DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT FEBRUARY 25, 2019

CON REVIEW: HG-NIS-0119-003

GPCH-GP, INC. D/B/A GARDEN PARK MEDICAL CENTER

PROVISION OF CARDIAC CATHETERIZATION AND

PERCUTANEOUS CORONARY INTERVENTION (PCI) SERVICES WITHOUT ON-

SITE OPEN-HEART SURGERY;

PROVISION OF PERIPHERAL VASCULAR CATHETERIZATION SERVICES; ACQUISITION OF EQUIPMENT TO PROVIDE CARDIAC CATHETERIZATION, PCI SERVICES, DIGITAL ANGIOGRAPHY SERVICES, AND PERIPHERAL VASCULAR CATHETERIZATION SERVICES (RELATED EQUIPMENT); AND RENOVATION OF ANGIOGRAPHY SUITE

CAPITAL EXPENDITURE: \$2,231,927

LOCATION: GULFPORT, HARRISON COUNTY, MISSISSIPPI

STAFF ANALYSIS

I. PROJECT SUMMARY

A. APPLICANT INFORMATION

GPCH-GP, Inc. d/b/a Garden Park Medical Center is a Delaware business corporation whose principal office is located in Nashville, Tennessee. GPCH-GP, Inc. d/b/a Garden Park Medical Center (Garden Park) is a 130-bed short-term, general acute care, hospital located in Gulfport, Mississippi and is an affiliate of HCA Holdings, Inc. (a 179 international hospital system commonly referred to as HCA). Garden Park's bed complement includes 121 acute care beds and nine (9) adult psychiatric beds. GPCH-GP, Inc. consists of three (3) directors and twenty eight (28) officers. Garden Park's management team consists of seven (7) administrative officers and a ten (10) member Board of Trustees.

Garden Park is certified to participate in the TRICARE and the Medicare and Medicaid programs and is accredited by The Joint Commission. The application included a Certificate from the Secretary of State's Office dated January 4, 2019 indicating that GPCH-GP, Inc. is in good standing with the State of Mississippi.

B. PROJECT DESCRIPTION

GPCH-GP, Inc. d/b/a Garden Park Medical Center ("Garden Park"), requests certificate of need (CON) authority to expand its cardiovascular and vascular services by (i) providing diagnostic cardiac catheterization services and percutaneous coronary intervention ("PCI") services without on-site open-heart surgery services; (ii) providing enhanced digital angiography services and peripheral vascular intervention services; (iii)

acquiring equipment necessary to provide such services; and (iv) renovating existing space in the hospital to house the catheterization lab, the control room, equipment and the holding area for a total estimated cost of \$2,231927 (the "Project").

The project entails renovation and reconfiguration of approximately 1,513 square feet of space located in the existing angiography suite and surrounding areas to house the catheterization laboratory. The applicant states that the space will also be reconfigured to house the Discovery IGS 7 system in its IGS 730 configuration, manufactured by GE. Discovery IGS 7 is a multi-purpose floor-mounted system designed to support a variety of interventional and diagnostic procedures. According to the applicant, this equipment will also replace Garden Park's existing digital angiography ("DA") equipment with new state-of-the-art equipment that has not only diagnostic capability but also peripheral vascular intervention capability. GE's Discovery IGS 7 includes the Mac-Lab IT Hemodynamic Recording system. In addition, Garden Park intends to include in their purchase of the Discovery IGS 7, the Carescape Patient Data Module and the Centricity Cardio Workflow without Physician Reporting. The applicant affirms that the net selling price for the proposed equipment is \$1,185,252.90.

The applicant projects that the project will require 3.6 additional full-time equivalent (FTEs) personnel at an estimated cost of \$278,580 for the first year of operation.

The applicant received site approval for the proposed facility from the Mississippi State Department of Health, Division of Licensure and Certification on October 15, 2018. Garden Park proposes to use Related Company Financing to fund the project. The applicant expects the capital expenditure will be obligated upon receipt of the CON and that the project will be complete within six months of receipt of the CON.

Garden Parks states that its final object of the proposed Project is to meet the needs of residents within Garden Park's service area who have or are suspected of having heart disease and/or peripheral vascular disease (PVD). Garden Park believes its ability to provide diagnostic catheterization services, PCI services, and peripheral vascular intervention(PVI) services will, among other things;

- (i) Lower death rates and reduce morbidity among persons experiencing a cardiac infarction:
- (ii) Provide the residents of Garden Park's service area and other residents residing in Cardiac Catheterization/Open Heart Surgery Planning Area ("CC/OHSPA") 9, especially those residing along and north of Interstate 10 and those residing in the rural areas of CC/OHSPA 9, an access point to receive primary PCI services more quickly in the event of an emergency;

- (iii) Provide the residents of Garden Park's service area and other residents residing in CC/OHSPA 9 an access point to receive elective PCI services, PVI services, and diagnostic catheterization services at a location more easily accessed;
- (iv) Add to Harrison County a provider of cardiac catheterization services, PCI services, and PVI services;
- (v) Provide a comprehensive heart rehabilitation program that will not only serve to enhance the health and quality of life of its patients with heart disease but will also reach out to the community to identify those with heart disease risks and provide such persons with appropriate education regarding their risks and methods for reducing them;
- (vi) Provide persons in danger of PVD with appropriate education regarding their risks of developing PVD and the methods for reducing such risks as well as providing persons who have been diagnosed with PVD with PVI services, information, and appropriate education in order to avoid the necessity of amputations; and
- (vii) Enhance the hospital's DA services.

