

**DIVISION OF HEALTH PLANNING
AND RESOURCE DEVELOPMENT
December 14, 2020**

**CON REVIEW: HG-NIS-1020-007
BILOXI H.M.A., INC. D/B/A MERIT HEALTH BILOXI
OFFERING OF PCI SERVICES IN A HOSPITAL WITHOUT ON-SITE
CARDIAC SURGERY
CAPITAL EXPENDITURE: \$5,000.00
LOCATION: BILOXI, HARRISON COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

The Applicant, Biloxi H.M.A., Inc., d/b/a Merit Health Biloxi, is a Mississippi Limited Liability Company located at 150 Reynoir Street, Biloxi, Mississippi. Merit Health is an acute care facility, located in Biloxi, which participates in the state's Trauma System. The six-story facility provides a broad scope of advanced medical technology and services. The hospital features private rooms, 24-hour emergency services, radiology services, cardiology, orthopedic and GI services, surgical services and a network of primary care and specialty physicians. Merit Health is controlled and operated by four (4) officers and directors.

The application contains a Certificate of Good Standing from the Mississippi Secretary of State, dated September 29, 2020, as evidence of good standing.

Merit Health Biloxi is certified to participate in the Medicare and Medicaid programs and is accredited by the Joint Commission.

B. Project Description

1. Biloxi H.M.A., Inc., d/b/a Merit Health Biloxi (the "Applicant" or "Merit Health") requests certificate of need (CON) authority to offer percutaneous coronary intervention (PCI) services in a hospital without on-site cardiac surgery.

The Applicant states the *FY 2020 State Health Plan* (the "Plan") recognizes the state has seen a decrease in mortality attributable to heart disease, yet it remains the leading cause of death. The Applicant recognizes that focusing on improving access to care for underserved populations has been and remains one of the priorities of the Plan.

The Applicant states while the hospital is a large acute care facility that provides many specialized services, the lack of PCI services at Merit

Health inhibits the comprehensiveness and continuity of cardiac care at the hospital. The Applicant affirms the hospital only has approval to provide diagnostic cardiac catheterization procedures. The Applicant further states, if a patient currently undergoing diagnostic catheterization needs a PCI intervention, the diagnostic catheterization must be stopped, and the patient must be rescheduled for another procedure with another provider. The Applicant states this delay cardiac care and results in the rescheduling of the procedure at another hospital under another physician, resulting in another statement of services. The Applicant also states, because the hospital cannot perform the PCI procedure, if necessary, during a diagnostic catheterization, many patients and physicians simply choose not to schedule diagnostic procedures at the hospital in order to avoid potential disruptions to scheduling. Merit Health believes that the approval of its application to offer PCI services will eliminate this concern and ensure PCI services are available to patients that arrive at the emergency department with cardiac concerns.

The Applicant states the hospital has recently announced an affiliation with Memorial Hospital at Gulfport (“Memorial”). The Applicant further states the affiliation will provide additional support for existing services at the hospital as well as support more specialized areas, like cardiology.

The Applicant states the hospital’s addition of PCI services can be done with very minimal capital expenditure because the hospital already provides diagnostic catheterization procedures, and the same catheterization lab and surrounding space will be utilized for the provision of PCI services. The total cost for the proposed project is \$5,000.00. Merit Health states no construction and no renovation costs are associated with the proposed project.

The Applicant suggests Merit Health complies with the Mississippi State Health Plan’s general CON policies to promote accessibility and continuity of care while promoting cost containment.

The application included a capital expenditure summary and a three-year (3) projected operating statement.

2. The Applicant states the anticipated date for obligation of the capital expenditure will be within three (3) months of the CON’s final approval and the anticipated date the project will be complete will be within three (3) months of the CON’s final approval.
3. The Applicant affirms the hospital is an existing provider for healthcare services and has submitted a site approval letter.
4. The Applicant’s final objectives for the project are providing PCI services at Merit Health so that hospital patients can receive more thorough and less fragmented cardiology care and treatment; to provide Merit Health’s affiliated physicians the ability to refer cardiology patients to a more

comprehensive heart program at Merit Health Biloxi; and to help Merit Health more efficiently treat patients presented to Merit Health's hospital emergency room.

5. The Applicant states the hospital is currently licensed for 153 short-term acute care beds, sixty-one beds are setup & staffed, and total beds at completion will be 153.
6. New construction or renovation for proposed project:
 - a. The Applicant states there will be no construction or renovation associated with the proposed project.
 - b. The Applicant affirms no construction or renovation is associated with the project and a schematic drawing is enclosed with the application.
 - c. The Applicant does not have any capital expenditure projects completed within the last two (2) years in excess of \$200,000.00.
 - d. The Applicant has no outstanding CON.
 - e. The Applicant states the hospital currently complies and will continue to comply with state and local building codes, zoning ordinances, and/or any other appropriate regulatory authority.
 - f. The Applicant affirms it currently complies and will continue to comply with all applicable State statutes and regulations for the protection of the environment, including approved water supplies, sewage and water disposal, hazardous waste disposal, water pollution control, air pollution control, and radiation control.
 - g. The Applicant affirms the proposed project does not contemplate renovation.
 - h. The Applicant states the proposed project does not contemplate radiation therapy services.

