division of Health Facilities Licensure and Certification approval for PET services at the hospital.

II. TYPE OF REVIEW REQUIRED

This project is reviewed in accordance with Section 41-7-173, 41-7-191(1)(d)(xv), and 41-7-193 of the Mississippi Code of 1972, Annotated, as amended, and duly adopted rules, procedures, plans, criteria, and standards of the Mississippi State Department of Health. MSDH will also review applications for CON according to the general criteria listed in the *Mississippi Certificate of Need Review Manual, September 1, 2019, Revision*; all adopted rules, procedures, plans, criteria and standards of the MSDH; and the specific criteria and standards listed below. The Department reviews projects for the provision of PET services if the proposed provider has not provided such service on a regular basis within the period of twelve (12) months prior to the time such service would be offered, regardless of the capital expenditure.

In accordance with Section 41-7-197(2) of the Mississippi Code 1972, Annotated, as amended, any affected person may request a public hearing on this project within ten (10) days of publication of the staff analysis. The opportunity to request a hearing expires on February 25, 2021.

III. CONFORMANCE WITH THE STATE HEALTH PLAN AND OTHER ADOPTED CRITERIA AND STANDARDS

A. State Health Plan (SHP)

The FY 2020 State Health Plan contains criteria and standards which the applicant is required to meet before receiving CON authority for the offering of fixed or mobile PET services. This application is in substantial compliance with the applicable policy, criteria and standards stated in the Plan for the offering of PET services.

Certificate of Need Criteria and Standards for Offering of Fixed or Mobile Positron Emission Tomography (PET) Services including Cardiac only PET Scanner

SHP Criterion 1 - Minimum Procedures

The applicant states Alliance Healthcare Services Radiology is placing BMHUC on an existing route with a unit that has CON approval. The applicant further states the route is currently providing more than 1,000 procedures annually. The applicant states the historical volume on this route since 2016 is as follows:

2019 – 1,232 scans 2018 – 845 scans 2017 – 770 scans 2016 – 797 scans

SHP Criterion 2 – PET Equipment Utilized by Multiple Providers

The applicant submits the facilities on the route and their 2021 expected volumes are as follows:

Monday - Merit Health Central-Jackson - 180/year Tuesday - Bethesda Cancer -Clarksdale - 350 Wednesday - Baptist Union County - 500

Thursday - Open day

Friday - Delta Regional-Greenville - 240

According to the applicant, on Saturday the unit alternates between FCI Forrest City, AR week 1 with 240 scans/year, and AR Department of Corrections – Malvern, AR week 2 with 240 scans/year, then repeats.

See SHP Criterion 1 above for the historical volume of the route.

SHP Criterion 3 – Quality Control and Environmental Requirements

The applicant submits Alliance will provide service on a mobile route and will continue to provide the environmental requirements monitored by the state.

SHP Criterion 4 – Division of Radiological Health Approval

BMHUC asserts the mobile route is active, and that the mobile pad has been approved and is operational at the hospital.

SHP Criterion 5 – Provision of On-Site Medical Cyclotron

The applicant states Alliance provides all necessary radiopharmaceuticals as approved for the mobile route.

SHP Criterion 6 – Staffing Requirements

- a. Fixed PET unit. The applicant asserts Alliance provides all necessary qualified staff to operate the PET/CT as necessary for the existing CON approved mobile route.
- **b.** Cyclotron on site. The applicant certifies a cyclotron is not part of the site.
- **c. Qualified engineering and physics personnel**. According to the applicant, Alliance will provide these personnel.
- d. Qualified radiation safety personnel. According to the applicant, qualified

radiation safety personnel will be provided by Alliance.

- **e.** Certified nuclear medicine technologists. As stated above, the applicant asserts Alliance will provide all necessary staff to operate the PET/CT.
- **f.** Other appropriate personnel. The applicant asserts Alliance provides all appropriate personnel for the mobile PET services equipment.

SHP Criterion 7 - Management of Medical Emergencies

The applicant submits BMHUC is an acute care hospital with an Emergency Department and an Ambulance Service available for medical emergency response. The applicant states medical emergencies will be managed in the PET unit in conformity with accepted medical practice.

SHP Criterion 8 – Accommodating Referred Patients

The applicant submits appointments will be made through BMHUC for all patients. The applicant also states the hospital will accept appropriate referrals from other local providers; patients will be accommodated to the fullest extent possible; and patients will be prioritized according to standards of need and appropriateness of service rather than source of referral.