Therefore, Garden Park states that the ultimate goal of this Project is to create a viable and robust (i) cardiac catheterization and PCI program (the "Cardiac Program") that will save lives, reduce morbidity and provide an additional access point to the residents of CC/OHSPA 9 to receive cardiac services, including cardiac rehabilitation services; and (ii) peripheral vascular disease intervention program (the "PVD Program") that will reduce the debilitating effects of PVD and lower the direct and indirect costs associated with PVD.

II. TYPE OF REVIEW REQUIRED

The Mississippi State Department of Health will review this project for the establishment of the Cardiac Program, enhanced PVD program, purchase of related equipment and renovation of Angiography Suite under the applicable statutory requirements of Sections 41-7-173, 41-7-191 (1)(d)(ii) and (f), 41-7-193 and 41-7-195, Mississippi Code of 1972, as amended, and duly adopted rules, procedures, plans, criteria, and standards of the Mississippi Department of Health.

In accordance with Section 41-7-197(2) of the Mississippi Code of 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 March 7, 2019.

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

A. State Health Plan (SHP)

The FY 2018 Mississippi State Health Plan (MSHP) contains policy statements, criteria and standards for Cardiac Catheterization Services and Open-Heart Surgery Services and the Acquisition or Otherwise Control of Cardiac Catheterization and Open-heart Surgery Equipment.

The *Plan* gives guidelines for all health planning in Mississippi. The goal of the FY 2018 MSHP is to improve access to cardiac care and to encourage the establishment of additional cardiac catheterization and open-heart surgery programs within the state that can serve the poor, minorities, and the rural population in greater numbers.

Garden Park proposes to provide cardiac catheterization and percutaneous coronary intervention ("PCI") services without on-site openheart surgery. The *FY 2018 Plan* defines PCI services in a hospital without on-site cardiac surgery as, and refers to, those therapeutic cardiac catheterization services involving primary and elective PCIs but not involving transseptal puncture, transthoracic left ventricular puncture, myocardial biopsy, and any other procedure that is currently defined as a structural heart disease procedure.

Certificate of Need Criteria and Standards for the Acquisition or Control of Diagnostic Cardiac Catheterization Equipment and/or the Offering of Diagnostic Cardiac Catheterization Services

SHP Need Criterion 1 - Minimum Procedures

An applicant proposing the establishment of diagnostic cardiac catheterization service only shall demonstrate that the proposed equipment/service utilization will be a minimum of 300 diagnostic cardiac catheterizations per year by its third year of operation.

Garden Park proposes to establish diagnostic cardiac catheterization services and PCI services without on-site cardiac surgery. The applicant proposes to provide a minimum of 300 cardiac catheterizations, both diagnostic and PCI, with at least 100 being total PCIs per year by its third year of operation. Please see additional discussion of need below.

SHP Need Criterion 2 - Staffing Standards

The applicant submits that Garden Park is an affiliate of HCA, one of the largest hospital systems in the world. The applicant states that of the 179 hospitals that comprise HCA, 161 provide cardiac catheterization and PCI

services to their patients. The applicant believes that with a huge reserve of experience on which to draw, Garden Park is well positioned to assume its responsibilities in this area of health care. Further, the applicant states that Garden Park has the ability and experienced support to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the cardiac catheterization and PCI program.

The application contained letters from five (5) cardiologists who will perform catheterization procedures at Garden Park upon its receipt of CON.

SHP Criterion 3 - Recording and Maintenance of Data

Garden Park affirms that it will record and maintain utilization data for diagnostic cardiac catheterization procedures (e.g. morbidity data, number of diagnostic cardiac catheterization procedures performed, and mortality data, all reported by race, sex, and payor status) and make such data available to MSDH annually.

SHP Criterion 4 – Referral Agreement

The applicant submits that Garden Park has in place formal transfer agreements with Ocean Springs Hospital and Tulane Medical Center, each of which provides cardiac service (including open-heart surgery). Copies of these agreements were provided in the application.

SHP Criterion 5 - Patient Selection

Garden Park submits that each patient will be reviewed to ensure that he or she meets the inclusion/exclusion criteria that are established by the hospital. The inclusion/exclusion criteria will be developed within the standards and criteria of the American College of Cardiology and approved by the cardiologists on staff at Garden Park. The applicant states that Garden Park will work with the cardiologists and other physicians at their hospital to coordinate and direct the establishment of protocols and procedures to ensure that patients who need open heart surgery or therapeutic catheterization services that are not PCI services are not catheterized at their hospital. Garden Park certified that only diagnostic cardiac catheterization and PCI procedures will be performed at the hospital.

SHP Criterion 6 – Regulatory Approval

Garden Park agrees not to utilize cardiac catheterization laboratory equipment or provide diagnostic cardiac catheterization services or PCI services prior to receiving CON approval.

Certificate of Need Criteria and Standards for the Acquisition or Control of Therapeutic Cardiac Catheterization Equipment for the performance of PCI Services in a Hospital Without On-Site Cardiac Surgery and/or

the Offering of PCI services in a Hospital Without In-Site Cardiac Surgery

SHP Need Criterion 1 – Minimum Procedures

The applicant proposes to provide diagnostic cardiac catheterization and PCI services in a hospital without on-site cardiac surgery. Garden Park asserts that it considered its patients diagnosed with cardiovascular disease and has consulted with cardiologists and other physicians on its medical staff. In addition, the applicant employed Daniel J. Sullivan (president of Sullivan Consulting Group, Inc.), an expert in health care planning, to evaluate and analyze specifically catheterization services in Harrison County, CC/OHSPA 9 and Mississippi as a whole, together with statewide and Gulf Coast population and usage trends with respect to the service.

