STAFF ANALYSIS

I. PROJECT SUMMARY

A. APPLICANT INFORMATION

Mississippi Coast Endoscopy and Ambulatory Surgical Center, LLC, is a Mississippi Limited Liability Company. Currently the governing Board is member managed.

Mississippi Coast Endoscopy and Ambulatory Surgical Center, LLC, is an ambulatory surgical facility and is currently licensed with the Mississippi State Department of Health to provide the service. The facility serves both Medicare and Medicaid patients. Also, the facility provides a reasonable amount of indigent care to the area.

B. PROJECT DESCRIPTION

Mississippi Coast Endoscopy and Ambulatory Surgical Center, LLC, is requesting CON authority to offer mobile Extracorporeal Shock Wave Lithotripsy (ESWL) services. The equipment is a mobile lithotriper that performs a non-invasive procedure to treat kidney stones by emitting high energy shock waves to zoom in on a stone to break the stone into small particles. In turn, the particles are passed through the urinary tract system. Before ESWL equipment is used, trained staff use radiographs, fluroscopy, or ultrasound to produce images of the stone so that physicians can see exactly where the stone is located to achieve fragmentation.

Mississippi Coast Endoscopy and Ambulatory Surgical Center, LLC, will use the mobile service offered by NexMed, a subsidiary of Pontchartrain Lithotripsy, which has already been approved by the Mississippi State Department of Health to operate in Mississippi. The service will be offered on a mobile basis one day per week. The piece of equipment used will be a Storz Modulith SLX coupled with an OEC9800 C-arm.

The Mississippi State Department of Health, Division of Licensure and Certification, has approved the site for new service.

There is no capital expenditure associated with this project and no financing.
II. TYPE OF REVIEW REQUESTED

The Mississippi State Department of Health reviews applications for the provision of mobile renal ESWL services in accordance with Section 41-7-191, subparagraph (1) (d) (xiii) Mississippi Code 1972 Annotated, as amended, and duly adopted rules, procedures, plans, criteria, and standards of the Mississippi State Department of Health.

In accordance with Section 41-7-1972 (2) of the Mississippi Code of 1972 Annotated, as amended, any affected person may request a public hearing on this project within 20 days of publication of the staff analysis. The opportunity to request a hearing expires March 6, 2003.

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

A. State Health Plan (SHP)

The FY 2003 State Health Plan contains criteria and standards which the applicant is required to meet before receiving CON authority for provision of ESWL services. This application is in substantial compliance with applicable criteria and standards.

SHP Criterion 1 - Need

The proposed facility will be available to all persons in the service area including low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups.

The applicant states that it will perform a minimum of 80 procedures the first full year of operation. The projected number of procedures is based on the historical referrals of patients with renal calculi for Renal ESWL to other facilities which offer the service during the most recent fiscal year. The projected procedures for this facility are within the required three procedures per month for 12 months or 36 procedures per year required by the FY 2003 State Health Plan.

SHP Criterion 2 - Documentation of Medical Personnel

The applicant affirms that there will be board certified general surgeons, certified urologists, and radiologists available 24 hours per day within the facility and will provide emergency services as required. The board certified radiologists will have experience in x-ray, CT, and ultrasound imaging.

SHP Criterion 3 - Imaging Capabilities

Mississippi Coast Endoscopy and Ambulatory Surgical Center, LLC, provides whole body CT scanning and ultrasound imaging at the facility.
SHP Criterion 4 - Scope of Privileges

The applicant affirms that the governing body of Mississippi Coast Endoscopy and Ambulatory Surgical Center, LLC will grant appropriate scope of privileges for access to their proposed lithotripter to any qualified physician who applies for privileges.

SHP Criterion 5 - Accessibility

The applicant affirms that the facility will offer a reasonable amount of indigent/charity care as described in the FY 2003 Mississippi State Health Plan as well as service all residents of General Hospital Service Area 7 regardless of age, race, gender, or disability.

SHP Criterion 6 - Recording of Data

Mississippi Coast Endoscopy and Ambulatory Surgical Center, LLC, affirms that the facility will record and maintain the information required by this criterion and shall make the data available to the Mississippi State Department of Health regarding the operation of ESWL equipment. Also, the facility states it will record source of payment of procedures and the total amounts charged during the fiscal year.

SHP Criterion 7 - Staffing

The facility has an established urological referral practice and an active radiology service. The applicant affirms that it is in compliance with this criterion.