II. TYPE OF REVIEW REQUIRED

The Mississippi State Department of Health reviews applications for the offering of percutaneous coronary intervention (PCI) services in a hospital without cardiac surgery under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193 of the 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 will expire December 28, 2020 due to December 24, 2020, being a holiday.

The Applicant states Merit Health complies with the Plan's four (4) General CON Policies: to improve the health of Mississippi residents; to increase the accessibility, acceptability, continuity, and quality of health services; to prevent unnecessary duplication of health resources; and to provide some cost containment. The Applicant affirms the hospital has dedicated space necessary to perform PCIs and will be able to utilize this existing space to perform PCI services with minimal capital expenditure. The Applicant further states the addition of PCI services at the hospital is not an unnecessary duplication of services but needed to improve the quality and continuity of the hospital's health services to its patients and nearby residents and visitors.

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

A. State Health Plan (SHP)

The *FY 2020 Mississippi State Health Plan* (MSHP) contains criteria and standards that an applicant must meet prior to the acquisition or otherwise control of therapeutic cardiac catheterization equipment for the performance or offering of PCI services in a hospital without on-site cardiac surgery. The Applicant is in substantial compliance with the applicable criteria and standards.

Policy Statement 1(b) defines percutaneous coronary intervention (PCI) services in a hospital without on-site cardiac surgery as 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.

The MSHP designates nine (9) Cardiac Catheterization/Open-Heart Surgery Planning Areas (CC/OHSPAs). Merit Health is located in CC/OHSPA 9, which contains six (6) counties; however, Merit Health identifies two (2) counties as its primary service area which includes Jackson County and Harrison County, located in CC/OHSPA 9.

B. Joint Policy Statement

Merit Health acknowledges review and consideration of each of the policy statements pertaining to the acquisition of equipment and/or provision of cardiac catheterization services contained in the MSHP.

C. Policy Statement Regarding Certificate of Need Application

1. Cardiac Catheterization Services: For purposes of the following CON criteria and standards the term “cardiac catheterization services” or “catheterization services” shall include three levels of cardiac catheterization services an applicant may provide: diagnostic cardiac catheterization services, percutaneous coronary intervention (PCI) in a hospital without on-site cardiac surgery, or therapeutic cardiac catheterization services.

- a. Diagnostic cardiac catheterization services are defined as, and refer to, cardiac catheterization services which are performed for the purpose of diagnosing, identifying, or evaluating cardiac related illness or disease. Diagnostic cardiac catheterization services include, but are not limited to, left heart catheterizations, right heart catheterizations, left ventricular angiography, coronary procedures, and other cardiac catheterization services of a diagnostic nature.
- b. Percutaneous coronary intervention (PCI) services in a hospital without on-site cardiac surgery are defined as, and refer to, those therapeutic cardiac catheterization services involving primary and elective PCIs but not involving transthoracic left ventricular puncture, myocardial biopsy, and any other procedure that is currently defined as a structural heart disease procedure.
- c. Therapeutic cardiac catheterization services are defined as, and refer to, cardiac catheterization services which are performed for the purpose of actively treating, as opposed to merely diagnosing, cardiac-related illness or disease. Therapeutic cardiac catheterization services include, but are not limited to, all PCIs (including primary and elective), transeptal puncture, transthoracic left ventricular puncture, myocardial biopsy, and any procedure that is currently defined as a structural heart disease procedure.

The Applicant states Merit Health recognizes these definitions.

2. Open-Heart Surgery Capability: MSDH shall not approve CON applications for the establishment of therapeutic cardiac catheterization services at any facility that does not have open-heart surgery capability, i.e., new therapeutic cardiac catheterization services may not be established, and existing therapeutic cardiac catheterization services may not be extended without approved and

operational open-heart surgery services in place. This policy does not preclude approval of a Certificate of Need application proposing the concurrent establishment of both therapeutic cardiac catheterization and open-heart surgery services. This policy also does not preclude approval of a Certificate of Need application to perform percutaneous coronary intervention (PCI) services in a hospital without on-site cardiac surgery or in a Cardiac Ambulatory Surgical Facility as defined in 515.06.

The Applicant affirms Merit Health recognizes the general requirement for open heart surgery. The Applicant further states, their application is requesting the authority to perform PCI services in a hospital without on-site cardiac surgery.

3. Service Areas: The State has nine designated Cardiac Catheterization/Open-Heart Surgery Planning Areas (CC/OHSPAs) presented in the Open-Heart Surgery section of the Plan. Map 5-2 shows the CC/OHSPAs.

The Applicant states Merit Health recognizes the statement and affirms the hospital is located in CC/OHSPA 9.

4. Pediatric Cardiac Catheterization: Because the number of pediatric patients requiring study is relatively small, the provision of cardiac catheterization for neonates, infants, and young children shall be restricted to those facilities currently providing the service. National standards indicate that a minimum of 150 cardiac catheterization cases should be done per year and that catheterization of infants should not be performed in facilities which do not have active pediatric cardiac-surgical programs.

The Applicant recognizes this statement and will not provide PCI services to neonates, infants, or young children.

5. Present Utilization of Cardiac Catheterization Equipment/Services: MSDH shall consider utilization of existing equipment/services and the presence of valid CONs for equipment/services within a given CC/OHSPA when reviewing CON applications. MSDH shall not consider utilization of equipment/services at any hospital owned and/or operated by the state or its agencies when reviewing CON applications. MSDH may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.