Based on its own evaluation and emergency room visits, Mr. Sullivan's exhaustive analysis, and local cardiologists' projections, Garden Park states that it has "very conservatively" projected that it will perform a minimum of 299 catheterizations during its first year of operation, of which 98 will be PCIs; 451 during its second year, of which 148 will be PCIs, and 605 during its third year, of which 199 will be PCI procedures.

In order to project utilization of Garden Park's proposed program, Mr. Sullivan first determined the population that would experience the greatest improvement in access. Populations considered include residents in Harrison County north of I-10 and residents of Pearl River, Stone and Hancock counties, who currently must travel to existing providers along the coast in Harrison and Jackson counties. This population for the first three years of the operation of Garden Park's cardiac catheterization program is presented below:

Garden Park Medical Center Population with Enhanced Access to Catheterization Services

	2020	2021	2022
Harrison County North of I-10	79,567	80,350	81,155
Stone County	18,247	18,294	18,346
Pearl River County	55,396	55,430	55,474
Hancock County	47,928	48,224	48,531
Total Population	201,138	202,299	203,506

Sources: Application(Spotlight/Claritas)

Further, to determine the total number of cardiac catheterizations in this area, the 2016 rates of catheterization per 1,000 population, both diagnostic and therapeutic, were applied to the projected populations for 2020 through 2022, the expected first three years of Garden Park's program's operation. Using population data for 2016 from the U.S. Census Bureau and total procedures listed in the *FY 2018 MSHP*, Mr. Sullivan determined that the use rate of total caths per 1,000 for CC/OHSPA 9 in 2016 was 14.87 (7,260/488,283 X

1,000). However, to make a more conservative projection of utilization for 2020, 2021, and 2022, he used a use rate of 9.99 per 1,000. These projections are presented below:

Garden Park Medical Center Projected Cardiac Catheterization Utilization

	2020	2021	2022
Service Area Population	201,138	202,299	203,506
CC/OHSPA 9 Diagnostic			
Catheterizations per 1,000 – 2016	9.99	9.99	9.99
Projected Service Area Diagnostic	2,009	2,021	2,033
Catheterizations			
GPMC Project Market Share	10%	15%	20%
ODMO Projected Diamontic	004	000	407
GPMC Projected Diagnostic	201	303	407
Catheterizations			
CC/OHSPA 9 Therapeutic	4.00	4.00	4.00
Catheterizations	4.88	4.88	4.88
Per 1,000 – 2016			
Projected Service Area Therapeutic	981	987	993
Catheterizations	301	307	333
GPMC Project Market Share	19%	15%	20%
,			
GPMC Projected Therapeutic	98	148	199
Catheterizations (PCIs)			
CPMC Total Projected Cardian	200	AEA	eoe.
GPMC Total Projected Cardiac Catheterizations	299	451	605
Catheterizations			

Based on these projections, Garden Park believes that its catheterization program can conservatively achieve volumes above the 300 procedure annual target in the MSHP, including both diagnostic and PCI, with more than 100 of these procedures being PCIs by the second year of operation.

SHP Need Criterion 2 – Staffing Standards

The applicant submits that Garden Park is an affiliate of HCA, one of the largest hospital systems in the world. The applicant further submits that of the 171 hospitals that comprise HCA, 161 provide cardiac catheterization and PCI services to their patients. The applicant believes that with a huge reserve of experience on which to draw, Garden Park is well positioned to

assume its responsibilities in this area of health care. Further, the applicant states that Garden Park has the ability and experienced support to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the cardiac catheterization and PCI program.

The application contained letters from five (5) cardiologists who will perform catheterization procedures at Garden Park upon its receipt of CON.

SHP Need Criterion 3 – Staff Residency

Garden Park certifies that the medial staff performing PCI procedures shall be onsite within thirty (30) minutes as required by this criterion.

SHP Need Criterion 4 – Recording and Maintenance of Data

Garden Park affirms that it will record and maintain separate utilization data for diagnostic and PCI catheterization procedures (e.g. morbidity data, number of diagnostic and therapeutic cardiac catheterization procedures performed, and mortality data, number of diagnostic cardiac catheterization and PCI procedures performed, and mortality data, all reported by race, sex, and payor status) and make such data available to the Mississippi State Department of Health annually.

SHP Need Criterion 5 – Open-Heart Surgery

a. Formal Emergency Transfer Agreement

Garden Park submits that it has in place formal transfer agreements with Ocean Springs Hospital and Tulane Medical Center, each of which provides open-heart surgery. Garden Park further affirms that such transfer will be accomplished within 120 minutes from the onset of PCI complications to cardiopulmonary bypass. During such transfer, Garden Park affirms that the transporting of patients to the receiving hospital will include the capability of providing an intra-aortic balloon pump.

b. Minimum PCIs

The applicant submits that four (4) cardiologists have projected that they will perform PCIs at Garden Park. These cardiologists have projected a total of 222 – 242 PCIs at Garden Park, including 88 of which will be primary PCIs. Mr. Sullivan, in his analysis, projected that Garden Park will perform at least 98 PCIs its first year of operation. Thereafter, Garden Park expects to perform at a minimum 100 PCIs, both primary and elective, per year with at least 12 of such PCIs being primary PCIs. Garden Park asserts that in 2017, it had to transfer 127 patients to a hospital that offers PCI services and 133 patients from January – November 2018 were transferred, each for immediate PCI.

