1 10A NCAC 14C .1601 is readopted as published in 36:02 NCR 94-108 as follows: 2 3 SECTION .1600 - CRITERIA AND STANDARDS FOR CARDIAC CATHETERIZATION EQUIPMENT AND CARDIAC ANGIOPLASTY FOUIPMENT 4 5 6 10A NCAC 14C .1601 **DEFINITIONS** 7 The following definitions shall apply to all rules in this Section: 8 "Approved" means the equipment was not in operation prior to the beginning of the review period 9 and had been issued a certificate of need. 10 "Capacity" of an item of cardiac catheterization equipment means 1500 diagnostic equivalent procedures per year. One therapeutic cardiac catheterization procedure is valued at 1.75 11 diagnostic equivalent procedures. One cardiac catheterization procedure performed on a patient age 12 13 14 or under is valued at two diagnostic equivalent procedures. All other procedures are valued at 14 one diagnostic equivalent procedure. "Cardiac catheterization equipment" shall have the same meaning as defined in G.S. 131E 176(2f). 15 (3)"Cardiac catheterization procedure," for the purpose of determining utilization in a certificate of 16 need review, means a single episode of diagnostic or therapeutic catheterization which occurs during 17 18 one visit to a cardiac catheterization room, whereby a flexible tube is inserted into the patient's body and advanced into the heart chambers to perform a hemodynamic or angiographic examination or 19 therapeutic intervention of the left or right heart chamber, or coronary arteries. A cardiac 20 21 catheterization procedure does not include a simple right heart catheterization for monitoring purposes as might be done in an electrophysiology laboratory, pulmonary angiography procedure, 22 23 cardiac pacing through a right electrode catheter, temporary pacemaker insertion, or procedures 24 performed in dedicated angiography or electrophysiology rooms. "Cardiac catheterization room" means a room or a mobile unit in which there is cardiac 25 (5)catheterization or cardiac angioplasty equipment for the performance of cardiac catheterization 26 procedures. Dedicated angiography rooms and electrophysiology rooms are not cardiac 27 28 catheterization rooms. "Cardiac catheterization service area" means a geographical area defined by the applicant, which 29 (6) has boundaries that are not farther than 90 road miles from the facility, if the facility has a 30 31 comprehensive cardiac services program; and not farther than 45 road miles from the facility if the facility performs only diagnostic cardiac catheterization procedures; except that the cardiac 32 33 eatheterization service area of an academic medical center teaching hospital designated in 10A

NCAC 14B shall not be limited to 90 road miles.

catheterization equipment in a cardiac catheterization room.

"Cardiac catheterization services" means the provision of diagnostic cardiac catheterization

procedures or therapeutic cardiac catheterization procedures performed utilizing cardiac

1 of 4

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(7)

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2		full range of clinical services associated with the treatment of cardiovascular disease including
3		community outreach, emergency treatment of cardiovascular illnesses, non invasive diagnostic
4		imaging modalities, diagnostic and therapeutic cardiac catheterization procedures, open heart
5		surgery and cardiac rehabilitation services. Community outreach and cardiac rehabilitation services
6		shall be provided by the applicant or through arrangements with other agencies and facilities located
7		in the same city. All other components of a comprehensive cardiac services program shall be
8		provided within a single facility.
9	(9)	"Diagnostic cardiac catheterization procedure," for the purpose of determining utilization in a
10		certificate of need review, means a cardiac catheterization procedure performed for the purpose of
11		detecting and identifying defects or diseases in the coronary arteries or veins of the heart, or
12		abnormalities in the heart structure, but not the pulmonary artery.
13	(10)	"Electrophysiology procedure" means a diagnostic or therapeutic procedure performed to study the
14		electrical conduction activity of the heart and characterization of atrial ventricular arrhythmias.
15	(11)	"Existing" means the equipment was in operation prior to the beginning of the review period.
16	(12)	"High risk patient" means a person with reduced life expectancy because of left main or multi-vessel
17		coronary artery disease, often with impaired left ventricular function and with other characteristics
18		as referenced in the American College of Cardiology/ Society for Cardiac Angiography and
19		Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory
20		Standards (June 2001) report.
21	(13)	"Mobile equipment" means cardiac catheterization equipment and transporting equipment which is
22		moved to provide services at two or more host facilities.
23	(14)	"Percutaneous transluminal coronary angioplasty (PTCA)" is one type of therapeutic cardiac
24		catheterization procedure used to treat coronary artery disease in which a balloon tipped catheter is
25		placed in the diseased artery and then inflated to compress the plaque blocking the artery.
26	(15)	"Primary cardiac catheterization service area" means a geographical area defined by the applicant,
27		which has boundaries that are not farther than 45 road miles from the facility, if the facility has a
28		comprehensive cardiac services program; and not farther than 23 road miles from the facility if the
29		facility performs only diagnostic cardiac catheterization procedures; except that the primary cardiac
30		catheterization service area of an academic medical center teaching hospital designated in 10A
31		NCAC 14B shall not be limited to 45 road miles.
32	(16)	"Therapeutic cardiac catheterization procedure," for the purpose of determining utilization in a
33		certificate of need review, means a cardiac catheterization procedure performed for the purpose of
34		treating or resolving anatomical or physiological conditions which have been determined to exist in
35		the heart or coronary arteries or veins of the heart, but not the pulmonary artery.
36	The following de	efinitions shall apply to all rules in this Section:

(8) "Comprehensive cardiac services program" means a cardiac services program which provides the

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	that are not cardiac catheterization services.
	that are not cardiac carrierization services.
<u>(2)</u>	"Approved cardiac catheterization equipment" means cardiac catheterization equipment that was
	issued a certificate of need but is not being used to provide cardiac catheterization services as of the
	application deadline for the review period.
<u>(3)</u>	"Cardiac catheterization equipment" shall have the same meaning as defined in G.S. 131E-176(2f).
<u>(4)</u>	"Cardiac catheterization services" shall have the same meaning as defined in G.S. 131E-176(2g).
<u>(5)</u>	"Diagnostic-equivalent cardiac catheterization procedures" shall have the same meaning as defined
	in the annual State Medical Facilities Plan in effect as of the first day of the review period.
<u>(6)</u>	"Existing cardiac catheterization equipment" means cardiac catheterization equipment that is being
	used to offer cardiac catheterization services as of the application deadline for the review period.
<u>(7)</u>	"Fixed cardiac catheterization equipment" means cardiac catheterization equipment that is not
	mobile or shared fixed cardiac catheterization equipment.
<u>(8)</u>	"Fixed cardiac catheterization equipment service area" shall have the same meaning as defined in
	the annual State Medical Facilities Plan in effect as of the first day of the review period.
<u>(9)</u>	"Host site" means the location where the mobile cardiac catheterization equipment provides cardiac
	catheterization services.
(10)	"Mobile cardiac catherization equipment" means cardiac catheterization equipment that is moved
	weekly to provide cardiac catheterization services at two or more host sites.
<u>(11)</u>	"Mobile cardiac catheterization equipment service area" shall have the same meaning as defined in
	the annual State Medical Facilities Plan in effect as of the first day of the review period.
(12)	"Proposed cardiac catheterization equipment" means the cardiac catheterization equipment
	proposed in the certificate of need application.
(13)	"Shared fixed cardiac catheterization equipment" means fixed cardiac catheterization equipment
	that is used to perform cardiac catheterization procedures and angiography procedures.
History Note:	Authority G.S. 131E-177(1); 131E-183; <u>131E-183(b);</u>
	Eff. January 1, 1987;
	Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule
	becomes effective, whichever is sooner;
	Amended Eff. November 1, 1996; February 1, 1994;
	Temporary Amendment Eff. January 1, 1999;
	Temporary Eff. January 1, 1999 Expired on October 12, 1999;
	Temporary Amendment Eff. January 1, 2000;
	Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking
	originally proposed to be effective August 1, 2000;
	Temporary Amendment Eff. January 1, 2001;
	(3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13)

1	Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking
2	originally proposed to be effective April 1, 2001;
3	Amended Eff. August 1, 2002;
4	Temporary Amendment Eff. February 1, 2006;
5	Amended Eff. November 1, 2006. <u>2006:</u>
6	Readopted Eff. January 1, 2022.

