

**EXTRA-CORPOREAL SHOCK
WAVE LITHOTRIPSY**



STATE OF TENNESSEE
STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

**EXTRA-CORPOREAL SHOCK WAVE
LITHOTRIPSY SERVICES**

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide extra-corporeal shock wave lithotripsy (ESWL) services. Rationale statements for each standard are provided in an appendix. Existing providers of ESWL services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for such services.

These proposed standards and criteria will become effective immediately upon approval and adoption by the governor. However, applications to provide ESWL services that are deemed complete by the HSDA prior to the approval and adoption of these standards and criteria shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

Lithotripsy: Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. Extracorporeal lithotripsy is lithotripsy that occurs outside the body. Extracorporeal shock wave lithotripsy is the non-invasive procedure that uses shock waves to pulverize urinary stones, which can then be expelled in the urine. An emitter is placed in contact with the patient relative to where the stone is located and the shock waves are focused on the stone, which is shattered by the force.

Procedure: A “procedure” is the single provision of ESWL services as reported by its ICD9 code or the ESWL services facility’s internal financial code that corresponds to the ESWL services CPT code.

Service Area: Refers to the county or counties represented by an applicant for ESWL services as the reasonable area to which the applicant intends to provide ESWL services and/or in which the majority of its current service recipients reside.

Standards and Criteria

1. **Determination of Need:** The need for ESWL services is determined by applying the following formula:

$$N = (U \times P) + O$$

N = number of ESWL services procedures needed in a Service Area;

U = latest available Tennessee use rate (number of procedures performed per 1,000 population in the state as determined by the Tennessee Department of Health);

P = projection of population (in thousands) in the service area as determined by the Tennessee Department of Health for Tennessee counties and the United States Census Bureau for non-Tennessee counties; and

O = the number of out-of-state resident procedures performed within the applicant's Service Area in the same time frame used to determine U based upon publically reported data. The applicant should document the methodology used to count volume in out-of-state resident procedures and, if different from the definition of "procedure" described in these standards and criteria, should distinguish out-of-state procedures from in-state cases.

The need shall be based upon the Service Area's current year's population projected three years forward.

2. **Minimum Volume Standard:** Applicants proposing to acquire and operate an ESWL services unit must project a minimum utilization of at least 250 procedures per year by the third year of operation, based on full-time use of an ESWL unit. The applicant must also document and provide data supporting the methodology used to project the patient utilization. An application to provide ESWL services on a part-time basis shall convert its projected use to that of a full-time equivalent ESWL unit.

3. **Current Service Area Utilization:** The applicant should document that all existing providers of ESWL services within the proposed Service Area each performed at least 300 ESWL procedures per year during the most recent 12 month period for which data are available. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. To characterize existing providers located within Tennessee, the applicant should use data provided by the Health Services and Development Agency. To characterize providers located outside of Tennessee, the applicant should use publicly available data, if available, and describe in its application the methodology these providers use to count volume.

In addition, the applicant should provide the HSDA with a report of patient destination for ESWL services based on the most recent 12 months of publicly reported data. This report should list all facilities that provided ESWL services to residents of the proposed Service Area and the number of ESWL procedures performed on residents of the Service Area for each facility. The Tennessee Department of Health will assist applicants in generating this report utilizing the HDDS.

4. **Adverse Impact on Existing Providers:** An application for ESWL services should not be approved if the new program will cause the annual caseload of existing ESWL programs within the Service Area to drop below an average of 300 procedures. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. The patient origin study conducted for Standard 2, an analysis of patient origin data collected for Standard 3, and the referral data documented for Standard 3 should be used to determine whether such an adverse impact on existing providers is likely to occur.
5. **Adequate Staffing and Services:** The applicant should document a plan for recruiting and maintaining a sufficient number of qualified professional and technical staff to provide the ESWL services and must document the following:
 - a. The existence of an active radiology service and an established referral urological practice;
 - b. The availability within 90 minutes' drive time of acute inpatient services for patients who experience complications; and
 - c. The fact that all individuals using the equipment meet the training and credentialing requirements of the American College of Surgeons' Advisory Council for Urology.

The applicant should also document an ongoing educational plan for all staff included in the ESWL services program.