Garden Park states that it recognized and understands that in the event its cardiac catheterization and PCI services program does not meet the requirements set forth in this Need Criterion 5(b), §515.04 that the Department of Health can revoke the authority granted to Garden Park to provide such services.

c. Operators' Experience

Garden Park asserts that it has been assured by the primary operators who will perform the PCI services at the hospital that each has a life-time experience of greater than 150 total PCIs with acceptable outcomes as primary operator after completing a cardiology fellowship. The application contains letters from each cardiologist indicating that each has successfully completed an Interventional Cardiology fellowship.

d. Participation in "ST" Segment Elevation Myocardial Infarction

Garden Park affirms that it will participate in the STEMI Network.

e. Justification for a PCI Program

Garden Park states it is fully aware and agrees that there is no justification for a PCI program without on-site surgery to perform only elective procedures and affirms that its primary PCI services will be available 24 hours/365 days per year. Garden Park avers that, together with Dr. Payment, Dr. Quintana, Dr. Zayed and Dr. Baker, they stand ready immediately to provide at the outset of the catheterization program primary PCI services 24 hours per day for 365 days per year.

f. Educational Programs

Garden Park asserts that it is committed to providing the very best quality care to its patients and all residents of CC/OHSPA 9 and the State and this commitment reaches those who are currently underserved, whether because of their location in rural areas, race, sex, age or ability to pay. In addition, Garden Park states that as a part of its expanded cardiac program, it will provide its heart patients heart rehabilitation services which will extend also to those in the community who have had no cardiac event but who, with education, are willing to take the appropriate measures to lower their risk of heart disease and improve their chances of avoiding such an event.

g. Charity Care

Garden Park affirms that it currently provides a "reasonable amount" of indigent/charity care and that it will continue to do so.

h. Monthly Multi-disciplinary Meetings

Garden Park affirms that it will hold monthly multi-disciplinary meetings to evaluate patient outcomes, to review quality improvement data, and to identify and implement solutions for any operation issues.

i. Guidelines from the Society of Cardiovascular Angiography and Interventions

Garden Park affirms that its cardiac catheterization program with PCI services will meet the following guideline from the Society of Cardiovascular Angiography and Interventions (SCAI)-ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention or such sections' update(s), if applicable, at the time of filing the CON application:

- (i) Garden Park affirms that it will have available in the catheterization lab the equipment in Section 4.1.1 entitled "Equipment" and that such will be routinely tested;
- (ii) Garden Park affirms that it will have available adequate staff in the catheterization lab as set forth in Section 4.1.2 entitled "Staffing" and that such staff will be certified on both basic life support and advanced cardiovascular life support;
- (iii) Garden Park affirms that "time-out" procedures will be implemented as discussed in Section 4.1.3 entitled "Time-Out' Procedures"; and
- (iv) Garden Park affirms that it will operate a quality improvement program and participate in a national PCI registry as discussed in Section 7.1 entitled "Quality Performance: Recommendations."

SHP Criterion 6 – Applicants for PCI Services in a Hospital without On-Site Cardiac Surgery Capabilities Currently Providing Diagnostic Catheterization Services

Garden Park does not currently provide diagnostic catheterization services.

SHP Need Criterion 7 – Regulatory Approval

Garden Park agrees not to utilize cardiac catheterization laboratory equipment or provide cardiac catheterization and PCI services prior to receiving certificate of need approval as determined by the Mississippi State Department of Health.

Invasive Digital Angiography and Peripheral Vascular Intervention Services

SHP Need Criterion 1 – Staffing Requirements

The FY 2018 MSHP requires that an applicant for invasive DA services demonstrate that proper protocols for screening and medical specialty

backup are in place before services are rendered by personnel other than those with specialized training.

Garden Park affirms that before providing PVI services it will implement proper protocols for screening and will assure medical specialty backup is in place before services are rendered by personnel other than those with specialized training.

Garden further affirms that such protocols will include, but not be limited to, having prior arrangements for backup from:

- **a.** a cardiologist/cardiosurgeon for procedures involving the heart;
- **b.** a neurologist/neurosurgeon for procedures involving the brain; and
- **c.** a vascular surgeon, cardiologist, radiologist of nephrologist credentialed and accredited for interventional peripheral vascular procedures.

SHP Need Criterion 2 – CON Exemption

Garden Park submits that it received authority to provide digital angiography services many years ago and, upon receipt of a CON to provide diagnostic catheterization services and PCI services, it will acquire the catheterization equipment and renovate the radiology suite. The new catheterization equipment, the Discovery IGS 7, is configured to allow the provision of PVI procedures. In addition, the applicant states that this new equipment will replace the current digital angiography equipment at Garden Park.

Certificate of Need Criteria and Standards for Construction, Renovation, Expansion, Capital Improvements, Replacement of Health Care Facilities, and Addition of Hospital Beds

SHP Need Criterion 1- Acute Care Bed Need

a. Projects Which Do Not Involve the Addition of any Acute Care Beds: The applicant states that although this project does not involve renovation of the emergency department, it will impact its emergency department by enabling Garden Park to address and assist immediately those who arrive in the emergency room in need of life-saving PCI.

Garden Park submits that it currently participates in the statewide trauma system as a Level III trauma hospital and is one of only two Level III trauma hospitals in Mississippi without cardiac catheterization services and the only one with more than 100 beds without the service.

The application contains a letter from AMR, the local EMS provider for Harrison and Hancock counties. The letter states that: "The geographical location of a proposed Garden Park Medical Center cardiac catheterization lab may reduce treatment times when these services are needed for citizens whom [sic] that

reside or work in the northern reached of Harrison and Hancock counties, as well as those residing in the eastern and northeast most portion of Harrison County."

b. Projects Which Involve the Addition of Beds: The applicant affirms that the proposed project does not involve the addition of beds; therefore, this criterion is not applicable to the proposed project.

SHP Need Criterion 2 – Bed Service Transfer/Reallocation/Relocation

The applicant affirms that Need Criterion 2 is not applicable to the proposed project.

