

**DIVISION OF HEALTH PLANNING
AND RESOURCE DEVELOPMENT
MAY 2003**

**CON REVIEW FS-NIS-0303-007
GULF COAST ENDOSCOPY A.S.C., LLC DBA GULF COAST SURGERY CENTER
ESTABLISHMENT OF EXTRACORPOREAL SHOCK WAVE
LITHOTRIPSY (ESWL) SERVICES, JACKSON COUNTY
CAPITAL EXPENDITURE: \$-0-
LOCATION: OCEAN SPRINGS, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Gulf Coast Endoscopy A.S.C., LLC, is a Mississippi limited liability company located at 90 Industrial Park Center in Ocean Springs, Mississippi. Gulf Coast Endoscopy A.S.C., LLC dba Gulf Coast Surgery Center (Center) is governed by a diverse, nine-member Board of Directors. The managing member of the Center is Alfred E. McNair, Jr., M.D.

The Center is accredited through the Joint Commission on Accreditation of Healthcare Organizations, American Accreditation of Ambulatory Health Care, and certified as a Medicare and Medicaid provider.

B. Project Description

Gulf Coast Endoscopy A.S.C., LLC requests Certificate of Need (CON) authority to offer mobile extracorporeal shock wave lithotripsy (ESWL) services on a part time(one day a month and more frequently if needed) basis in Jackson County. The Center proposes to expand its scope of care by providing ESWL services to its patients and residents of the community. The applicant proposes to enter into an agreement with United Medical System (DE), Inc. to provide state-of-the-art mobile lithotripsy equipment. United Medical System, the vendor and owner of a mobile ESWL unit, received approval for CON exemption from the Department on March 4, 2003, to lease lithotripsy equipment to hospitals or other health care facilities in Mississippi. The mobile ESWL unit (**a Dornier compact delta-SN 60 lithotripter**) will arrive at the Center in a vendor-provided van and will be moved from the van to a large procedure room in the Center in order to provide ESWL services to the applicant's patients.

Gulf Coast Endoscopy A.S.C., LLC, does not propose to purchase any new equipment as a result of this project. The Center has been approved by the Division of Health Facilities Licensure and Certification, MSDH, for the proposed project. Any increase in utilization of ancillary services at the Center can be handled efficiently by its existing ancillary support services. The costs and charges are not expected to be increased in any ancillary support department.

The proposed project requires no capital expenditure, modification or construction for the provision of ESWL services. According to the applicant the proposed project will be

implemented immediately upon Certificate of Need approval.

II. TYPE OF REVIEW REQUIRED

Projects which propose the establishment of mobile ESWL services are reviewed in accordance with Section 41-7-191, subparagraph (1)(d) (Xiii), Mississippi Code of 1972 Annotated, as amended, and duly adopted rules, procedures, plans, criteria and standards of the Mississippi State Department of Health.

In accordance with Section 41-7-197(2), of the Mississippi Code 1972 Annotated, as amended, an 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 on June 4, 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 addresses policy statements, criteria, and standards which an applicant is required to meet before receiving CON authority to provide ESWL services. This application is in substantial compliance with applicable criteria and standards. The proposal is for the establishment of ESWL services.

SHP Criterion 1 - Need

The applicant states that there is a need in General Hospital Service Area 7 to provide additional ESWL service to the area. According to the applicant, utilizing the equipment of a vendor with a mobile ESWL unit would improve the Center's treatment capabilities and allow Gulf Coast Endoscopy to offer additional procedures with minimal expenses.

The applicant asserts that according to the population projections found in the Mississippi Population Projections for 2005, 2010, and 2015 developed by the Center for Policy Research and Planning, Jackson County, the county in which the hospital is located, is the second most highly populated county in the state and will, by the year 2005, have a population of 147,894. Further, that population is expected to grow to 164,123 by the year 2015, an increase of 11 percent. With this in mind, the applicant believes the rapid growth of the area will increase the need to have additional ESWL services in the service area.

The applicant includes an affidavit from two physicians/urologists stating that they have treated a total of 287 kidney stone patients from January 1, 2002, through December 31, 2002. Out of the 287 patients treated during the identified period, the urologists performed ESWL treatment on 74 of their patients. Although the urologists express a need for the proposed mobile ESWL services at the Center, they stated that had the Center been authorized to provide ESWL services during the referenced period, they would have recommended that 45 procedures be performed at the Center.