6. **ESWL Equipment:** Only applications that provide for the provision of ESWL services using equipment that has been approved by the United States Food and Drug Administration for clinical use shall be approvable.

7. **Quality Control and Monitoring:** The applicant should identify and document its intention to participate in a data reporting, quality improvement, outcome monitoring, and peer review system that benchmarks outcomes based on national norms. The system should provide for peer review among professionals practicing in facilities and programs other than the applicant.
8. **Data Requirements:** Applicants should agree to provide the Department of Health and/or the HSDA with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.
9. **Transfer and/or Affiliation Agreements:** If an applicant is not a designated Level 1 trauma center, an applicant must document an acceptable plan for the development of transfer and/or affiliation agreements with hospitals in the service area (this criterion does not preclude the development of transfer agreements with facilities outside the applicant's Service Area).
10. **Access:** In addition to the factors set forth in HSDA Rule 0720-11-.01 (1) (listing the factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant:
 - a. That is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
 - b. That documents that the service area population experiences a prevalence and/or incidence of urinary stones or other clinical conditions applicable to extra-corporeal shock wave lithotripsy services that is substantially higher than the State of Tennessee average; or
 - c. That is a "safety net hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program.

CERTIFICATE OF NEED STANDARDS AND CRITERIA

Extra-Corporeal Shock Wave Lithotripsy Services

Definitions for “Lithotripsy,” “Procedure,” and “Service Area” are provided in the standards and criteria.

Rationale

- 1. Determination of Need:** The formula for determination of need is based on a state utilization rate formula for ESWL services, rather than one unit per 250,000 people. Data available in the future may enable the need determination to be based on regional utilization rates. The need determination also takes into account out-of-state residents’ utilization of Tennessee-based ESWL services. Need is based upon population projected three years forward, instead of the current four years provided by the Guidelines for Growth, reflecting the comparatively low capitalization requirements to institute ESWL services.
- 2. Minimum Volume:** Based on the responses to the Questionnaire and the comments at the public meeting, it appears that a reasonable minimum annual volume projection for an ESWL unit by its third year of operation is 250 procedures, which allows for future growth in services (the former Guidelines for Growth also required a projection of 250 procedures). An application to provide ESWL services on a part-time basis is converted to a full-time equivalent ESWL unit projected use.
- 3. Current Service Area Utilization:** Converting part-time ESWL unit utilization numbers to full-time equivalents, the average number of ESWL procedures performed by ESWL units in Tennessee in 2009 was 589. The Questionnaire responses and the public meeting comments showed strong and reasonable interest in ensuring greater accessibility to ESWL services statewide, as is contemplated by the State Health Plan’s Principle No. 2 for Achieving Better Health (“Every citizen should have reasonable access to health care”). This standard states that each existing Service Area ESWL unit should have performed at least 300 procedures in the most recent 12 month period in order for an application to show need for ESWL services in the Service Area. This standard also requires an applicant to provide patient origin data analysis.
- 4. Adverse Impact:** This standard suggests that existing ESWL programs in a Service Area should not drop below a projected annual utilization number of 300 procedures as a result of the granting of an application to provide ESWL services. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit.
- 5. Staffing/Services:** Availability of acute inpatient services within a 90 minute drive time has been added, replacing the current undefined “proximity” guideline, thus providing a

more definite access-to-care standard. The Guidelines for Growth referenced the “American Lithotripsy Society,” which no longer exists. That reference has been replaced by one to the “American College of Surgeons’ Advisory Council for Urology.”

6. **Equipment:** This standard reflects the one in the former Guidelines for Growth.
7. **Quality:** This standard reflects the connection to the State Health Plan’s Principle No. 4 for Achieving Better Health, “Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.”
8. **Data:** The ability to measure improvements in access to care and in cost of care can only be discerned by having access to necessary data. This standard reflects the continuing need for accurate data.
9. **Transfer Agreements:** This standard differs from the Guidelines for Growth in providing that an applicant that is a Level 1 Trauma Center need not provide a transfer and/or affiliation agreement.
10. **Access:** To ensure reasonable access to ESWL services in underserved areas, as is contemplated by the State Health Plan’s Principle No. 2 for Achieving Better Health (“Every citizen should have reasonable access to health care”), the HSDA may choose to give special consideration to applicants that meet these particular conditions.