SHP Criterion 8 - Guidelines and Standards

The facility affirms that all persons using the lithotripsy equipment meet the applicable minimum standards for training and proficiency in the operation of Renal ESWL Equipment as outlined in the American Urological Associations’s guidelines.

SHP Criterion 9 - CON Exemption

The applicant provided information to indicate that the lithotripsy vendor, NexMed, has CON approval as determined by the Mississippi State Department of Health.

B. General Review (GR) Criteria

Chapter 8 of the Mississippi Certificate of Need Review Manual, 2000 revisions, addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria.
GR Criterion 3 - Availability of Alternatives

The applicant states that the facility determined there were no other alternatives to provide ESWL services, thus, embraced the idea of applying for the service by submitting a CON as opposed to doing nothing at all.

GR Criterion 4 - Economic Viability

Three year operating projections reflect a first year net profit of $43,200, a second year profit of $46,440, and a third year profit of $52,380. There is no capital expenditure associated with this program.

GR Criterion 5 - Need for the Project

The proposed facility will be available to all persons in the service area including low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups.

This project based its need methodology on historical data from other facilities having ESWL services in the most recent fiscal year in the area. The projected number of procedures was 80 for the first year, 86 for the second year, and 97 for the third year. An affidavit from Mark S. Lyell, M.D., was included for support.

The applicant affirms that this application is fully supported by the community.

GR Criterion 7 - Information Requirement

Mississippi Coast Endoscopy and Ambulatory Surgical Center, LLC affirms that they 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

The applicant affirms that this project will have no adverse effect on facilities currently offering the service in the area.

GR Criterion 9 - Availability of Resources

The applicant affirms that qualified health personnel, management personnel, and required staff will be available for lithotripsy services through Mississippi Coast Endoscopy and Ambulatory Surgical Center, LLC. The applicant has on file a list of full time staff members who are employed at Mississippi Coast Endoscopy and Ambulatory Surgical Center, LLC, and states that these employees will be available to provide various ranges of quality healthcare to the residents in the area.
GR Criterion 10 - Relationship to Ancillary or Support Services

As a result of this project there will be no increase in the utilization of ancillary services.

GR Criterion 16 - Quality of Care

The applicant affirms that it exemplifies quality of care to its patients. The applicant is licensed by the Mississippi State Department of Health.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

There is no capital expenditure associated with this project.

B. Method of Financing

There will be no financing associated with this project.

C. Effects on Operating Costs

The applicant projects the following expenses, utilization, and results from operation for the first three years of operation:

<table>
<thead>
<tr>
<th>Expense</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Expense</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment Lease</td>
<td>$360,000</td>
<td>$387,000</td>
<td>$436,500</td>
</tr>
<tr>
<td>Revenue</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Gross Revenue</td>
<td>$560,000</td>
<td>$602,000</td>
<td>$679,000</td>
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<tr>
<td>Contractual Adjust.</td>
<td>$156,800</td>
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<td>$191,120</td>
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<tr>
<td><strong>Net Revenue</strong></td>
<td><strong>$403,200</strong></td>
<td><strong>$433,440</strong></td>
<td><strong>$488,780</strong></td>
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<tr>
<td><strong>Net Profit</strong></td>
<td><strong>$43,200</strong></td>
<td><strong>$46,440</strong></td>
<td><strong>$51,380</strong></td>
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<tr>
<td>Number of Procedures</td>
<td>80</td>
<td>86</td>
<td>97</td>
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<tr>
<td>Charge per Procedure</td>
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<tr>
<td>Cost Per Procedure</td>
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<td>$4,500</td>
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D. **Cost to Medicaid/Medicare**

<table>
<thead>
<tr>
<th>Payor</th>
<th>Expense for First Full Year to Various Payors:</th>
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<tbody>
<tr>
<td>Medicaid</td>
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<tr>
<td>Medicare</td>
<td>$220,147</td>
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<td>Private Pay</td>
<td>$148,781</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>$403,200</strong></td>
</tr>
</tbody>
</table>

V. **RECOMMENDATION OF OTHER AFFECTED AGENCIES**

The Division of Medicaid was provided a copy of this application for comment. However, no comments were received from the Division of Medicaid.

VI. **CONCLUSION AND RECOMMENDATION**

This project is in substantial compliance with the criteria and standards for the provision of mobile renal ESWL services contained in the FY 2003 Mississippi State Health Plan; Chapter 8 of the Mississippi Certificate of Need Review Manual, 2000 revisions; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Division of Health Planning and Resource Development recommends approval of this application submitted by Mississippi Coast Endoscopy and Ambulatory Surgical Center, LLC.