The applicant also lists information from the National Center for Health Statistics, indicating that the South has a higher incidence of kidney stone disease than the remaining United

States. The Center shows that the U.S. has a 1.42 percent incidence rate per 1000 population compared to 1.84 percent rate in the South. Even though Mississippi's incidence rate cannot be retrieved from the center, the applicant believes that the state is considered to have one of the highest incidence rates in the southern region and in the United States.

Gulf Coast Endoscopy used three methodologies to assess the need in General Hospital Service Area 7. They are as follows: the American Hospital Association, Dornier, and Theta.

The following table shows extracorporeal shock wave lithotripsy utilization in GHSA 7.

of ESWL Procedures FY 2001
241

SHP Criterion 2 - Documentation of Medical Personnel

Gulf Coast Endoscopy asserts that the medical personnel required of this criterion shall reside within the hospital service area and shall be available 24 hours per day for emergency services required as a result of treatment by renal ESWL.

SHP Criterion 3 - Imaging Capabilities

The applicant indicates that the required capabilities of this criterion will be available for the proposed project.

SHP Criterion 4 - Scope of Privileges

The Center certifies that it will grant an appropriate scope of privileges for access to the lithotripter to any qualified physician who applies for privileges.

SHP Criterion 5 - Accessibility

The applicant indicates that all residents in the Center's primary and secondary service areas and GHSA 7, including Medicare and Medicaid recipients and medically indigent patients, have and will continue to have access to the services of the Center. The Center offers care for the indigent and does not have admission policies that will adversely affect access to care for indigents.

SHP Criterion 6 - Recording of Data

The applicant will record and maintain the information required of this criterion and will make it available to the Department within fifteen (15) business days of request.

SHP Criterion 7 - Staffing

The applicant asserts that Gulf Coast Endoscopy possesses a highly active and full-service radiology department. The Center has an established urological referral practice.

SHP Criterion 8 - Guidelines and Standards

The applicant asserts that the Center shall require that all individuals using the ESWL equipment shall meet, at a minimum, the AUA's guidelines and standards for training and proficiency in the operation of renal ESWL equipment.

SHP Criterion 9 - CON Exemption

United Medical Systems, Inc., the applicant's proposed ESWL vendor, was granted a Determination of Non-reviewability from the Department on March 4, 2003, to lease lithotripsy equipment to hospitals or other health care facilities in Mississippi.

B. General Review (GR) Criteria

Chapter 8 of the Mississippi Certificate of Need Review Manual, revised May 13, 2000, addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria.

GR Criterion 2 - Long Range Plan

According to the applicant, the proposed project comports with its goal to provide quality, efficient health care to all residents of the community and is compatible with its long range plans.

GR Criterion 3 - Availability of Alternatives

According to the applicant, the provision of ESWL services by Gulf Coast Endoscopy A.S.C., LLC is compatible with its long range plans to provide its patients with quality care; therefore, the Center rejected the alternative of doing nothing. The applicant considered the alternative of purchasing its own ESWL equipment. However, since that would require an outlay of capital which would not be as efficient as using mobile ESWL equipment owned by a vendor, that alternative was also rejected.

GR Criterion 4 - Economic Viability

Gulf Coast Endoscopy A.S.C., LLC's projects that its proposed project will experience incomes of \$39,375 for year one, \$38,180 for year two and \$37,632 for year three of operation.

GR Criterion 5 - Need for the Project

According to the applicant, all residents of the area, including low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, and the elderly, will have access to the proposed ESWL services provided at the Center.

According to the applicant, there is a need in GHSA 7 to provide additional ESWL service to the area. Utilizing the equipment of a vendor with a mobile ESWL unit would improve the Center's treatment capabilities and allow Gulf Coast Endoscopy A.S.C. to offer additional procedures with minimal expenses. The applicant includes affidavits from two physicians/urologists stating that they have treated a total of 287 kidney stone patients from January 1, 2002, through December 31, 2002. Out of the 287 patients treated during the identified period, the urologists performed ESWL treatment on 74 of their patients.

