

1 10A NCAC 14C .2701 is proposed for readoption with substantive changes as follows:

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3 **SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER**

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5 **10A NCAC 14C .2701 DEFINITIONS**

6 The following definitions apply to all rules in this Section:

- 7 (1) ~~"Approved MRI scanner" means an MRI scanner which was not operational prior to the beginning~~  
8 ~~of the review period but which had been issued a certificate of need.~~
- 9 (2) ~~"Capacity of fixed MRI scanner" means 100 percent of the procedure volume that the MRI scanner~~  
10 ~~is capable of completing in a year, given perfect scheduling, no machine or room downtime, no~~  
11 ~~cancellations, no patient transportation problems, no staffing or physician delays and no MRI~~  
12 ~~procedures outside the norm. Annual capacity of a fixed MRI scanner is 6,864 weighted MRI~~  
13 ~~procedures, which assumes two weighted MRI procedures are performed per hour and the scanner~~  
14 ~~is operated 66 hours per week, 52 weeks per year.~~
- 15 (3) ~~"Capacity of mobile MRI scanner" means 100 percent of the procedure volume that the MRI scanner~~  
16 ~~is capable of completing in a year, given perfect scheduling, no machine or room downtime, no~~  
17 ~~cancellations, no patient transportation problems, no staffing or physician delays and no MRI~~  
18 ~~procedures outside the norm. Annual capacity of a mobile MRI scanner is 4,160 weighted MRI~~  
19 ~~procedures, which assumes two weighted MRI procedures are performed per hour and the scanner~~  
20 ~~is operated 40 hours per week, 52 weeks per year.~~
- 21 (4) ~~"Dedicated breast MRI scanner" means an MRI scanner that is configured to perform only breast~~  
22 ~~MRI procedures and is not capable of performing other types of non breast MRI procedures.~~
- 23 (5) ~~"Existing MRI scanner" means an MRI scanner in operation prior to the beginning of the review~~  
24 ~~period.~~
- 25 (6) ~~"Extremity MRI scanner" means an MRI scanner that is utilized for the imaging of extremities and~~  
26 ~~is of open design with a field of view no greater than 25 centimeters.~~
- 27 (7) ~~"Fixed MRI scanner" means an MRI scanner that is not a mobile MRI scanner.~~
- 28 (8) ~~"Magnetic Resonance Imaging" (MRI) means a non invasive diagnostic modality in which~~  
29 ~~electronic equipment is used to create tomographic images of body structure. The MRI scanner~~  
30 ~~exposes the target area to nonionizing magnetic energy and radio frequency fields, focusing on the~~  
31 ~~nuclei of atoms such as hydrogen in the body tissue. Response of selected nuclei to this stimulus is~~  
32 ~~translated into images for evaluation by the physician.~~
- 33 (9) ~~"Magnetic resonance imaging scanner" (MRI Scanner) is defined in G.S. 131E 176(14m).~~
- 34 (10) ~~"Mobile MRI region" means either the eastern part of the State which includes the counties in Health~~  
35 ~~Service Areas IV, V and VI (Eastern Mobile MRI Region), or the western part of the State which~~  
36 ~~includes the counties in Health Service Areas I, II, and III (Western Mobile MRI Region). The~~

1            ~~counties in each Health Service Area are identified in Appendix A of the State Medical Facilities~~  
2            ~~Plan.~~

3            (11) ~~—"Mobile MRI scanner" means an MRI scanner and transporting equipment which is moved at least~~  
4            ~~weekly to provide services at two or more campuses or physical locations.~~

5            (12) ~~—"MRI procedure" means a single discrete MRI study of one patient.~~

6            (13) ~~—"MRI service area" means the Magnetic Resonance Imaging Planning Areas, as defined in the~~  
7            ~~applicable State Medical Facilities Plan, except for proposed new mobile MRI scanners for which~~  
8            ~~the service area is a mobile MRI region.~~

9            (14) ~~—"MRI study" means one or more scans relative to a single diagnosis or symptom.~~

10           (15) ~~—"Multi position MRI scanner" means an MRI scanner as defined in the State Medical Facilities Plan,~~  
11           ~~pursuant to a special need determination for a demonstration project.~~

12           (16) ~~—"Related entity" means the parent company of the applicant, a subsidiary company of the applicant~~  
13           ~~(i.e., the applicant owns 50 percent or more of another company), a joint venture in which the~~  
14           ~~applicant is a member, or a company that shares common ownership with the applicant (i.e., the~~  
15           ~~applicant and another company are owned by some of the same persons).~~