SHP Need Criterion 3 – Charity/Indigent Care

Garden Park affirms that it currently provides a "reasonable amount" of indigent/charity care and that it will continue to do so.

SHP Need Criterion 4 – Cost of Project

- **a. Cost Per Square Foot:** As shown in the Financial Feasibility Section of this Staff Analysis, the cost of this project is \$2,231,927, which includes a 15% contingency reserve for both the cost of the renovation and the cost of the equipment. The square footage cost for renovation, including the contingency reserve, is \$574.28. The applicant submits that the renovation involves 1,513 square feet of space for a catheterization lab, the cost of which is higher than the cost to renovate other areas in a hospital that are not dedicated to treatment areas. *RSMeans Construction Cost Data* does not compare costs for hospital renovation projects.
- **b. Equipment Cost:** The applicant affirms that the equipment cost for the proposed project does not exceed the median cost for equipment of similar quality by more than 15%.

SHP Criterion 5 – Project Specifications

- a. Gross Square Footage: The applicant states that the gross square footage of the one-room catheterization suite is 1,513 square feet of renovation. The applicant states this compares favorably with similar one-room catheterization suites at other HCA hospitals.
- b. Architectural Design: The applicant states that the building in which the hospital is housed was constructed as a replacement hospital in FY 2000. As a result, Garden Park's architectural design was developed with knowledge of current healthcare needs and trends. The applicant affirms that there is no restraint on the proposed project created because of the hospital's architectural design.
- **c. Special Considerations:** The applicant affirms that Garden Park is located north of Interstate 10 in Gulfport. The applicant states that it is the only

hospital in the lowest three counties of Mississippi located north of I-10. This location positions Garden Park in the best position in the event of a hurricane. The applicant affirms that Garden Park is and will continue to be committed to the safety of its patients, including keeping them safe from the violent storms that are not unexpected along the Gulf Coast.

SHP Criterion 6 – Renovation/Expansion Justification

Garden Park asserts that the cost of the proposed renovation does not exceed 85% of the cost of a replacement facility.

SHP Criterion 7 - Need for Service

See discussion above regarding the service specific criteria and standards regarding the provision of diagnostic cardiac catheterization, PCI services and PVI services and the acquisition of cardiac catheterization equipment.

B. <u>General Review (GR) Criteria</u>

Chapter 8 of the *Mississippi Certificate of Need Review Manual, April 9, 2017, Revision,* addresses general criteria by which all CON applications are reviewed.

GR Criterion 1 - State Health Plan (SHP)

The project has been reviewed for consistency with the *FY 2018 Mississippi State Health Plan* and was found to be in substantial compliance with the Plan and the Department's rules and regulations, as discussed above.

GR Criterion 2 - Long Range Plan

The applicant states that because of its location, Garden Park has for years realized the need for it to provide a heart program that is responsive to the needs of its community. The applicant asserts that the need for another life-saving catheterization program in Harrison County is obvious, and it believes that Garden Park is the appropriate provider to establish such a program, given its location in conjunction with the Coast's growing and shifting population.

GR Criterion 3 - Availability of Alternatives

Garden Park submits that it considered the following alternative approaches to the project:

(i) Maintain the status quo: Given the number of patients who arrive at the hospital's emergency room in need of an immediate PCI, Garden Park states it quickly rejected this alternative.

Furthermore, it states that for many years, various physicians, stressing the need for catheterization services in Garden Park's accessible location, have encouraged Garden Park to provide catheterization services.

- (ii) Apply for diagnostic catheterization only: Garden Park states that because such a limited service would not address the need in the community and because the delivery of PCI services without onsite open-heart surgery has now been determined to be very safe, this alternative was also quickly rejected.
- (iii) Apply for catheterization services and open-heart surgery services: Garden Park indicates that it rejected this alternative because many studies have demonstrated that PCI procedures are safely performed in hospitals without open-heart surgery. Furthermore, PCI procedures are far less invasive than open-heart surgery with far less recovery time, and it is now well established that PCI can be as effective for many patients as open-heart surgery in providing revascularization. In addition, it states that Garden Park has transfer agreements in place with other hospitals that provide open-heart surgery services.
- (iv) Replace its DA equipment only: Garden Park states that it considered upgrading its DA equipment without seeking cardiac catheterization services but rejected this alternative for the reasons stated above. It further states that by utilizing the Discovery IGS 7 to perform also invasive DA and PVI services, the hospital will be able to provide a much needed service in the State that has an extremely high prevalence of the health conditions that pace people at risk for PVD without any extra equipment cost.

The applicant states that there is not a less costly alternative to this project, since Garden Park will be able to utilize such equipment to replace its aging DA equipment and to provide cardiac catheterization service, PCI services, enhanced DA services and PVI services.

The applicant does not believe the project is an unnecessary duplication of services because, Harrison County, the second most highly populated county in the State, has only one catheterization program with PCI services and only one PVI program.

GR Criterion 4 - Economic Viability

According to the applicant, reimbursement compares favorably with similar facilities in the area and the services provided will be in compliance with the regulations for each payor source. Overall, the net operating income for a catheterization procedure, diagnostic catheterization, PCI, or a PVI and whether provided for an inpatient or an

outpatient, averages only \$2,632 per procedure ($$892,143 \div 339$ (PCI and PVI procedures) = \$2,632).

The applicant states that the hospital utilized a conservative approach in projecting the number of cardiac catheterization procedures Garden Park will perform. The applicant projects to perform 299 catheterizations, including PCIs, during the first year of operation, 451 during the second year of operation and 605 during the third year of operation. In addition, the applicant states that given the average number of catheterizations performed in the existing nine (9) catheterization labs in CC/OHSPA 9 as of 2015 is 807, Garden Park's program will not only be consistent with the current average utilization, it will have no adverse impact on the existing programs that provided a total of 7,260 catheterizations in 2016.