The Applicant recognizes this policy statement and states there are four (4) cardiac catheterization providers in the service area per the MSHP. The Applicant states the MSHP excludes Garden Park, however, Garden Park recently received approval of a six-month extension request to provide PCI services without open heart surgery on-site. The Applicant

further states there are actually five (5) catheterization providers in the service area.

6. Minimum Caseload: Applicants for a diagnostic cardiac catheterization Certificate of Need must be able to project a caseload of at least 300 diagnostic catheterizations per year per year by the end of the third year of operation. Applicants for a therapeutic cardiac catheterization Certificate of Need must be able to project a caseload of at least 450 catheterizations, diagnostic and therapeutic, per year by the end of the third year of operation. Applicant for a Certificate of Need to provide PCI services in a hospital without on-site cardiac surgery must be able to project a caseload of at least 300 catheterizations, diagnostic and PCI, with at least 100 being PCIs, per year by the end of the third year of operation.

The Applicant states Merit Health anticipates it will exceed 300 total cardiac catheterization per year by its third year of operation of which at least 100 will be PCI procedures.

7. Residence of Medical Staff: Cardiac catheterizations must be under the control of and performed by personnel living and working within the specific hospital area. No site shall be approved for the provision of services by traveling teams.

The Applicant recognizes this statement and certifies that the medical staff performing the proposed PCI procedures will live and work within the Applicant's specific hospital area. The Applicant further states, traveling teams will not be utilized to provide the proposed services.

8. Hospital-Based: All cardiac catheterizations and open-heart surgery services shall be located in acute care hospitals or in a Cardiac Ambulatory Surgical Facility, subject to the policy statements and need criteria and standards set forth in Sections 515.06 and 515.07 of the State Health Plan.

The Applicant recognizes this statement and states the proposed PCI services will be provided in an acute care hospital.

9. Conversion of Existing Therapeutic Cardiac Catheterization Services to PCI Services in a Hospital without On-Site Cardiac Surgery Capabilities: A hospital currently providing therapeutic cardiac catheterization services may convert their cardiac catheterization program to provide PCI services in the hospital without on-site cardiac surgery capability without certificate of need review; provided, however, that the facility shall submit an application for determination of non-reviewability prior to eliminating on-site cardiac surgery. The hospital must attest in the application for determination of non-reviewability that it will meet the CON criteria and standards as set out in Rule 515.04 of the Plan. If,

at any time, the hospital goes twelve (12) consecutive months of providing PCI services without on-site cardiac surgery, the hospital wants to convert back to a therapeutic cardiac catheterization program, the hospital must submit a certificate of need application for review.

The Applicant recognizes this statement and affirms this statement is not applicable to their application as the Applicant is not a current provider of therapeutic cardiac catheterization services.

- D. Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Therapeutic Cardiac Catherization 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 On-Site Cardiac Surgery.**

SHP Need Criterion 1 - Minimum Procedures

An applicant proposing the establishment of PCI services in a hospital without on-site cardiac surgery shall demonstrate that the proposed equipment/service utilization will be 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. Applicants must certify they will submit volume data to demonstrate and verify the utilization of the service at a minimum of every three (3) years.

The Applicant asserts Merit Health anticipates it will exceed 300 total cardiac catheterizations per year by its third year of operation which will include a minimum of 100 total PCIs. The Applicant also certifies that it will submit volume data to demonstrate and verify the utilization of the service at a minimum of every three (3) years.

SHP Need Criterion 2 – Staffing Requirements

The Applicant shall document that it has, or can obtain, the ability to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the programs.

The Applicant affirms Merit Health currently provides cardiac services including diagnostic catheterization services at the hospital. The Applicant further states prior to offering PCI services, the hospital will develop any needed protocols for staffing requirements, quality protocols, performance standards, and training so that only sufficiently trained and experienced professional staff provides PCI services at the hospital.

SHP Need Criterion 3 – Staff Residency

The Applicant shall certify that medical staff performing PCI procedures shall be onsite within thirty (30) minutes.

The Applicant certifies that the medical staff performing PCIs shall be onsite within thirty (30) minutes.

SHP Need Criterion 4 – Recording and Maintenance of Data

In addition to the certification in Need Criterion 1, applicants shall provide, as required under licensure standards, written assurance that they will record and maintain separate utilization data for diagnostic and PCI catheterization procedures (e.g., morbidity data, number of diagnostic cardiac catheterization and PCI procedures performed and mortality data, all reported by race, sex and payor status) and make that data available to the Mississippi State Department of Health annually.

The Applicant certifies it shall record and maintain separate utilization data for diagnostic and PCI catheterization procedures (e.g., morbidity data, number of diagnostic cardiac catheterization and PCI procedures performed and mortality data, all reported by race, sex and payor status). The Applicant further affirms that this data will be made available to the Mississippi State Department of Health annually.

SHP Need Criterion 5 – Open-Heart Surgery

An applicant proposing the establishment of PCI services without on-site cardiac surgery shall:

- a. Document that open-heart surgery services will be available through a formal emergency transfer agreement to a hospital providing open heart surgery. Such transfer must be done at a minimum of less than 120 minutes to accomplish transfer from the onset of PCI complications to cardiopulmonary bypass. Transporting of the patient to the receiving hospital must include the capability to provide an intra-aortic balloon pump (IABP).**

Merit Health certifies that it has a formal emergency transfer agreement with Memorial Hospital at Gulfport (approximately fifteen (15) miles away) and Singing River Health (approximately thirty-two (32) miles away). The Applicant states that all transfers will be done in less than 120 minutes from the onset of PCI complications to cardiopulmonary bypass. The Applicant certifies Merit Health will obtain an intra-aortic balloon pump (IABP) for use during transfers.