16           (17) ~~—"Temporary MRI scanner" means an MRI scanner that the Certificate of Need Section has approved~~  
17           ~~to be temporarily located in North Carolina at a facility that holds a certificate of need for a new~~  
18           ~~fixed MRI scanner, but which is not operational because the project is not yet complete.~~

19           (18) ~~—"Weighted MRI procedures" means MRI procedures which are adjusted to account for the length of~~  
20           ~~time to complete the procedure, based on the following weights: one outpatient MRI procedure~~  
21           ~~without contrast or sedation is valued at 1.0 weighted MRI procedure, one outpatient MRI procedure~~  
22           ~~with contrast or sedation is valued at 1.4 weighted MRI procedures, one inpatient MRI procedure~~  
23           ~~without contrast or sedation is valued at 1.4 weighted MRI procedures; and one inpatient MRI~~  
24           ~~procedure with contrast or sedation is valued at 1.8 weighted MRI procedures.~~

25           (19) ~~—"Weighted breast MRI procedures" means MRI procedures which are performed on a dedicated~~  
26           ~~breast MRI scanner and are adjusted to account for the length of time to complete the procedure,~~  
27           ~~based on the following weights: one diagnostic breast MRI procedure is valued at 1.0 weighted MRI~~  
28           ~~procedure (based on an average of 60 minutes per procedure), one MRI guided breast needle~~  
29           ~~localization MRI procedure is valued at 1.1 weighted MRI procedure (based on an average of 66~~  
30           ~~minutes per procedure), and one MRI guided breast biopsy procedure is valued at 1.6 weighted MRI~~  
31           ~~procedures (based on an average of 96 minutes per procedure).~~

32           The following definitions shall apply to all rules in this Section:

33           (1) "Adjusted MRI procedure" shall have the same meaning as defined in the annual State Medical  
34           Facilities Plan in effect as of the first day of the review period.

35           (2) "Approved MRI scanner" means a magnetic resonance imaging (MRI) scanner that was issued a  
36           certificate of need but is not being used to provide services as of the application deadline for the  
37           review period.

- 1           (3) “Existing MRI scanner” means an MRI scanner that is being used to provide services as of the  
 2           application deadline for the review period.
- 3           (4) “Fixed MRI scanner” means an MRI scanner that is not a mobile MRI scanner.
- 4           (5) “Fixed MRI scanner service area” shall have the same meaning as defined in the annual State  
 5           Medical Facilities Plan in effect as of the first day of the review period.
- 6           (6) “Host site” means the location where the mobile MRI scanner provides services.
- 7           (7) “Magnetic resonance imaging (MRI) scanner” shall have the same meaning as defined in G.S. 131E-  
 8           176(14m).
- 9           (8) “Mobile MRI scanner” means an MRI scanner that is moved weekly to provide services at two or  
 10           more host sites.
- 11           (9) “Mobile MRI scanner service area” shall have the same meaning as defined in the annual State  
 12           Medical Facilities Plan in effect as of the first day of the review period.
- 13           (10) “Proposed MRI scanner” means the MRI scanner proposed in the application under review.

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15 *History Note: Authority G.S. 131E-177(1); 131E-183(b);*  
 16 *Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule*  
 17 *becomes effective, whichever is sooner;*  
 18 *Eff. February 1, 1994;*  
 19 *Temporary Amendment Eff. January 1, 1999;*  
 20 *Temporary Amendment Eff. January 1, 1999 Expired on October 12, 1999;*  
 21 *Temporary Amendment Eff. January 1, 2000;*  
 22 *Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking*  
 23 *originally proposed to be effective August 2000;*  
 24 *Temporary Amendment Eff. January 1, 2001;*  
 25 *Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking*  
 26 *originally proposed to be effective April 1, 2001;*  
 27 *Temporary Amendment Eff. January 1, 2002;*  
 28 *Amended Eff. August 1, 2002;*  
 29 *Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective*  
 30 *August 1, 2002;*  
 31 *Temporary Amendment Eff. January 1, 2003;*  
 32 *Amended Eff. August 1, 2004; April 1, 2003;*  
 33 *Temporary Amendment Eff. January 1, 2005;*  
 34 *Amended Eff. November 1, 2005;*  
 35 *Temporary Amendment Eff. February 1, 2006;*  
 36 *Amended Eff. November 1, 2006;*  
 37 *Temporary Amendment Eff. February 1, 2008;*

- 1                    *Amended Eff. November 1, 2008;*
- 2                    *Temporary Amendment Eff. February 1, 2009;*
- 3                    *Amended Eff. November 1, 2009;*
- 4                    *Temporary Amendment Eff. February 1, 2010;*
- 5                    *Amended Eff. November 1, ~~2010~~ 2010;*
- 6                    *Readopted Eff. January 1, 2022.*