1 10A NCAC 14C .1603 is readopted as published in 36:02 NCR 94-108 as follows: 2 3 10A NCAC 14C .1603 PERFORMANCE STANDARDS 4 (a) An applicant proposing to acquire cardiac catheterization equipment shall demonstrate that the project is capable 5 of meeting the following standards: 6 each proposed item of cardiac catheterization equipment, including mobile equipment but excluding (1)7 shared fixed cardiac catheterization equipment, shall be utilized at an annual rate of at least 60 8 percent of capacity excluding procedures not defined as cardiac catheterization procedures in 10A 9 NCAC 14C .1601(5), measured during the fourth quarter of the third year following completion of 10 the project; if the applicant proposes to perform therapeutic cardiac catheterization procedures, each of the 11 applicant's therapeutic cardiac catheterization teams shall be performing at an annual rate of at least 12 13 100 therapeutic cardiac catheterization procedures, during the third year of operation following 14 completion of the project; if the applicant proposes to perform diagnostic cardiac catheterization procedures, each diagnostic 15 (3)cardiac catheterization team shall be performing at an annual rate of at least 200 16 diagnostic equivalent cardiac catheterization procedures by the end of the third year following 17 18 completion of the project; 19 at least 50 percent of the projected cardiac catheterization procedures shall be performed on patients (4)20 residing within the primary cardiac catheterization service area; 21 (b) An applicant proposing to acquire mobile cardiac catheterization equipment shall: 22 demonstrate that each existing item of cardiac catheterization equipment, excluding mobile (1)23 equipment, located in the proposed primary cardiac catheterization service area of each host facility 24 shall have been operated at a level of at least 80 percent of capacity during the 12 month period reflected in the most recent licensure form on file with the Division of Health Service Regulation; 25 demonstrate that the utilization of each existing or approved item of cardiac catheterization 26 (2)equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization 27 28 service area of each host facility shall not be expected to fall below 60 percent of capacity due to the acquisition of the proposed mobile cardiac catheterization equipment; 29 30 (3)demonstrate that each item of existing mobile equipment operating in the proposed primary cardiac 31 catheterization service area of each host facility shall have been performing at least an average of four diagnostic equivalent cardiac catheterization procedures per day per site in the proposed 32 33 eardiac catheterization service area in the 12 month period preceding the submittal of the 34 application; 35 (4)demonstrate that each item of existing or approved mobile equipment to be operating in the proposed primary cardiac catheterization service area of each host facility shall be performing at least an 36

1		average of four diagnostic equivalent cardiac catheterization procedures per day per site in the
2		proposed cardiac catheterization service area in the applicant's third year of operation; and
3	(5)	provide documentation of all assumptions and data used in the development of the projections
4		required in this Rule.
5	(c) An applicar	at proposing to acquire cardiac catheterization equipment excluding shared fixed and mobile cardiac
6	catheterization s	shall:
7	(1)	demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment,
8		located in the proposed cardiac catheterization service area operated at an average of at least 80
9		percent of capacity during the twelve month period reflected in the most recent licensure renewal
10		application form on file with the Division of Health Service Regulation;
11	(2)	demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment,
12		shall be utilized at an average annual rate of at least 60 percent of capacity, measured during the
13		fourth quarter of the third year following completion of the project; and
14	(3)	provide documentation of all assumptions and data used in the development of the projections
15		required in this Rule.
16	(d) An applica	nt proposing to acquire shared fixed cardiac catheterization equipment as defined in the applicable
17	State Medical Fa	acilities Plan shall:
18	(1)	demonstrate that each proposed item of shared fixed cardiac catheterization equipment shall perform
19		a combined total of at least 225 cardiac catheterization and angiography procedures during the fourth
20		quarter of the third year following completion of the project; and
21	(2)	provide documentation of all assumptions and data used in the development of the projections
22		required in this Rule.
23	(e) If the applic	ant proposes to perform cardiac catheterization procedures on patients age 14 and under, the applicant
24	shall demonstrat	te that it meets the following additional criteria:
25	(1)	the facility has the capability to perform diagnostic and therapeutic cardiac catheterization
26		procedures and open heart surgery services on patients age 14 and under; and
27	(2)	the proposed project shall be performing at an annual rate of at least 100 cardiac catheterization
28		procedures on patients age 14 or under during the fourth quarter of the third year following initiation
29		of the proposed cardiac catheterization procedures for patients age 14 and under.
30	(a) An applican	t proposing to acquire fixed cardiac catheterization equipment pursuant to a need determination in the
31	annual State Me	edical Facilities Plan in effect as of the first day of the review period shall:
32	<u>(1)</u>	identify the existing fixed cardiac catheterization equipment owned or operated by the applicant or
33		a related entity and located in the proposed fixed cardiac catheterization equipment service area;
34	<u>(2)</u>	identify the approved fixed cardiac catheterization equipment owned or operated by the applicant
35		or a related entity and located in the proposed fixed cardiac catheterization equipment service area;

