

LITHOTRIPSY SERVICES

I. DEFINITIONS

Extracorporeal Shockwave Lithotripsy (ESWL) uses intense soundwaves (shockwaves) generated outside the body (extracorporeally) to pulverize stones in the kidney, ureter, or bladder. ESWL was first used in Germany in 1980 and approved for use in the United States in 1984.

A. TYPES OF LITHOTRIPTER UNITS:

1. Fixed Lithotripter: A lithotripter unit that requires dedicated space within the acute care facility.
2. Mobile Lithotripter: A new, more mobile lithotripter unit that does not require dedicated space and can be moved from room to room within an acute care facility.
3. Shared Service Mobile Lithotripter: A lithotripter unit that is transported by truck and shared between two or more acute care facilities. This type of service shall continue to be subject to the criteria contained in W. Va. C.S.R. §65-7-16, "Exemption for Shared Services."

B. Historically, a lithotripsy unit required its own dedicated space or was available as a mobile/shared unit transported by truck. Due to technological advances, lithotripters are now available in smaller, more mobile units that do not require a dedicated space. The new more mobile units can be utilized within a facility and moved between surgical suites. The unit provides both convenience and flexibility because it can remain on site and be available full-time at various locations.

C. Other technology, referred to as orthopedic lithotripsy, uses shockwave technology, such as Extracorporeal Pressure Wave (ECPW) or Extracorporeal Shockwave Therapy (ESWT), for treatment of heel pain/spurs, tennis elbow, shoulder injuries, and non-union fractures.

II. CURRENT INVENTORY

The Health Care Authority (Authority) shall provide to each applicant a current inventory of existing Lithotripsy systems in the state. The inventory will identify each device as fixed, mobile, or shared service mobile.

III. NEED METHODOLOGY

A. Acute care facilities currently providing either Fixed Lithotripter or Shared Service Mobile Lithotripter services shall not be subject to further certificate of need review for the acquisition of a Mobile Lithotripter.

B. Acute care facilities not currently providing either Fixed Lithotripter or Shared Service Mobile Lithotripter services shall meet the following criteria before developing lithotripter services.

1. The acute care facility shall delineate its proposed service area from which it expects to draw patients.
2. The acute care facility shall estimate expected utilization or demand for lithotripter services based on a calculated West Virginia use rate. The calculation of expected utilization shall be based upon ICD-9-CM Codes for lithotripsy or upon projections generally relied upon by professionals engaged in health planning or the development of health services.
3. After establishing expected utilization or demand, the acute care facility shall document the number of existing providers within the service area and the extent to which the expected utilization is currently being met.

IV. QUALITY

A. In order to determine an application for lithotripsy services complete, the lithotripsy unit to be acquired and used for patient care must have pre-market approval (PMA) by the Food and Drug Administration (FDA) for clinical use, or the applicant must document that the unit to be acquired has received an Investigational Device Exemption (IDE) from the FDA, and the applicant must document that its site has received approval from the FDA as an IDE site.

B. Acute care facilities seeking to provide lithotripsy services shall document, prior to implementation, that a full-time board-certified physician with the appropriate training in the type of service to be provided shall be responsible for managing operation of the lithotripsy unit.

C. Acute care facilities seeking to provide lithotripsy services shall prepare a written plan, prior to implementation of the service, for training technologists in the use of the type of lithotripsy equipment to be acquired.

D. Acute care facilities seeking to provide lithotripsy services shall ensure that at least one staff member trained in CPR is on duty in the unit during its use.

E. Acute care facilities must demonstrate that it has in place effective utilization review, quality assurance, and peer review.

V. CONTINUUM OF CARE

A. Acute care facilities proposing to provide lithotripsy services shall have available on staff, or through referral, qualified physicians in the medical specialties appropriate for the service to be provided.

B. Acute care facilities proposing to provide lithotripsy services shall assure that such services are a part of an integrated program of services with on-site access to the necessary equipment and personnel.

C. Acute care facilities seeking to provide lithotripsy services shall, prior to the implementation of the services, document the design of a complete database that includes technical factors that may be related to patient safety. The database shall be designed so that it can become a part of a national database.

VI. COST

Applicants shall demonstrate the financial feasibility of the proposal by providing an analysis of the cost-effectiveness of the proposed project to include:

1. A three (3) year projection of revenues and expenses for the project;
2. Evidence that sufficient capital is available to initiate and operate the proposed project;
3. Evidence that financing arrangements are reasonable and secure;
4. Documentation that all indigent persons needing the service can be served without jeopardizing the viability of the project;
5. Demonstration that the applicant is willing to participate in reasonable utilization management programs sponsored by peer review or managed care organizations; and,
6. That the charges and costs used in projecting financial feasibility are equitable in comparison to prevailing rates for similar services in similar hospitals as defined by the Authority.

VII. ACCESSIBILITY

Applicants seeking to provide lithotripsy services shall document:

1. A scheduling priority system based on patient need;
2. Charges for referral services at rates no higher than those charged customarily to patients in the facility providing the service; and,

3. Compliance with all applicable state and federal laws regarding accessibility to the disabled.

VIII. OTHER

The applicant must provide additional information, as may be requested by the Authority, regarding demographics data, financial data, and clinical data for patients receiving the service.