- b. Programs must project and annually perform a minimum of 100 total PCIs per year to include at a minimum 12 primary PCIs per year by the end of the third year of operation. New programs**

should have three years to reach the absolute minimum volume, but after that, programs failing to reach this volume for two consecutive years should not remain open. MSDH has the discretion under a finding of rare or unique circumstances to grant an exception to the above based on a finding of need of access and quality of care by the program.

Merit Health projects its PCI program will annually perform a minimum of 100 total PCIs per year which will include at a minimum twelve (12) primary PCIs per year by the end of the third year of operation. The Applicant acknowledges that the Department has the authority, with the available discretion to grant an exception, to close the hospital's program if the minimum volume is not reached.

- c. Certify that the proposed primary operators for the service have a life-time experience of greater than 150 total PCIs with acceptable outcomes as primary operator after completing a cardiology fellowship. Successful completion of an Interventional Cardiology fellowship is considered adequate certification.**

The Applicant certifies that the primary operators for the PCI service will have a lifetime experience of greater than 150 PCIs with acceptable outcomes. The Applicant further states the hospital certifies that these primary operators will have completed a cardiology fellowship.

- d. New and Existing Programs must actively participate in the STEMI ("ST"-Segment Elevation Myocardial Infarction) Network, including, but not limited to, the submission of data to the STEMI databank.**

Merit Health affirms that it will actively participate in the STEMI ("ST"-Segment Elevation Myocardial Infarction) Network, including, but not limited to, the submission of data to the STEMI databank.

- e. At the present time, there is no justification for a PCI program without on-site surgery to perform only elective procedures or not provide availability to primary PCI 24 hours/365 days per year. The Mississippi State Department of Health has the discretion under a finding of rare or unique circumstances to grant exception to the above based on a finding of need of access and quality of care by the program.**

The Applicant states that Merit Health will provide primary and elective PCIs. The Applicant further states Primary PCI service will be available 24 hours/365 days per year.

- f. Certify that the Applicant will provide educational programs to underserved patient populations (low income, racial and ethnic**

minorities, women, Medicaid eligible, and handicapped persons) with the goal of decreasing cardiac mortality rates in such populations.

The Applicant certifies that it will provide educational programs to underserved patient populations with the goal of decreasing cardiac mortality rates in the State's underserved patient populations.

- g. Certify that the applicant will provide a reasonable amount of charity care.**

The Applicant confirms that it currently provides, and will continue to provide, a reasonable amount of charity care.

- h. Certify that the applicant will hold monthly multi-disciplinary meetings to evaluate patient outcomes, review quality improvement data, and to identify and implement solutions for any operational issues.**

The Applicant certifies that it currently conducts monthly multi-disciplinary meetings for other services and will conduct multi-disciplinary improvement meetings for the PCI service.

- i. Certify that 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 certificate of need application will be met:**

- (i) Certify the applicant will have available in the catheterization lab the equipment in Section 4.1.1 entitled "Equipment" and that such will be routinely tested.**

The Applicant affirms the catheterization lab equipment will be routinely tested as required in section 4.1.1 and in compliance with the hospital's policies. The Applicant states Merit Health has developed and maintains a written management plan describing the process it implements to effectively manage risks associated with the use of clinical equipment technology. The Applicant affirms the plan is evaluated annually, and changed as necessary, based on changes in conditions, regulations, standards, and identified needs. The Applicant further states that it has the appropriate equipment referenced in Section 4.1.1, of the guideline for Percutaneous Coronary Intervention, namely defibrillators, consoles for ancillary devices (Doppler wires, pressure-tipped sensor wires and IVUS catheters), point-of-care testing devices (for testing activate clotting time and arterial blood gas machines), digital cine images, and x-ray imaging equipment.

- (ii) Certify the availability of 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.**

Merit Health affirms that it will maintain adequate and qualified staff as required by Section 4.1.2, namely that an interventional cardiologist, qualified nursing personnel and technical personnel will be present in the catheterization lab for the duration of the PCI procedure. All personnel in the catheterization lab involved with the provision of PCI services will maintain or become certified in basic life and advanced cardiovascular life support.

- (iii) Certify that “time-out” procedures will be implemented as discussed in Section 4.1.3 entitled “Time-Out Procedures”;**

The Applicant certifies, currently the hospital has “time-out” procedures at Merit Health and certifies that it will have a similar “time-out” procedure that will comply with Section 4.1.3.

- (iv) Certify that the applicant will operate a quality improvement program and participate in a national PCI registry as discussed in Section 7.1 entitled “Quality Performance: Recommendations”.**

Merit Health affirms that it currently operates a quality improvement program and that it will continue this program in line with Section 7.1, namely that there will be a routine review of: the quality and outcomes of the program; results of individual operators; risk adjustment; peer review of difficult or complicated cases; and random case reviews. The Applicant states the Quality Assessment and Performance Improvement Plan/Policy (“QAPI”) will be reviewed and implemented as necessary to ensure compliance with Section 7.1. The Applicant further states the hospital will participate in a national PCI registry for the purpose of benchmarking its outcomes compared to norms.