1	(3)	provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs
2		(a)(1) and (a)(2) of this Paragraph and the proposed fixed cardiac catheterization equipment during
3		each of the first three full fiscal years of operation following completion of the project;
4	<u>(4)</u>	provide the assumptions and methodology used to project the utilization required by Subparagraph
5		(a)(3) of this Paragraph; and
6	(5)	project that the cardiac catheterization equipment identified in Subparagraphs (a)(1) and (a)(2) of
7		this Paragraph and the proposed fixed cardiac catheterization equipment shall perform 900 or more
8		diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization
9		equipment during the third full fiscal year of operation following completion of the project.
10	(b) An applican	t proposing to acquire shared fixed cardiac catheterization equipment pursuant to a need determination
11	in the annual Sta	ate Medical Facilities Plan in effect as of the first day of the review period shall:
12	<u>(1)</u>	provide projected utilization of the proposed shared fixed cardiac catheterization equipment during
13		each of the first three full fiscal years of operation following completion of the project;
14	<u>(2)</u>	provide the assumptions and methodology used to project the utilization required by Subparagraph
15		(b)(1) of this Paragraph; and
16	(3)	project that the proposed shared fixed cardiac catheterization equipment shall perform 225 or more
17		diagnostic-equivalent cardiac catheterization and angiography procedures during the third full fiscal
18		year of operation following completion of the project.
19	(c) An applican	nt proposing to acquire mobile cardiac catheterization equipment pursuant to a need determination in
20	the State Medica	al Facilities Plan in effect as of the first day of the review period shall:
21	(1)	identify the existing mobile cardiac catheterization equipment owned or operated by the applicant
22		or a related entity that provides cardiac catheterization services at host sites located in the proposed
23		mobile cardiac catheterization equipment service area;
24	(2)	identify the approved mobile cardiac catheterization equipment owned or operated by the applicant
25		or a related entity that will provide cardiac catheterization services at host sites located in the
26		proposed mobile cardiac catheterization equipment service area;
27	(3)	provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs
28		(c)(1) and (c)(2) of this Paragraph and the proposed mobile cardiac catheterization equipment during
29		each of the first three full fiscal years of operation following completion of the project;
30	<u>(4)</u>	provide the assumptions and methodology used to project the utilization required by Subparagraph
31		(c)(3) of this Paragraph; and
32	<u>(5)</u>	project that the cardiac catheterization equipment identified in Subparagraphs (c)(1) and (c)(2) of
33		this Paragraph and the proposed mobile cardiac catheterization equipment shall perform 225 or more
34		diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization
35		equipment during the third full fiscal year of operation following completion of the project.
36		
37	History Note:	Authority G.S. 131E-177(1); 131E-183(b);

1	Eff. January 1, 1987;
2	Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule
3	becomes effective, whichever is sooner;
4	Amended Eff. November 1, 1996; February 1, 1994;
5	Temporary Amendment Eff. January 1, 1999;
6	Temporary Eff. January 1, 1999 Expired on October 12, 1999;
7	Temporary Amendment Eff. January 1, 2000;
8	Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking
9	originally proposed to be effective August 2000;
10	Temporary Amendment Eff. January 1, 2001;
11	Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking
12	originally proposed to be effective April 1, 2001;
13	Temporary Amendment Eff. January 1, 2002;
14	Amended Eff. August 1, 2002;
15	Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective
16	August 1, 2002;
17	Amended Eff. April 1, 2003;
18	Temporary Amendment Eff. February 1, 2006;
19	Amended Eff. November 1, 2006. <u>2006;</u>
20	Readopted Eff. January 1, 2022.