SHP Criterion 9 – Medical Necessity

The applicant affirms that protocols will be established to assure that all clinical PET procedures performed are medically necessary and cannot be performed as well by other, less expensive, established modalities.

SHP Criterion 10 - Notification of Procedures Offered

The applicant affirms BMHUC will maintain a full listing of all currently approved and appropriate procedures which can and should be performed using PET. The applicant affirms BMHUC will make the list available for use by referring physicians.

SHP Criterion 11 – Data Requirements

The applicant affirms BMHUC will keep the required data regarding PET service and will make the data available to MSDH upon request.

SHP Criterion 12 – CON Approval/Exemption for PET Equipment

The applicant provided written evidence that the PET/CT 80 equipment provider has CON approval.

The applicant provided affidavits from physicians who are supporters of the project. The applicant states based on historical utilization, the number of provider referrals

in the first year of operation as shown in the affidavits is 517. While the number from the affidavits is higher than that included in the Alliance Route for the first year (500), the applicant asserts the lower number is a conservative approach to ensuring the route maintain the 1,000 scan minimum requirement. BMHUC further states the hospital has used 534 scans in the financial worksheets to include industry estimates of increases of PET scans for oncology patients as shown in the article included in Exhibit 5 of the application. According to the applicant, the article appeared in late 2018 and states PET scans will increase by nine percent (9%) through 2021. The applicant further states if thirty-six (36) months are used through the end of 2021, in relation to the affidavits, the projection is 534 for Year One (517 x 1.09 = 563.53 over 3 years or approximately 1.29 per month; 1.29 per month x 13 months = 16.77 or 17 additional scans; affidavits (517) + projected increase (17) = 1534. The applicant asserts the activity in 2020 was heavily influenced by the COVID-19 pandemic.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, Revised September* 1, 2019; addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria contained in the manual.

GR Criterion 1- State Health Plan

The applicant asserts the project is in substantial compliance with applicable CON criteria, and standards contained in the FY 2020 Mississippi State Health Plan.

GR Criterion 2 - Long Range Plan

The applicant submits BMHUC's long-range plan is to meet the needs of the people it serves with the highest quality in a sophisticated, compassionate and caring environment. BMHUC states this project improves access for patients and all residents of the hospital's service area. Furthermore, the applicant states it is responsive to the needs of cancer patients in a growing service line led by physicians who have recently joined Baptist's Medical Group. The applicant also states that patients who are served by the hospital will have access to the service and more complete information stored in their electronic medical record.

GR Criterion 3 - Availability of Alternatives

- a. Advantages and Disadvantages: The applicant states BMHUC considered three alternatives to the proposed project: (1) maintain the current status; (2) acquire a PET/CT unit for the hospital; and (3) add service through a mobile PET/CT. These alternatives are discussed as follows:
 - 1. <u>Maintain the current status.</u> The applicant submits this alternative was rejected because it would not allow the hospital to effectively

meet the needs of the people it serves. The applicant further asserts growth in oncology visits requires attention; travel for frail chemotherapy patients can be difficult; and access to local PET services is justified by the number of referrals and the number of people requiring the service.

- Acquire a PET/CT unit for the hospital. The applicant states this alternative was dismissed since the need does not justify a permanent PET scanner. The applicant further states this proposal would not meet CON criteria and would have resulted in an inefficient service configuration with unacceptable expense and potential staffing difficulties.
- 3. Add service through a mobile PET/CT. The applicant submits sharing a mobile unit on an established route was the best practical solution for the need.
- **b. New Construction Projects.** The applicant affirms this criterion is not applicable for the proposed project.
- c. Beneficial Effects to the Health Care System: The applicant states the solution maximizes the benefits of sharing complex mobile technology to make existing resources more effective and efficient.
- **d. Effective and Less Costly Alternatives:** BMHUC asserts the selection chosen is the most effective alternative for providing PET service in the area.
 - i. Unnecessary Duplication of Services: The applicant states BMHUC will be able to provide high quality care in a sophisticated, compassionate, and caring environment.
 - **ii. Efficient Solution**: The applicant asserts the proposed project is the most efficient solution to meet the community's need.
- **e. Improvements and Innovations:** The applicant asserts the mobile PET/CT will provide patient access through the same program that provides therapeutic cancer services in the community.
- f. Relevancy. BMHUC submits the goal of this project is to provide a service responsive to the community's immediate and longer-term health care needs for cancer center services. The applicant further submits the growth in the hospital's cancer services will support the service. The applicant also submits federal and commercial payers are encouraging providers to provide services in the least expensive settings. The applicant states the course of the foreseeable future has been somewhat dimed by the COVID-19 pandemic, but the course is clearly set for making services accessible to the

populations who need them.