Garden Park submits that its confident in its projected revenues because such projections are conservative when one considers the cardiologists' projected number of catheterization procedures (637 – 657), the increase in the elderly population in Harrison County and CC/OHSPA 9, the high prevalence of PVD in the elderly, and the quality of services that Garden Park provides and will continue to provide. In addition, Garden Park is a part of HCA, and as such, Garden Park states it has access to many resources that ensure that it will be able to cover all of the project's expenses even if the project fails to meet the projected revenues.

The applicant provided a three-year projected operating statement. The total operating revenue over a projected three-year period, any income increases or decreases or net losses are shown in Attachment 1 of this document.

The application included a letter from Garden Park's Chief Financial Officer attesting to the financial feasibility of the project.

GR Criterion 5 - Need for the Project

Garden Park states that it provides services to all persons, including the elderly, low income persons, racial and ethnic minorities, women, handicapped persons and other underserved groups.

The applicant states that although the overall population of the State is expected to decrease between 2018 (2,614,616) and 2023 (2,602,766), the aging population as well as the overall population in Garden Park's service area is increasing. According to the applicant, the number of people in Harrison County aged 65+ in 2018 (27,739) is expected to increase by 16.1% by 2023 (32,204), and in CC/OHSPA9 that age cohort in 2018 (75,526) is expected to increase by 15.67% by 2023 (87,364). In addition, the applicant states that although in 2018 those aged 65+ in Harrison County comprised only 13.68% of the population, in 2023 they are expected to comprise 15.66% of the population. The applicant believes that this increase will require additional access to cardiovascular

care and care for those suffering from PBD, especially cardiac catheterization services, PCI services and PVI services.

The application contains a letter from the Chief Medical Officer at Garden Park, addressing the need for catheterization services at the hospital. The request is based on several factors:

- Gulfport, Mississippi is the second largest city in the state, and Garden Park Hospital is geographically situated at the second busiest interchange in the state. As a result, the ER volumes have increased each year; there are higher numbers of chest pain in patients with myocardial infarction who required transfer to other institutions;
- Without a cardiac catheterization lab, it is impossible to maintain an adequate number of active cardiologists on staff to help provide care to critically ill patients;
- 3) There is strong support for a catheterization lab at Garden Park from area cardiologists; and
- 4) Garden Park Medical Center is currently a Level III Trauma Center, as mandated by the State Board of Health. Because of its location and catchment area, Garden Park states it often receives high acuity "Alpha Trauma" patients with severe thoracic and vascular injuries that require subsequent transfer to a Level II or Level I Trauma Center. The applicant states that without a cath lab, it is unable to recruit and maintain vascular surgeons and cardiothoracic surgeons who are necessary in the treatment of many penetrating traumas as well as severe blunt traumas.

There are currently three facilities in CC/OHSPA 9 that provide both diagnostic catheterizations and PCI procedures. These facilities and their utilizations are as follows:

Catheterization Procedures in CC/OHSPA 9

Year	Memorial at Gulfport (4 Labs)	Ocean Springs (2 Labs)	Singing River (2 Labs)	Total (8 Labs)	Average Per Lab
2014	3,608	2,186	1,470	7,264	908
2015	3,791	2,322	1,550	7,663	958
2016	3,818	2,066	1,361	7,245	906

Sources: Application (2018 State Health Plan and Special Report for 2014)

The applicant states that one (1) other facility (Merit Health Biloxi) provides diagnostic catheterizations only. If added, the applicant states

that the number of catheterizations per lab, per year was 807 in 2016, 957 in 2015, and 818 in 2014. Garden Park's projected utilization of 299 cardiac catheterizations during its first year of operation, 451 during its second year of operation, and 605 during its third year of operation are conservative but not inconsistent with the current utilization and the expected population growth, particularly in CC/OHSPA 9, according to the applicant.

Garden Park states that the probable effect of initiating catheterization services that include PCI services without on-site open-heart surgery is that it will save lives, reduce morbidity and reduce coronary risks for persons who currently exhibit such risks because they suffer from obesity, inactivity, diabetes and/or hypertension.

The application contained eleven (11) letters of support from cardiologists, physicians with non-cardiology specialties, the ambulance company serving the Gulf Coast, and Gulf Coast public servants/consumers.

Memorial Hospital at Gulfport also submitted a letter in opposition to the proposed project. Memorial Hospital at Gulfport states that: if approved, this project will unnecessarily duplicate some of the services offered at its facility less than ten (10) miles away.

Garden Park states in its response that the proposed project is not an unnecessary duplication of services, as there is a need for the services requested in the Application. The applicant states the approval of the project will save lives and reduce morbidity that results from delays in providing a patient with immediate quality care.

GR Criterion 6- Accessibility

Garden Park states that all residents of the health planning service area, hospital service area or patient service area, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons and the elderly have access to the services of the existing facility and will continue to have access. Furthermore, Garden Park states it is certified by both Medicare and Medicaid, is in all of Mississippi's health exchanges, and provides its share of care to the indigent.

The following table indicates the percentage of gross patient revenue and actual dollar amount of health care provided to medically indigent and charity care patients for the last two years as well as the projected amount for the two years following completion of the project.

Garden Park Medical Center Gross Patient Revenue

	Medically	Charity	Medically	Charity Care
	Indigent (%)	Care (%)	Indigent (\$)	(\$)
Historical				
Year 2017	12.34%	2%	\$77,104,012	\$14,319,026
Historical				
Year 2018	9.6%	4%	\$62,139,140	\$24,811,428
Projected				
Year 1	9.1%	3%	\$65,326,285	\$23,331,811
Projected				
Year 2	10.0%	3%	\$77,975,211	\$25,450,573

Garden Park estimates that approximately 12.1% of its gross patient revenue will be attributable to medically indigent/charity care during the first year of operation of its catheterization lab.