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

In addition to Need Criteria 1-5, an applicant proposing the establishment of PCI services in a hospital without open heart surgery capabilities, who is already an existing provider of diagnostic catheterization services, shall demonstrate that its diagnostic cardiac catheterization unit has been utilized for a minimum of 300 procedures per year for the two most recent years as reflected in the data supplied to and/or verified by the Mississippi State Department of Health or that its primary operators for the

service have a life-time experience of greater than 250 total procedures (including both diagnostic catheterizations and PCIs) with acceptable outcomes after completing a cardiology fellowship. Successful completion of an Interventional Cardiology fellowship is considered adequate certification.

The Applicant states Merit Health currently provides diagnostic catheterization services. The Applicant states that due to the inability of Merit Health to perform PCI services, the number of catheterization procedures performed at Merit Health is below the 300-procedure threshold. However, Merit Health certifies that its primary operators for the PCI service will have a life-time experience of greater than 250 total (diagnostic and PCI) catheterization procedures with acceptable outcomes and will have completed an interventional cardiology fellowship. The application contains affidavits from interventional cardiologists who will perform PCI procedures at Merit Health.

SHP Need Criterion 7 - Regulatory Approval.

Before utilizing or providing the equipment or service, the applicant desiring to provide the cardiac catheterization equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

The Applicant acknowledges this requirement and has filed this application to seek approval.

E. General Review (GR) Criteria

GR Criterion 1 – State Health Plan: The relationship of the health services being reviewed to the applicable State Health Plan.

This Applicant affirms this application has been reviewed for compliance with the FY 2020 State Health Plan.

GR Criterion 2 – Long Range Plan: The relationship of services reviewed to the long-range development plan, if any, of the institution providing or proposing the services.

The Applicant believes that their ability to provide PCI services will enable Merit Health to reach its long-range plan of providing comprehensive cardiac care at the hospital and improving access to cardiac care for all patients.

GR Criterion 3 – Availability of Alternatives: The availability of less costly or more effective alternative methods of providing the service to be offered, expanded or relocated.

- a. **Advantages and Disadvantages of Alternatives:** The Applicant states Merit Health considered continuing to offer diagnostic only catheterization services; however, this limited catheterization service does not meet the needs of the hospital, its patients, or physicians. By limiting services to diagnostic catheterization only, the Applicant states it impacts a patient's schedule if a procedure has to be stopped in order to transfer for a needed PCI; impacts scheduling of cardiac catheterization services at the hospital; and impacts the availability of services for those patients that present at the emergency department. The Applicant further states by providing more thorough cardiac services, the hospital will be able to provide more comprehensive cardiac care for its patients.
- b. **New Construction Projects:** The Applicant states this criterion is not applicable for this project.
- c. **Beneficial Effects to the Health Care System:** The Applicant affirms comprehensive cardiac care services at the hospital will enable a patient to receive care at one location. The Applicant further states the addition of PCI services will also improve the accessibility of services for underserved populations.
- d. **Effective and Less Costly Alternatives:**
 - i. **Unnecessary Duplication of Services:** The Applicant states that the proposed project seeks to enhance services already provided at Merit Health, thereby improving patients' continuity of care.
 - ii. **Efficient Solution:** The Applicant determined that during a diagnostic cardiac catheterization procedure that PCI services are needed. The Applicant states the hospital will be able to address that need immediately without delay, transfer, rescheduling and/or recatheterization. The Applicant further states patients presenting to the Emergency Department in need of PCI services will be able to receive needed intervention without delay.
- e. **Improvements and Innovations:** The Applicant states by expanding cardiac services at the hospital to include PCI services, the hospital's patients and those residents near the hospital and visiting the area will have increased access to potentially lifesaving care. The Applicant further states the hospital can begin providing the PCI service with

minimal capital expenditure as the catheterization lab area is already in operation.

GR Criterion 4 – Economic Viability: The immediate and long-term financial feasibility of the proposal, as well as the probable effect of the proposal on the costs and charges for providing health services by the institution or service. Projections should be reasonable and based upon generally accepted accounting procedures.

- a. **Proposed Charges:** The Applicant states that Merit Health determined its charges after reviewing Medicare and Medicaid reimbursement levels. The Applicant affirms that expected profitability was determined by measuring expected reimbursement alongside expected supply costs, as well as human resource needs.
- b. **Projected Levels of Utilization:** The Applicant believes its projections are reasonable based on physicians' comments and support, requests for service, demographics of the hospital's service area, and patients presenting to the emergency department for cardiac complaints.
- c. **Financial Feasibility Study:** The Applicant affirms the capital expenditure for the proposed project is \$5,000.00 and does not require a financial feasibility study prepared by an accountant, CPA, or the facility's financial officer.
- d. **Financial Forecast:** The Applicant affirms this criterion is not applicable.
- e. **Covered Expenses:** The Applicant believes its projections are reasonable; however, in the event it fails to meet its projections, the hospital and/or its parent company, Community Health System, Inc. will support the service.
- f. **Impact of Proposed Project on Health Care Cost:** The Applicant asserts that as the Department's policy statement and goals set forth, heart disease remains the leading cause of death in Mississippi. The Applicant states that in order to tackle heart disease's impact, improving the availability of cardiac care in Mississippi is necessary. Thus, the Applicant asserts the addition of PCI services at Merit Health should not impact the overall cost of healthcare as those patients should receive the service regardless of location. The hospital does not anticipate any substantial impact on gross revenues or impact on Medicaid expenses per procedure.