GR Criterion 4 - Economic Viability

- a. Proposed Charge: The applicant submits the sole member of BMHUC is Baptist Memorial Health Care Corporation ("BMHCC"). The applicant further states Alliance mobile PET equipment serves other BMHCC facilities including Baptist Memorial Hospital DeSoto. PET services are provided by PET units at BMH-Golden Triangle, Mississippi Baptist Medical Center in Jackson and BMH-North Mississippi in Oxford. The applicant states BMHCC has contracts with Commercial Insurance Carriers, Medicare and Medicaid. The applicant asserts proposed charges at BMHUC will be comparable to other BMHCC locations; reimbursement rates are established by Medicare and Medicaid; and that new federal rules also require transparent charges.
- b. Projected Levels of Utilization: The applicant asserts there are no other units in the service area. The applicant further states utilization levels will be consistent with the CON criteria and patients are currently being provided oncology services at the hospital.
- **c.** Financial Feasibility Study: The applicant affirms that a capital expenditure is not required for this project; therefore, this criterion is not applicable.
- **d. Financial Forecasts:** The applicant states BMHUC does not anticipate that actual operating results in the three-year period will significantly deviate from the economic forecast in this application. Furthermore, the applicant states the financial forecasts do not deviate significantly from historical utilization.
- e. Covered Expenses: The applicant states costs are tied to utilization, and the projections are based on the historical normal operations of BMHUC. The applicant states it does not anticipate the project will fail to meet revenue projections; however, BMHCC, the parent of BMHUC, has the financial resources needed to cover any unexpected expenses.
- f. Impact of Proposed Project on Health Care Cost: BMHUC submits no additional capital investment is required by this project. The applicant states the cost of travel will decrease for patients that are currently traveling long distances to receive PET scans. The applicant further states the project is not expected to have a material impact on governmental or private payors. The applicant states the project is meeting an existing need in the community.

GR Criterion 5 - Need for the Project

- a. Access by Population Served: The applicant asserts that the population for this project is patients of the hospital's cancer center. BMHUC further states physicians need the results of the PET/CT scans for treatment planning and the community needs access to the service. BMHUC is the only hospital in the county and the patient population includes medically underserved groups, including racial and ethnic minorities Medicaid recipients, and the indigent.
- **b. Relocation of Services**: Not applicable. The project does not propose the relocation or replacement of services.
- c. Current and Projected Utilization of Comparable Facilities: The applicant submits the primary service area for the hospital is Union County, followed by Tippah, Pontotoc and Benton. According to the applicant, those counties make up more than seventy-five percent (75%) of the BMHUC service area as determined by patient origin. Located in General Hospital Service Area 2 (GHSA 2), the applicant states the other locations of PET services in GHSA 2 include a mobile unit in Alcorn County and a fixed unit in Lee County. The applicant further states patients affected by this proposal are currently being provided cancer care services at BMHUC, which is the only hospital located in Union County.
- d. Probable Effect on Existing Facilities in the Area: The applicant asserts the request for a one day per week mobile PET at BMHUC is not anticipated to substantially effect units in other counties within GHSA 2. The applicant submits patients are currently being provided cancer care services at BMHUC.
- **e. Community Reaction**: The application contains affidavits from eight (8) physicians in support of the project.

GR Criterion 6 - Access to the Facility or Service

a. Access to Services. The applicant submits BMHUC is accessible to all residents of its service area and to others who schedule services or emergent needs at the hospital. The applicant further states BMHUC does not exclude patients because of race, age, sex, ethnicity or ability to pay, and medically underserved groups will continue to have access to all facilities and services available at the hospital, including the mobile PET/CT.