The applicant submits that the number of lithotripsy procedures that the urologists expect to perform at the Center during a one year period (45) and the heightened need for the procedures in the "stone belt" demonstrates the need for ESWL services in GHSA 7 and at Gulf Coast Endoscopy A.S.C.

The applicant projects the following number of ESWL procedures for the next three years of operation for the proposed project:

Projected ESWL Procedures

Year	Year 1	Year 2	Year 3
# of ESWL Procedures	45	46	48

The applicant believes that failure to implement this project will leave the residents of the Ocean Springs area without an adequate number of access points providing this care.

Two endorsement letters from community physicians were received in support of the ESWL service.

GR Criterion 6 - Access to the Facility or Service

The applicant asserts that all residents of the Gulf Coast, GHSA 7 and the state, including Medicaid recipients, charity/indigent patients, racial and ethnic minorities, women, handicapped persons and the elderly have access to the services of the existing facility and will have access to the proposed mobile ESWL services. According to the applicant, Gulf Coast Endoscopy A.S.C., LLC offers services to patients in need of care without regard to race, age, creed, sex or ethnic origin in full compliance with applicable state and federal regulation.

The following table gives the percentage of gross patient revenue and actual dollar amount of health care provided to medically indigent patients for the last three years at Gulf Coast Endoscopy A.S.C. LLC:

2000	2001	2002
\$3,465,437	\$4,134,205	\$4,362,342
5.0%	5.0%	5.0%

GR Criterion 7 - Information Requirement

Gulf Coast Endoscopy A.S.C., LLC affirms that it will record and maintain the information required by this criterion and make it available to the Mississippi State Department of Health within 15 business days of request.

GR Criterion 8 - Relationship to Existing Health Care System

There are presently six mobile ESWL units in GHSA 7. The applicant believes that the proposed project will have no adverse impact on the existing health care system of the area; on the contrary, it will serve as a complement to the system. The applicant asserts that because of the growth the Mississippi Gulf Coast area is experiencing, the offering of ESWL services by Gulf Coast Endoscopy A.S.C., LLC using mobile equipment will be an asset to the community and the existing health care system of the area.

GR Criterion 9 - Availability of Resources

According to the applicant, all additional necessary personnel will be provided by United Medical System, Inc. (**vendor**) pursuant to the service agreement for the proposed project.

GR Criterion 16 - Quality of Care

The applicant asserts that the Center provides and will continue to provide high quality medical care to the Mississippi Gulf Coast community. It is accredited by the JCAHO and AAAHC and 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.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

This proposed project requires no capital expenditure.

B. Method of Financing

There is no cost to the applicant for the proposed project.

C. Effect on Operating Cost

Gulf Coast Endoscopy projects the following expenses, revenues, and utilization for the first three years of operation for the proposed project:

Total Expense	YEAR 1	YEAR 2	YEAR 3
Leased Services & Equipment	\$67,500	\$ 71,070	\$ 76,368

Utilization, Cost and Charges

# of Scans	45	46	48
Cost/per Scan	\$1,500	\$1,545	\$1,591
Charge/Per Scan	\$2,500	\$2,500	\$2,500

Revenues

Gross Pat. Revenue	\$ 112,500	\$ 115,000	\$120,000
Deductions from Revenue	\$(5,625)	\$(5,750)	\$(6,000)
Net Pat. Service Revenue	\$ 106,875	\$109,250	\$114,000
Net Income (Loss)	\$ 39,375	\$ 38,180	\$37,632

D. Cost to Medicaid/Medicare

Currently, neither the Medicaid program nor the Medicare program reimburses ambulatory surgery centers for the provision of ESWL services. Therefore, this project will have negligible effect on these programs.

Applicant projects approximately 5 percent of gross revenue for medically indigent, bad debt and charity care patients.

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review. According to Medicaid, outpatient services are paid as outlined in the State Plan, therefore the Division of Medicaid takes no position on the proposed project.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the establishment of extracorporeal shock wave lithotripsy services as contained in the FY 2003 State Health Plan and Chapter 8 of the Mississippi Certificate of Need Review Manual, revised 2000, 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 Gulf Coast Endoscopy A.S.C., LLC.

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Attachment I