8

1 10A NCAC 14C .1701 is readopted as published in 36:02 NCR 94-108 as follows: 2 3 SECTION .1700 - CRITERIA AND STANDARDS FOR OPEN-HEART SURGERY SERVICES AND 4 HEART-LUNG BYPASS MACHINES 5 6 10A NCAC 14C .1701 **DEFINITIONS** 7 The following definitions apply to all rules in this Section: 8 "Approved heart lung bypass machine" means a heart lung bypass machine that was not operational 9 prior to the beginning of the review period. 10 "Capacity" of a heart lung bypass machine means 400 adult equivalent open heart surgical procedures per year. One open heart surgical procedure on persons age 14 and under is valued at 11 two adult open heart surgical procedures. For purposes of determining capacity, one open heart 12 13 surgical procedure is defined to be one visit or trip by a patient to an operating room for an open 14 heart operation. "Cardiac Surgical Intensive Care Unit" means an intensive care unit as defined in 10A NCAC 14C 15 (3).1201(2) and that is for exclusive use by post surgical open heart patients. 16 "Existing heart lung bypass machine" means a heart lung bypass machine in operation prior to the 17 18 beginning of the review period. "Heart lung bypass machine" has the same meaning as defined in G.S. 131E 176(10a). 19 (5)"Open heart surgery services" has the same meaning as defined in G.S. 131E 176(18b). 20 (6) 21 (7) "Open heart surgical procedures" means specialized surgical procedures that: 22 (a) utilize a heart lung bypass machine (the "pump"); and 23 (b) are designed to correct congenital or acquired cardiac and coronary disease by opening the chest for surgery on the heart muscle, valves, arteries, or other parts of the heart. 24 25 The following definitions shall apply to all rules in this Section: 26 (1) "Approved heart-lung bypass machine" means a heart-lung bypass machine that was issued a certificate of need but is not being used as of the application deadline for the review period. 27 28 (2) "Existing heart-lung bypass machine" means a heart-lung bypass machine that is being used as of 29 the application deadline for the review period. "Health service facility" shall have the same meaning as defined in G.S. 131E-176(9b). 30 (3) 31 "Heart-lung bypass machine" shall have the same meaning as defined in G.S. 131E-176(10a). (4) "Open-heart surgical procedure" means one visit by a patient to an operating room for open heart 32 (5) 33 surgery services. 34 (6) "Open-heart surgery services" shall have the same meaning as defined in G.S. 131E-176(18b). "Proposed heart-lung bypass machine" means the heart-lung bypass machine proposed in the 35 (7) 36 application under review. 37

1	History Note:	Authority G.S. 131E-177(1); 131E-183; <u>131E-183(b);</u>
2		Eff. January 1, 1987;
3		Amended Eff. November 1, 1989;
4		Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule
5		becomes effective, whichever is sooner;
6		Amended Eff. November 1, 1996; January 4, 1994;
7		Temporary Amendment Eff. January 1, 1999;
8		Temporary Eff. January 1, 1999 Expired on October 12, 1999;
9		Temporary Amendment Eff. January 1, 2000 and shall expire on the date on which the permanent
10		amendment to this Rule, approved by the Rules Review Commission on November 17, 1999, becomes
11		effective;
12		Amended Eff. July 1, 2000;
13		Temporary Amendment Eff. March 1, 2010;
14		Amended Eff. January 1, 2013; November 1, 2010. <u>2010;</u>
15		Readopted Eff. January 1, 2022.