The following table shows the historical and projected estimated gross patient revenues of health care provided to charity/medically indigent patients for years one and two for the proposed project:

	Medically Indigent/ Percent	, , , , , , , , , , , , , , , , , , ,			
Historical Year	\$4,791,678.91	\$16,224,906.00			
2019	(1.77%)	(6.10%)			
Historical Year	\$4,715,632.30	\$11,971,418.00			
2020	(1.82%)	(4.62%)			
Projected Year 1	\$5,015,546.51	\$12,611,889.00			
	(1.82%)	(4.57%)			
Projected Year 2	\$5,025,577.61	\$13,286,625.00			
	(1.79%)	(4.72%)			

- **b. Existing Obligations:** The applicant submits that BMHUC does not have any obligations under any federal regulations requiring provision of uncompensated care, community service, or access by minority/handicapped persons.
- c. Unmet Needs of Medicare/Medicaid and Medically Indigent Patients: The applicant states all patient groups, particularly cancer patients, including medically underserved, will greatly benefit by more convenient access to the proposed PET service.
- **d.** Access to Proposed Facility: The applicant submits BMHUC admissions policies state that patients will not be denied access to the hospital or its services due to race, age, sex, ethnicity, or ability to pay.

e. Access Issues:

- **Transportation and Travel**: The applicant submits access to the mobile unit will not impact transportation and travel time to BMHUC.
- **ii.** Restrictive Admissions Policy: The application contains a copy of BMHUC Admissions Policy which ensures access to care by all groups.
- iii. Access to Care by Medically Indigent Patients: BMHUC insures access to medically indigent patients through its admissions policies and practices.
- iv. Operational Hours of Service: BMHUC states PET service will be operational one day per week from 8:00 a.m. to 5:00 p.m. with one (1) hour downtime for lunch.

GR Criterion 7 - Information Requirement

The applicant affirms that BMHUC will record and maintain, at a minimum the information regarding charity care, care to the medically indigent, and Medicaid populations as required by this criterion and make information available to the Mississippi State Department of Health within fifteen (15) business days of receipt.

GR Criterion 8 - Relationship to Existing Health Care System

a. Comparable Services. The applicant asserts Baptist Memorial Hospital-Union County is the only hospital in Union County with the closest BMHCC facility located in Lafayette County, which is in another General Hospital Service Area. The applicant states PET services will serve a growing number of cancer care patients at the hospital one day per week.

b. Effect on Existing Health Services

- i. Complement Existing Services: The applicant states cancer care patients will have access to the service at the same treatment location.
- ii. Provide Alternative or Unique Service: The applicant asserts the mobile PET will provide convenient access for patients of the hospital.
- iii. Provide a service for a specified target population: BMHUC states the primary population is oncology patients who are in need of diagnostic treatment planning service.
- iv. Provide services for which there is an unmet need: BMHUC submits the primary need is access to more comprehensive services with a consolidated electronic medical record.
- **c.** Adverse Impact. The applicant submits if the service is not made accessible, frail patients will continue to face travel and potentially additional expenses.
- **d.** Transfer/Referral/Affiliation Agreements. The applicant asserts BMHUC has agreements and access to other facilities within the Baptist Memorial Health Care System.

GR Criterion 9 - Availability of Resources

- **a. New Personnel.** The applicant states personnel are provided by Alliance.
- **b.** Contractual Services. The applicant states PET service will be provided by Alliance through contract with BMHCC which is the sole member of BMHUC.

- **c.** Existing Facilities or Services. The applicant states BMHUC has consistently demonstrated a satisfactory operational and staffing history, as evidenced, in part, by its accreditation by the Joint Commission.
- **d.** Alternative Uses of Resources. The applicant states only minimal operational costs are involved for a necessary service requested by patients and physicians.

GR Criterion 10 - Relationship to Ancillary or Support Services

- **a. Support and Ancillary Services.** The applicant asserts BMHUC has current support and services for the ED that will be maintained.
- **b.** Changes in Costs or Charges. The applicant states BMHUC does not project that this proposed project will result in a material change in costs or charges.
- **c.** Accommodation of Changes in Cost or Charges. The applicant submits personnel are provided.

GR Criterion 11 – Health Professional Training Programs

The applicant affirms the mobile service will not affect the health training needs but may improve opportunities for student experiences.

GR Criterion 12 – Access by Health Professional Schools

The applicant states BMHUC will work with health professional schools in order to offer appropriate access to cancer care experiences for health professional training programs.

GR Criterion 13 – Access by Individuals Outside Service Area

The applicant affirms this criterion is not applicable to this project. The applicant states most patients reside in BMHUC's primary or secondary service areas; however, patients from other areas will be admitted to the hospital programs.

GR Criterion 14 - Construction Projects

The applicant affirms this criterion is not applicable as the mobile pad is operational. Therefore, no construction is needed for the proposed project.