Garden Park operates and will continue to operate 24 hours a day/ 7 days per week.

GR Criterion 7- Information Requirement

The applicant affirms that Garden Park will record and maintain the information required by this criterion and shall make the data available to the Mississippi State Department of Health within fifteen (15) business days of request.

GR Criterion 8 - Relationship to Existing Health Care System

As stated earlier, there are currently three (3) providers of cardiac catheterization services, both therapeutic and diagnostic, and one additional provider of diagnostic cardiac cath in CC/OHSPA 9. The table below shows the current providers and their utilization for the past three years.

CC/OHSPA 9
Cardiac Catheterization Utilization

			Total Catheterizations (Diagnostic and Therapeutic)		
Provider	County	Labs	2014	2015	2016
Merit Health Biloxi*	Harrison	1	100	50	15
Memorial Hospital at	Harrison	4	3,608	3,791	3,818
Gulfport					
Ocean Springs Hosp.	Jackson	2	2,186	2,322	2,066
Singing River Hosp.	Jackson	2	1,470	1,550	1,361
Total		9	7,364	7,713	7,260

CC/OHSPA 9 Therapeutic Catheterization Utilization (including PCI)

			Therapeutic Catheterizations (Including PCIs)		
Provider	County	Labs	2014	2015	2016
Merit Health Biloxi*	Harrison	1	-	-	-
Memorial Hospital at	Harrison	4	1,058	1,112	1,074
Gulfport					
Ocean Springs Hosp.	Jackson	2	861	940	816
Singing River Hosp.	Jackson	2	495	569	492
Total		9	2,414	2,621	2,382

^{*}Diagnostic Only

Sources: Application (2018 State Health Plan)

As demonstrated in GR Criterion 5 above, each of the eight (8) labs that provide PCI services averaged 906 procedures in 2016, 958 in 2015 and 908 in 2014. Therefore, the applicant believes that the proposed project will have no significant adverse impact, if any, on existing providers.

Staff notes, however, that Memorial Hospital at Gulfport filed a letter of opposition to the project claiming that the proposed project will "unnecessarily duplicate some of" the services offed at Memorial.

The applicant submits that while Memorial Hospital at Gulfport does offer catheterization with PCI services, these services are also needed at Garden Park. The applicant further submits that Harrison County, which is currently the second most highly populated county in the State and is projected to be the second most highly populated county in the State in 2023, has only one catheterization program with PCI services. The applicant submitted the following table to show the catheterization programs authorized to provide PCI services in some of the most highly populated counties in Mississippi:

County		Number of Hospitals
	2023 Population	with PCI Services
Hinds	261,558	4 (including UMC)
Harrison	205,589	1
DeSoto	178,466	2
Jackson	147,528	2
Forrest/Lamar	Forrest (78,443)	2
(Hattiesburg)	Lamar (66,071)	
	Total of 144,514	

Sources: Application, 2023 Population Projections, 2018 State Health Plan, Map 5-1

Furthermore, the applicant states that the approval of this project will save lives and reduce morbidity that results from delays in providing a patient with immediate, appropriate quality care.

GR Criterion 9 - Availability of Resources

Garden Park estimates that it will need 3.6 FTE additional personnel during the first year it provides cardiac catheterization services. It states that the cardiac catheterization program and the enhanced PVD program at the hospital will have sufficient physicians available to ensure proper implementation of the Project.

The applicant further states that Garden Park has a good record of hiring and retaining appropriate staffing and is confident that it will experience no problem in hiring the needed employees.

GR Criterion 10 - Relationship to Ancillary or Support Services

Garden Park states that all necessary support and ancillary services are currently in place at Garden Park and are capable of providing any increase in the use of such ancillary or support services. The applicant state that there are no anticipated changes in existing charges as a result of the implementation of this project.

GR Criterion 11- Health Professional Training Programs

The applicant states that Garden Park will consider each request made by any health professional training program that is convenient to its service area. Each request will be reviewed based upon the merits of the training and the participants.

GR Criterion 12- Access by Health Professional Schools

The applicant states that Garden Park will consider each request made by any health professional training program that is convenient to its service area. Each request will be reviewed based upon the merits of the training and the participants.

GR Criterion 13 – Services Outside Service Area

Garden Park states it will provide diagnostic cardiac catheterization, PCI, DA and PVI services to everyone in need regardless of their ability to pay.

GR Criterion 14 - Construction Projects

The project requires approximately 1,513 square feet of renovation at an estimated cost of \$575.28 per square foot. The RSMeans Construction Cost Data does not compare costs of projects for renovation.

GR Criterion 15 – Competing Applications

There are no competing applications on file with the Department for this project.

GR Criterion 16 - Quality of Care

The applicant states that Garden Park has a history of providing high quality medical care to the residents of its service area. Garden Park states that it has in place a quality improvement program, the purpose of which is to ensure the delivery of the highest quality care to its patients in the most efficient and effective manner with the resources available.

According to the applicant, in Fall 2018, Garden Park received an "A" from the Leapfrog Group that grades hospitals on matters of patient safety and is the only hospital on the Coast that voluntarily participates in the survey.