GR Criterion 5 – Need for the Project: One or more of the following items may be considered in determining whether a need for the project exists:

- a. **Access by the Population Served:** The Applicant states that Merit Health serves all patients seeking services including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, as well as the elderly. The MSHP's goals demonstrate the need to improve access to cardiac care by encouraging the establishment of additional catheterization programs. The Applicant states Merit Health proposes to make PCI services available to all patients, including underserved groups, and especially to those patients who already use the system for their care.

The Applicant further states with the approval of their proposed project, the hospital will be able to provide additional PCI services in the community, with very little capital expenditure, to help decrease the mortality of the State's residents as it relates to heart disease.

- b. **Relocation of Services:** This project does not propose the relocation of services. Therefore, the Applicant states this criterion is not applicable.
- c. **Current and Projected Utilization of Comparable Facilities:** The Applicant submits while the service area does contain existing cardiac catheterization equipment/services, the goal of the 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, minority, and rural populations in greater numbers. The Applicant further states Merit Health seeks to expand its already existing cardiac service to improve access to interventional cardiac care to all patients in compliance with the Plan's requirements and goals.
- d. **Probable Effect on Existing Facilities in the Area:** The Applicant anticipates that many of the patients that will receive PCI services at the hospital are patients that would have otherwise received PCI services at the hospital had such services been available.
- e. The Applicant has received sixteen (16) letters of support from physicians and healthcare providers and eighteen (18) opposition letters physicians and healthcare providers.

GR Criterion 6 – Access to the Facility or Service: The contribution of the proposed service in meeting the health related needs of members of medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services (for example, Medicaid eligible, low income persons, racial and ethnic minorities, women, and handicapped persons), particularly those needs identified in the applicable State Health Plan as deserving priority. For the purpose of determining the extent to

which the proposed service will be accessible, the state agency shall consider:

1. **Access to Services:** The Applicant affirms 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 person and the elderly currently have access to the services provided at the hospital.

The Applicant affirms as described in the application, residents will continue to have access to the proposed services and/or facility.

The following table shows the historical and projected gross patient revenue estimates of health care to medically indigent and charity care patients for years one (1) and two (2) of the proposed project.

Gross Patient Revenue

| | Medically Indigent (%) | Charity Care (%) | Medically Indigent (\$) | Charity Care (\$) |
|----------------------|------------------------|------------------|-------------------------|-------------------|
| Historical Year 2018 | 4.2% | * | \$43,325,300.00 | * |
| Historical Year 2019 | 4.3% | * | \$44,352,305.00 | * |
| Projection Year 1 | 4.3% | * | \$37,406,700.00 | * |
| Projection Year 2 | 4.3% | * | \$39,068,600.00 | * |

***The Applicant states Merit Health does not separate its indigent/charity care cases. All patients in these categories are capture together.**

- b. **Existing Obligations:** The Applicant states the hospital does not have existing obligations under any federal regulation 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 affirms Merit Health will treat all patients regardless of payor source.
- d. **Access to Proposed Facility:** The Applicant states the availability of PCI services at the hospital will enable patients at the hospital to receive diagnostic catheterization and PCI services at one location. The Applicant further states it will also allow

patients arriving through the emergency department access to interventional services at the hospital.

- e. **Access Issues:** Transportation and Travel Time to the Facility
 - i. **Transportation and Travel:** The Applicant submits the hospital is conveniently located to residents of the service area off Reynoir Street in Biloxi.
 - ii. **Restrictive Admission Policy:** The Applicant provided a copy of its Admissions and Discharge of Patients Policy in the application.
 - iii. **Access to Care by Medically Indigent Patients:** The Applicant affirms the availability of PCI services at the hospital will enable all patients at the hospital to receive both a diagnostic catheterization and PCI services at one site.
 - iv. **Operational Hours of Service:**
 - 1. **Regular Operation:** The Applicant states elective services will be scheduled during traditional business hours, generally, 7am-5pm, five (5) days per week.
 - 2. **Emergency Only Operation:** The Applicant states primary/emergency PCI services will be available 24 hours per day, seven (7) days per week, 365 days per year.

GR Criterion 7 – Information Requirement: The applicants shall affirm in their application that they will record and maintain, at a minimum, the following information regarding charity care, care to the medically indigent, and Medicaid populations and make it available to the Mississippi Department of Health within fifteen (15) business days of request:

The Applicant affirms it will record and maintain the required information regarding charity care, care to the medically indigent, and Medicaid populations and make it available to the Department with fifteen (15) business days of the Department's request.

GR Criterion 8 - Relationship to Existing Health Care System: The relationship of the services proposed to be provided to the existing health care system of the area in which the services are proposed to be provided.

- a. **Comparable Services:** The Applicant states allowing the hospital's patients to remain at the hospital for their care is important for the patient-physician relationship and will improve continuity and quality of care for the patient. The Applicant further states patients presenting to the emergency department in need of PCI services will receive those services in a more efficient and timely manner.

The Applicant submits that while CC/OHSPA 9 does contain existing cardiac catheterization equipment/services, the goal of the 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." MSHP at 136. The Applicant further states the Department "shall interpret and implement all standards in this Plan in recognition of the stated findings and so as to achieve the stated goal." Plan at 136. Merit Health seeks to expand its already existing cardiac care program to improve access to interventional cardiac care to all patients in compliance with the MSHP's requirements and goals.

