

1 10A NCAC 14C .1703 is proposed for amendment as follows:

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3 **10A NCAC 14C .1703 PERFORMANCE STANDARDS**

4 (a) An applicant that proposes to develop open-heart surgery services shall:

5 ~~The applicant shall demonstrate that the proposed project is capable of meeting the following standards:~~

- 6 ~~(1) an applicant's existing and new or additional heart lung bypass machines shall be utilized at an~~
7 ~~annual rate of 200 open heart surgical procedures per machine, measured during the twelfth~~
8 ~~quarter following completion of the project;~~
9 ~~(2) at least 50 percent of the projected open heart surgical procedures shall be performed on patients~~
10 ~~residing within the primary open heart surgery service area;~~
11 ~~(3) (1) the applicant's demonstrate that the projected utilization and proposed staffing patterns are such~~
12 ~~that each open heart surgical team shall perform at least 150 open heart surgical procedures in the~~
13 ~~third year following completion of the project; project; and~~
14 ~~(4) (2) the applicant shall document the assumptions and provide data supporting the methodology used~~
15 ~~to make these projections; and projections.~~
16 ~~(5) heart lung bypass machines that have been acquired for non surgical use or for non heart surgical~~
17 ~~procedure use shall not be utilized in the performance of open heart surgical procedures.~~

18 (b) An applicant that proposes to acquire a heart-lung bypass machine shall demonstrate either:

- 19 (1) that the applicant's projected annual utilization of its existing, approved, and proposed heart-lung
20 bypass machines (other than a machine acquired pursuant to 10A NCAC 14C.1703(b)(3)) will be at
21 least 200 open heart surgical procedures per machine during the third year following completion
22 of the project;
23 (2) that the projected annual utilization of its existing, approved, and proposed heart-lung bypass
24 machines (other than a machine acquired pursuant to 10A NCAC 14C.1703(b)(3)), will be at least
25 900 hours per year during the third year following completion of the project, as measured in
26 minutes used or staffed on standby for all procedures; or
27 (3) that the proposed machine is needed to provide coverage for open-heart surgery emergencies and
28 will not be scheduled for use at the same time as the applicant's equipment used to support
29 scheduled open heart surgical procedures.

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31 *History Note: Authority G.S. 131E-177(1); 131E-183(b);*
32 *Eff. January 1, 1987;*
33 *Amended Eff. November 1, 1989;*
34 *Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent*
35 *rule becomes effective, whichever is sooner;*
36 *Amended Eff. January 4, 1994;*
37 *Temporary Amendment January 1, 1999;*

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Temporary Eff. January 1, 1999 expired October 12, 1999;
Temporary Amendment Eff. January 1, 2000 and shall expire on the date the permanent amendment to this rule, approved by the Rules Review Commission on November 17, 1999, becomes effective;
Amended Eff. July 1, 2000;
Temporary Amendment Eff. January 1, 2002;
Amended Eff. April 1, 2003;
Temporary Amendment Eff. February 1, 2010;
Amended Eff. January 1, 2013; November 1, 2010.