Garden Park is accredited by The Joint Commission and is certified to participate in TRICARE and the Medicare and Medicaid programs.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost	% of Total
Construction Cost – New	\$ 0	0%
Construction Cost – Renovation	755,554	33.86%
Capital Improvements	0	0%
Total Fixed Equipment Costs	0	0%
Total Non-Fixed Equipment Cost	1,185,253	53.11%
Land Cost	0	0%
Site Prep Cost	0	0%
Fees (Architectural, Consultant)	0	0%
Contingency Reserve	113,332	5.08%
Capitalized Interest	0	0%
Other (Equip. Contingency)	177,788	7.97%
Total Proposed Capital Expenditure	\$2,231,927	100.00%

The project requires approximately 1,513 square feet of renovation an estimate cost of \$575.28 per square foot. The RSMeans Construction Cost Data does not compare costs of projects for renovation.

B. Method of Financing

To applicant proposes to finance the project with related company financing.

C. Effects on Operating Costs

The applicant's projections of gross revenues for the first, second, and third year of operation, expenses, and net income are shown in Attachment 1. Utilization, cost, and charges are also included in the applicant's Three-Year Projected Operating Statement (See Attachment 1).

D. Cost to Medicaid/Medicare

The estimated cost to third party payors are as follows based on the applicant's source of revenue for the Project Only:

GPCH-GP, Inc. d/b/a Garden Park Medical Center				
Payor	Utilization Percentage	First Year Revenue		
Medicaid	12%	\$ 2,454,678		
Medicare	61/%	\$ 12,219,421		
Self Pay	3%	\$ 636,021		
Commercial	19%	\$ 3,935,434		
Charity Care	1%	\$ 97,954		
Other	4%	\$ 845,063		
Total	100%	<u>\$ 20,188,571</u>		

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review; however, no comments were received as of the date of this staff analysis.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the Acquisition or Control of Therapeutic Cardiac Catheterization Equipment for the performance of PCI Services in a Hospital Without On-Site Cardiac Surgery and/or the Offering of PCI services in a Hospital Without In-Site Cardiac Surgery as contained in the FY 2018 Mississippi State Health Plan; Chapter 8 of the Mississippi Certificate of Need Review Manual, April 9, 2017 Revision; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

Therefore, the Division of Health Planning and Resource Development recommends approval of this application submitted GPCH-GP, Inc., d/b/a Garden Park Medical Center for the provision of cardiac catheterization and percutaneous coronary intervention (PCI) services without on-site open heart surgery; provision of peripheral vascular catheterization services; acquisition of equipment to provide cardiac catheterization, PCI services, and peripheral vascular catheterization services; and renovation of angiography suite.

ATTACHMENT 1

GPCH-GP, Inc., d/b/a Garden Park Medical Center Provision of Cardiac Catheterization and PCI Services without On-Site Open Heart Surgery (Project Only)

	Year 1	Year 2	Year 3
Revenue			
Inpatient Care	\$ 1,851,960	\$ 3,066,843	\$ 4,464,248
Outpatient Care	18,336,611	29,915,067	43,530,804
Gross Patient Care Rev.	\$ 20,188,571	\$ 32,981,910	\$ 47,995,052
Charity Care	97,954	139,354	199,705
Deductions for Revenue	<u>17,975,178</u>	29,600,387	43,426,247
Net Patient Care Revenue	\$ 2,115,439	\$ 3,242,169	\$ 4,369,100
Total Operating Revenue	\$ 2,115,439	\$ 3,242,169	<u>\$ 4,369,100</u>
Operating Expenses			
Salaries	\$ 220,047	\$ 299,533	\$ 317,706
Benefits	58,533	79,676	84,510
Supplies	609,330	944,090	1,299,408
Services	15,050	16,630	18,250
Lease	0	0	0
Depreciation	281,608	281,608	281,608
Interest	0	0	0
Other	<u>38,728</u>	<u>152,585</u>	<u>152,585</u>
Total Operating Expenses	<u>\$ 1,223,296</u>	\$ 1,774,122	\$ 2,154,067
Net Operating Income (Loss)	<u>\$ 892,143</u>	<u>\$ 1,468,047</u>	<u>\$ 2,215,033</u>
Inpatient Days	50	77	104
Outpatient Days	299	451	606
Procedures	314	474	637
Charge per outpatient day	\$ 61,326	\$ 66,331	\$ 71,833
Charge per inpatient day	\$ 37,039	\$ 39,829	\$ 42,925
Charge per procedure	\$ 64,295	\$ 69,582	\$ 75,345
Cost per inpatient day	\$ 24,466	\$ 23,041	\$ 20,712
Cost per outpatient day	\$ 4,091	\$ 3,934	\$ 3,555
Cost per procedure	\$ 3,896	\$ 3,743	\$ 3,382

ATTACHMENT 2

GPCH-GP, Inc., d/b/a Garden Park Medical Center Cath Lab

Computation of Construction and Renovation Cost

	<u>Total</u>	New Construction	Renovation
Cost Component			
New Construction Cost		\$0	
Renovation Cost	\$755,554		\$755,554
Total Fixed Equipment Cost	\$0		
Total Non-Fixed Equipment Cost	\$1,185,253	\$0	
Capital Improvement	\$0		
Land Cost	\$0	\$0	
Site Preparation Cost	\$0	\$0	
Fees (Architectural, Consultant, etc.)		\$0	\$0
Contingency Reserve	\$113,332	\$0	\$113,332
Capitalized Interest		\$0	\$0
Other	\$177,788		
Total Proposed Capital Expenditure	\$2,231,927	\$0	\$868,886
_			
Square Footage	1,513	0	1,513
Allocation Percent		0.00%	100.00%
Costs Less Land, Non-Fixed Eqt.&			
Cap. Improvement	\$1,046,674	\$0	\$868,886
	,		
Cost Per Square Foot	\$691.79	\$0.00	\$574.28