

## D. LITHOTRIPTERS<sup>1</sup>

### Introduction

A *lithotripter*, according to G.S. § 131E-176(14i), means “extra-corporeal shockwave technology used to treat persons with kidney stones and gallstones.” Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. A technician places an emitter in contact with the patient's abdomen to focus the shock waves on the stone. The shock waves then shatter the stone, which can be expelled in the urine. Extracorporeal shock wave lithotripsy (ESWL) is the non-invasive procedure to which this section pertains.

### Changes from the Previous Plan

This chapter contains no substantive changes from the previous State Medical Facilities Plan (SMFP). However, it contains technical changes that do not alter the methodology. Tables labeled as 15D-1 and 15D-2 in the previous SMFP have been combined into a single table (now Table 15D-1) and the narrative has been revised to align with the consolidated Table 15D-1.

### Data Sources

In addition to the standard data sources listed in the introduction to this chapter, this methodology also obtains the North Carolina Office of State Budget and Management’s July 1 projected population data for the current SMFP publication year, which is two years beyond the current reporting year.

### Definition

A lithotripter’s service area is statewide. A *statewide service area* is defined as a planning area that encompasses the entire state when determining need. For mobile equipment, the definition does not imply that a CON applicant is required to project that it will provide mobile services in a certain number of counties, health service areas (HSA), or regions. Similarly, once developed, the equipment does not have to serve a certain number of counties, HSAs, or regions.

### Assumptions of the Methodology

1. The incidence of urinary stone disease forms the basis of the methodology. The annual incidence of urinary stone disease is approximately 16 per 10,000 population. Lithotripsy is not an appropriate treatment for all cases of urinary stone disease. It has been estimated that lithotripsy is appropriate for 85% to 90% of kidney stone patients, when surgery is indicated.<sup>2</sup> Therefore, the need determination methodology assumes that lithotripsy is appropriate in 90% of cases of urinary stone disease.
2. The annual treatment capacity of a lithotripter is 1,500 cases. The methodology considers 67% (or 1,000 cases) to be full utilization for purposes of projecting need.

### Application of the Methodology

**Step 1:** Divide the July 1 estimated state population by 10,000 and multiply the result by 16, which yields the estimated incidence of urinary stone disease per 10,000 population.

<sup>1</sup> Note that “lithotripter” is the spelling used in the CON statute. “Lithotriptor” is the current accepted spelling in the medical field. The SMFP uses the latter spelling, but the term refers to the same equipment as “lithotripter” in the CON statute.

<sup>2</sup> Pahiri, J.J. & Razack, A.A. (2001) “Chapter 9: Nephrolithiasis.” In *Clinical Manual of Urology*, 3<sup>rd</sup> edition, by Philip M. Hanno, Alan J. Wein, & S. Bruce Malkowicz. New York: McGraw-Hill.

**Step 2:** Multiply the result from Step 1 by 90% to calculate the number of patients in the state who have the potential to be treated by lithotripsy in one year.

**Step 3:** Divide the result of Step 2 by 1,000 and round to the nearest whole number to calculate the low range of the annual treatment capacity of a lithotripter. A remainder of 0.50 or greater rounds to the next highest whole number; a remainder of less than 0.50 rounds to the next lowest whole number. [This calculation yields the number of lithotripters that the state requires.](#)

**Step 4:** Sum the number of existing mobile and fixed lithotripters in the state (~~Table 15D-1~~), the number of CON-approved [mobile and fixed](#) lithotripters under development, and the number of [mobile and fixed](#) lithotripters available pursuant to need determinations pending review or appeal ([Table 15D-1, Column B](#)).

**Step 5:** Subtract the result of Step 4 from the result of Step 3 to calculate the number of additional lithotripters needed in the state ([Table 15D-1, Column I](#)).

Unless otherwise specified by the methodology, calculations do not use rounded values. However, fractional values are rounded automatically when displayed.