

CHAPTER 33B**EXTRACORPOREAL SHOCKWAVE LITHOTRIPSY****Authority**

N.J.S.A. 26:2H-1 et seq.

Source and Effective Date

R.1996 d.103, effective February 20, 1996.
See: 27 N.J.R. 4201(a), 28 N.J.R. 1250(a).

Executive Order No. 66 (1978) Expiration Date

Chapter 33B, Extracorporeal Shockwave Lithotripsy, expires on February 20, 1998.

Chapter Historical Note

Chapter 33B, Extracorporeal Shock Wave Lithotripsy became effective October 7, 1985 as R.1985 d.497. Pursuant to Executive Order No. 66(1978), Chapter 33B was readopted as R.1990 d.418, effective July 27, 1990. See: 22 N.J.R. 1495(a), 22 N.J.R. 2506(b). Chapter 33B expired on July 27, 1995, pursuant to Executive Order No. 66(1978).

Chapter 33B, Extracorporeal Shockwave Lithotripsy, was adopted as new rules by R.1996 d.103, effective February 20, 1996. See: Source and Effective Date.

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SUBCHAPTER 1. GENERAL PROVISIONS**8:33B-1.1 Purpose and scope**

(a) The purpose of this chapter is to establish standards for the review of certificate of need applications to provide ESWL services in New Jersey.

(b) ESWL is limited in application solely to a finite number of patients for whom surgical removal of kidney stones would otherwise be the only choice of treatment. A regional approach to the delivery of this service is, therefore, necessary to assure quality ESWL services are readily available to those who are in need of this service and that the service is efficiently provided.

8:33B-1.2 Definitions

The following words and terms, when used in the chapter, shall have the following meanings:

“Department” means the New Jersey State Department of Health.

“Extracorporeal shock wave lithotripsy (ESWL)” means the technique by which kidney stones are disintegrated through the use of shock waves.

“Lithotripter” means a medical device which removes kidney stones without surgical intervention.

SUBCHAPTER 2. REQUIREMENTS**8:33B-2.1 New ESWL services**

(a) A certificate of need shall be required prior to the initiation of new ESWL services.

(b) The Department will accept certificate of need applications for new ESWL services where all existing ESWL providers in the State have achieved an annual utilization level of 1,500 procedures per year/per device in the most recent calendar year immediately prior to the Commissioner's call for certificate of need applications.

(c) Certificate of need applications shall be reviewed in accordance with procedures for full review as set forth at N.J.A.C. 8:33-4.1(a).

(d) Each applicant for a certificate of need for new ESWL services shall provide the Department with the following:

1. Documentation as to its ability to perform a minimum volume of ESWL procedures per year. The minimum acceptable number of ESWL procedures per device/per year is 500. Volume of patients diagnosed with, and hospitalized for, urinary calculi located in either the kidney or upper ureter is an indicator of potential ESWL candidates. Applicants shall, therefore, document sizable volumes of patients diagnosed and surgically treated by the applicant for removal of calculi located in the upper ureter or the kidney during the past three years. For purposes of reviewing applications, priority shall be given to applicants who can demonstrate volumes above the minimum;

2. Documentation that a minimal staff complement will be available on a full time basis to the ESWL unit. Staffing shall include, at a minimum:

- i. One urologist/surgeon;
- ii. One registered nurse;
- iii. One anesthesiologist; and
- iv. One technician;

3. Documentation of sufficient support personnel, consistent with the efficient delivery of quality ESWL service (for example, aides, secretaries, clerks, etc.);

4. Documentation of the existence, either on site or through formal written agreements, of:

- i. Active radiology and urology programs;
- ii. Teaching and research backup;
- iii. An established referral urological practice; and
- iv. An appropriate specialty backup;

5. Documentation that ESWL services shall be made available to all patients, regardless of the patient's race, religion, diagnosis, gender, age or ability to pay;

6. Documentation of written cooperative agreements with other institutions;

7. Shared or multi-institution applicants shall provide formal written agreements providing for inter-hospital referral and patient transfer agreements, which insure adequate follow up after the lithotripsy treatment;

8. Written documentation of the purchase and operational costs of the unit. This analysis shall include direct as well as indirect costs, construction/renovation costs, and cost impact analysis upon radiology and urology departments. In addition, the application must include a projection of costs and revenues for at least two years beyond the break-even point; and

9. Physical plans, reviewed and approved by the Health Facilities Construction Services unit of the New Jersey Department of Health, in accordance with N.J.A.C. 8:43A-29.4, showing adequate space to house the unit, accommodate patient needs (pre and post-treatment), and support staff needs.

8:33B-2.2 Data requirements

Patient utilization of the lithotripter (inpatient and outpatient) shall be provided by the applicant upon written request by the Department.