GR Criterion 15 – Competing Applications

There are no competing applications on file with the Mississippi State Department of

Health for the offering of mobile PET services. The applicant states it does not anticipate competing projects.

GR Criterion 16 - Quality of Care

- a. Past Quality of Care. The applicant submits BMHUC is accredited by the Joint Commission, licensed by the Mississippi State Department of Health, and certified for participation in the Medicare and Mississippi Medicaid programs.
- **b. Improvement of Quality of Care.** The applicant states the project will improve access and satisfaction for patients, families, and physicians.
- **c.** Accreditations and/or Certifications. As stated above, the applicant submits it is certified for participation in the Medicare and Medicaid programs, and is accredited by the Joint Commission.

IV. FINANCIAL FEASIBILITY

A. <u>Capital Expenditure Summary</u>

The proposed project does not require a capital expenditure.

B. Method of Financing

The project does not require a capital expenditure; therefore, this criterion is not applicable.

C. <u>Effect on Operating Cost</u>

The Hospital's three-year projected operating statement is presented at Attachment 1.

D. Cost to Medicaid/Medicare

The applicant projects the gross patient revenue cost to third party payors as follows:

Payor Mix	Utilization Percentage (%)	First Year Revenue (\$)
Medicare	69.00%	\$3,190,524.00
Medicaid	7.00%	\$345,082.00
Commercial	20.00%	\$941,876.00
Self Pay	3.00%	\$147,143.00
Charity Care	0.00%	\$0.00
Other	0.00%	\$0.00
Total	100.00%	\$4,624,625.00

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment. In a letter dated January 26, 2021, the Division of Medicaid responded:

Effective September 1, 2012, the Division changed the methodology by which it reimburses outpatient services so that the cost incurred subsequent to that date will no longer affect outpatient payments. Effective October 1, 2012, the Division changed the methodology by which it reimburses inpatient services so that the cost incurred subsequent to that date will only affect outlier payments. Therefore, payments resulting from this CON cannot be determined.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the offering of mobile or fixed PET services contained in the FY 2020 Mississippi State Health Plan and the Mississippi Certificate of Need Review Manual, September 1, 2019 Revision; and duly adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Division of Health Planning and Resource Development recommends approval of the application submitted by Baptist Memorial Hospital – Union County for the offering of mobile Positron Emission Tomography (PET) services.

Attachment 1

Baptist Memorial Hospital – Union County Three-Year Operating Statement (Project Only)							
		Year I		Year 2	Year 3		
Revenue							
Patient Revenue:							
Inpatient							
Outpatient	\$	4,624,625.00	\$	4,855,856.00	\$	5,087,088.00	
Gross Patient Revenue	\$	4,624,625.00	\$	4,855,856.00	\$	5,087,088.00	
Charity Care							
Deductions from Revenue	\$	3,930.425.00	\$	4,126,946.00	\$	4,323,468.00	
Net Patient Revenue	\$	694,200.00	\$	728,910.00	\$	763,620.00	
Other Operating Revenue							
Total Operating Revenue	\$	694,200.00	\$	728,910.00	\$	763,620.00	
Expenses							
Operating Expenses:					_		
Salaries	\$	0.00	\$	0.00	\$	0.00	
Benefits	\$	0.00	\$	0.00	\$	0.00	
Supplies	\$	0.00	\$	0.00	\$	0.00	
Services		\$ 0.00		\$ 0.00		\$ 0.00	
Lease		\$		\$		\$	
5	•	368,460.00	•	386,883.00	•	405,306.00	
Depreciation	\$	0.00	\$	0.00	\$	0.00	
Interest	\$	0.00	\$	0.00	\$	0.00	
Other	\$	10,269.00	\$	10,782.00	\$	11,296.00	
Total Expenses	<u>\$</u>	378,729.00	\$	397,665.00	\$	416,602.00	
Net Income (Loss)	\$	315,471.00	\$	331,245.00	\$	347,018.00	
Assumptions							
Inpatient days		0		0		0	
Outpatient days		0		0		0	
Procedures		534		561		587	
Charge/outpatient day		N/A		N/A		N/A	
Charge per inpatient day		N/A		N/A		N/A	
Charge per procedure	\$	8,660.00	\$	8,660.00	\$	8,660.00	
Cost per inpatient day		N/A		N/A		N/A	
Cost per outpatient day		NA		NA		NA	
Cost per procedure	\$	709.00	\$	709.00	\$	709.00	