As stated earlier, Merit Health submits that it is an existing provider of health care services to the poor, minorities, and rural populations. Through expanding its cardiac care capabilities, Merit Health prepares to provide additional access to these underserved populations. The Applicant asserts that the availability of PCI services at Merit Health will help to improve quality and continuity of care for all patients.

- b. **The Proposed Project Effect on Existing Health Services:**
 - i. **Complement Existing Services:** The Applicant states the project proposes to improve cardiac care at the hospital by adding PCI services to its existing diagnostic catheterization capabilities thus creating a more comprehensive cardiac care program for its patients.
 - ii. **Provide Alternative or Unique Services:** The Applicant submits that approval of this application will allow PCI services to be provided at an already existing cardiac program, thereby, improving patients' health in a state where heart disease is the leading cause of death.

- iii. **Provide Services for a Specific Target Population:** The Applicant affirms patients with heart disease or other heart health issues in the service area will have another access point to receive cardiac services. For those patients which present at the emergency department, the establishment of PCI services at the hospital will improve efficiency and decrease unnecessary delays in treatment.
 - iv. **Provide Services for Which There is an Unmet Need:** The Applicant asserts, currently, Merit Health Biloxi's patients and those patients presenting at the hospital in need of PCI services must be treated at another provider. The Applicant states this disrupts the patient's continuity of care and leads to unnecessary delays in treatment. The Applicant further states approval of the proposed project will eliminate these issues.
- c. **Adverse Impact:** The Applicant states failure to implement this project will continue to have a negative impact on continuity of care for patients who desire to have their healthcare provided at the hospital and those patients who present to the hospital's emergency room with cardiac issues. The Applicant states there will continue to be an unnecessary loss of critical time in the delivery of care and a disruption to the patients' continuity of care if patients are transferred.
- d. **Transfer/Referral/Affiliation Agreements:** The Applicant has provided a list of emergency patient transfer agreements with Memorial Hospital at Gulfport and Singing River Health System.

GR Criterion 9 – Availability of Resources: The availability of resources (including health personnel, management personnel, and funds for capital and operating needs) for the services proposed to be provided and the need for alternative uses of these resources as identified by the applicable State Health Plan.

- a. **New Personnel:** The Applicant states the current catheterization lab staff is qualified to provide diagnostic catheterization services. The Applicant further states additional staff will be hired as needed to help oversee existing staff until staff complete any necessary training and certification.
- b. **Contractual Services:** The Applicant submits Merit Health is a full service general acute care hospital and will provide any necessary service for the proposed service.

- c. **Existing Facilities or Services:** The Applicant affirms the hospital successfully and efficiently staffs its current service lines and will continue to do so. The Applicant states the anticipated primary operators are interventional cardiologists, that will perform PCI procedures at Merit Health Biloxi and existing members of the hospital medical staff. In addition, the Applicant states qualified interventional cardiologists will be added to the medical staff.
- d. **Alternative Uses of Resources:** The Applicant states the hospital will provide additional training to its existing cardiac catheterization personnel regarding interventional procedures.

GR Criterion 10 – Relationship to Ancillary or Support Services: The relationship, including the organizational relationship, of the health services proposed to be provided to ancillary or support services.

- a. **Support and Ancillary Services:** The Applicant states, as a full service general acute care hospital, all necessary support and ancillary services are available to the proposed services.
- b. **Changes in Cost or Charges:** The Applicant affirms no significant change in costs or charges is anticipated as a result of this proposed project.
- c. **Accommodations of Changes in Costs or Charges:** The Applicant states no significant change in costs or charges is anticipated as a result of this proposed project.

GR Criterion 11 – Health Professional Training Programs: The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.

The Applicant affirms Merit Health Biloxi works with the University of Mississippi Medical Center, University of Southern Mississippi Nursing School, Mississippi Gulf Coast Community College Nursing and Paramedic Program and William Carey’s Nursing, Pharmacy and Doctor of Osteopathic Medicine Programs to support health training programs in the area and to provide clinical and hospital experience for students.

GR Criterion 12 – Access by Health Professional Schools: If proposed health services are to be available in a limited number of facilities, the extent to which any health professional school in the area will have access to the services for training purposes.

The Applicant asserts it currently works with health professional training programs in the area (see GR 11).

GR Criterion 13 – Service to Residents Outside Service Area: Special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health services areas in which the entities are located or in adjacent health service areas. These entities may include medical and other health professional schools, multi-disciplinary clinics, and specialty centers, etc.

The Applicant states that it does not anticipate providing services to those residents outside the service area. However, in the event such a person presents to the hospital with cardiac problems, services will be available.

GR Criterion 14 – Construction Projects: All construction projects shall be designed and constructed with the objective of maximizing cost containment, protection of the environment, and conservation of energy. The impact of the construction costs, including financing charges on the cost of providing health care, shall be considered.

The proposed project does not require construction. Therefore, Criterion 14 is not applicable.

GR Criterion 15 – Competing Applications:

The Applicant states it is not aware of any competing applications for PCI services in CC/OHSPA 9 filed with the Department.

GR Criterion 16 – Quality of Care: In the case of existing services or facilities, the quality of care provided by those facilities in the past.

- a. **Past Quality of Care:** The Applicant states this need criterion is not applicable to the proposed project. The Applicant affirms the hospital maintains its Joint Commission accreditation which is an indicator for quality of care.

- b. **Improvements of Quality of Care:** The Applicant affirms the addition of the proposed service at the hospital will improve patient care by enhancing patient’s continuity of care and improving and increasing the services available at the hospital.
- c. **Accreditation and/or Certificates:** The Applicant is accredited by the Joint Commission.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

| Cost Item | Projected Cost | Percentage% of Total |
|--------------------------------------|-----------------------|-----------------------------|
| Construction Cost - New | \$ 0 | 0.00% |
| Construction Cost - Renovation | \$ 0 | 0.00% |
| Capital Improvements | \$ 0 | 0.00% |
| Fees (Architectural/Consultant/etc.) | \$ 0 | 0.00% |
| Contingency Reserve | \$ 0 | 0.00% |
| Capitalized Interest | \$ 0 | 0.00% |
| Other | \$ 0 | 0.00% |
| Fixed Equipment | \$ 0 | 0.00% |
| Non-Fixed Equipment | \$ 5,000 | 100.00% |
| Legal and Accounting Fees | \$ 0 | 0.00% |
| Other | \$ 0 | 0.00% |
| Total Proposed Expenditures | \$ 5,000 | 100.00% |

As stated previously, no new construction or renovation is associated with the proposed project.

B. Method of Financing

To fund the project, Merit Health Hospital Biloxi will use cash reserves in the amount of \$5,000.00.

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

Merit Health River Oaks provides the following revenue source projections for each payor category listed below (Project Only):

| Payor | Utilization Percentage (%) | First Year Revenue (\$) |
|---------------------|-----------------------------------|--------------------------------|
| Medicare | 30.00% | \$ 712,500.00 |
| Medicaid | 29.00% | \$ 688,750.00 |
| Commercial | 29.00% | \$ 688,750.00 |
| Self-Pay | 5.00% | \$ 118,750.00 |
| Charity Care | 1.00% | \$ 23,750.00 |
| Other | 6.00% | \$ 142,500.00 |
| Total | 100.00% | \$2,375,000.00 |

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment. In a letter dated November 13, 2020, the Division of Medicaid commented that 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 cost outlier payment. The Division estimates that increased cost outlier payments resulting from this project cannot be determined at this time; therefore, the Division had no opinion at this time.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for Offering of PCI Services in a Hospital without On-Site Cardiac Surgery as contained in the *FY 2020 Mississippi State Health Plan*; Chapter 8 of the *Mississippi Certificate of Need Review Manual, April 9, 2019 Revision*; and all adopted rules, procedures, and plans of the Mississippi Department of Health.

Therefore, the Division of Health Planning and Resource Development recommends approval of this application submitted by Biloxi H.M.A., Inc. d/b/a Merit Health Biloxi for the offering of PCI services in a hospital without on-site cardiac surgery.

ATTACHMENT 1

Biloxi H.M.A., Inc. d/b/a Merit Health Biloxi Offering of PCI Services in a Hospital without On-Site Cardiac Surgery

Three-Year Projected Operating Statement (Project Only)

| Merit Health Biloxi Three-Year Operating Statement (Project Only) | | | |
|--|--------------------|--------------------|---------------------|
| | Year 1 | Year 2 | Year 3 |
| Revenue | | | |
| Patient Revenue: | | | |
| Inpatient | \$4,906,750 | \$6,559,550 | \$8,186,525 |
| Outpatient | \$2,375,000 | \$3,175,000 | \$3,962,500 |
| Gross Patient Revenue | \$7,281,750 | \$9,734,550 | \$12,149,025 |
| Charity Care | \$49,067 | \$65,595 | \$81,865 |
| Deductions | \$5,744,473 | \$7,679,451 | \$9,577,903 |
| Net Patient Revenue | \$1,488,210 | \$1,989,504 | \$2,489,257 |
| Other Operating Revenue | \$ 0 | \$ 0 | \$ 0 |
| Total Operating Revenue | \$1,488,210 | \$1,989,504 | \$2,489,257 |
| Expenses | | | |
| Operating Expenses: | | | |
| Salaries | \$191,590 | \$206,603 | \$221,381 |
| Benefits | \$40,234 | \$43,387 | \$46,491 |
| Supplies | \$180,253 | \$240,970 | \$301,687 |
| Services | \$6,277 | \$6,277 | \$6,277 |
| Lease | 0 | 0 | 0 |
| Depreciation | 0 | 0 | 0 |
| Interest | 0 | 0 | 0 |
| Other | \$20,000 | \$10,000 | \$10,000 |
| Total Expenses | \$438,354 | \$507,237 | \$585,836 |
| Net Income (Loss) | \$1,049,856 | \$1,482,267 | \$1,903,421 |
| | | | |
| Inpatient days | 0 | 0 | 0 |
| Outpatient visits | 0 | 0 | 0 |
| Procedures | 190 | 254 | 317 |
| Charge/outpatient day | 0 | 0 | 0 |
| Charge per inpatient day | 0 | 0 | 0 |
| Charge per procedure | \$ 38,325 | \$ 38,325 | \$ 38,325 |
| Cost per inpatient day | 0 | 0 | 0 |
| Cost per outpatient day | 0 | 0 | 0 |
| Cost per procedure | *\$2,307 | *\$1,997 | *\$1,848 |

*Figures may be off by due to rounding.