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1	10A NCAC 14C .1901 is readopted as published in 36:02 NCR 94-108 as follows:	
2		
3	SECTION .1900 – CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT LINEA	R
4	<u>ACCELERATORS</u>	
5		
6	10A NCAC 14C .1901 DEFINITIONS	
7	These definitions shall apply to all rules in this Section:	
8	(1) "Approved linear accelerator" means a linear accelerator which was not operational prior to	the
9	beginning of the review period.	
10	(2) "Complex Radiation treatment" is equal to 1.0 ESTV and means: treatment on three or more si	tes
11	on the body; use of techniques such as tangential fields with wedges, rotational or are technique	es;
12	or use of custom blocking.	
13	(3) "Equivalent Simple Treatment Visit [ESTV]" means one basic unit of radiation therapy wh	ich
14	normally requires up to fifteen (15) minutes for the uncomplicated set up and treatment of a pati	ent
15	on a megavoltage teletherapy unit including the time necessary for portal filming.	
16	(4) "Existing linear accelerator" means a linear accelerator in operation prior to the beginning of	the
17	review period.	
18	(5) "Intermediate Radiation treatment" means treatment on two separate sites on the body, three or m	əre
19	fields to a single treatment site or use of multiple blocking and is equal to 1.0 ESTV.	
20	(6) "Linear accelerator" shall have the same meaning as defined in G.S. 131E 176(14g).	
21	(7) "Linear accelerator service area" means a single or multi-county area as used in the development	of
22	the need determination in the applicable State Medical Facilities Plan.	
23	(8) "Megavoltage unit" means MRT equipment which provides a form of teletherapy that involves	the
24	delivery of energy greater than, or equivalent to, one million volts by the emission of x-rays, gam	ma
25	rays, electrons, or other radiation.	
26	(9) "Megavoltage radiation therapy (MRT)" means the use of ionizing radiation in excess of one mill	i on
27	electron volts in the treatment of cancer.	
28	(10) "MRT equipment" means a machine or energy source used to provide megavoltage radiation there	ı ру
29	including linear accelerators and other particle accelerators.	
30	(11) "Radiation therapy equipment" means medical equipment which is used to provide radiation there	ı ру
31	services.	
32	(12) "Radiation therapy services" means those services which involve the delivery of controlled a	ınd
33	monitored doses of radiation to a defined volume of tumor bearing tissue within a patient. Radiat	i on
34	may be delivered to the tumor region by the use of radioactive implants or by beams of ioniz	i ng
35	radiation or it may be delivered to the tumor region systemically.	
36	(13) "Radiation therapy service area" means a single or multi-county area as used in the development	: of
37	the need determination in the applicable State Medical Facilities Plan.	

1	(14)	"Simple Radiation treatment" means treatment on a single site on the body, single treatment field or
2		parallel opposed fields with no more than simple blocks and is equal to 1 ESTV.
3	(15)	"Simulator" shall have the same meaning as defined in G.S. 131E-176(24b).
4	(16)	"Special technique" means radiation therapy treatments that may require increased time for each
5		patient visit including:
6		(a) total body irradiation (photons or electrons) which equals 2.5 ESTVs;
7		(b) hemi body irradiation which equals 2.0 ESTVs;
8		(c) intraoperative radiation therapy which equals 10.0 ESTVs;
9		(d) neutron and proton radiation therapy which equals 2.0 ESTVs;
10		(e) intensity modulated radiation treatment (IMRT) which equals 1.0 ESTV;
11		(f) limb salvage irradiation at lengthened SSD which equals 1.0 ESTV;
12		(g) additional field check radiographs which equals .50 ESTV;
13		(h) stereotactic radiosurgery treatment management with linear accelerator or gamma knife
14		which equals 3.0. ESTVs; and
15		(i) pediatric patient under anesthesia which equals 1.5 ESTVs.
16	The following d	lefinitions shall apply to all rules in this Section:
17	<u>(1)</u>	"Approved LINAC" means a linear accelerator (LINAC) that was issued a certificate of need but is
18		not being used to provide services as of the application deadline for the review period.
19	(2)	"Equivalent Simple Treatment Visit (ESTV)" shall have the same meaning as defined in the annual
20		State Medical Facilities Plan in effect as of the first day of the review period.
21	(3)	"Existing LINAC" means a LINAC that is being used to provide services as of the application
22		deadline for the review period.
23	<u>(4)</u>	"LINAC service area" shall have the same meaning as defined in the annual State Medical Facilities
24		Plan in effect as of the first day of the review period.
25	<u>(5)</u>	"Linear accelerator (LINAC)" shall have the same meaning as defined in G.S. 131E-176(14g).
26	<u>(6)</u>	"Proposed LINAC" means the LINAC proposed in the application under review.
27		
28	History Note:	Authority G.S. 131E-177(1); 131E-183(b);
29		Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule
30		becomes effective, whichever is sooner;
31		Eff. January 4, 1994;
32		Amended Eff. November 1, 1996;
33		Temporary Amendment January 1, 1999;
34		Temporary Amendment Eff. January 1, 1999 expired October 12, 1999;
35		Temporary Amendment Eff. January 1, 2000;
36		Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking
37		originally proposed to be effective August 2000;

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1	Amended Eff. April 1, 2001;
2	Temporary Amendment Eff. January 1, 2002;
3	Amended Eff. April 1, 2003;
4	Temporary Amendment Eff. January 1, 2005;
5	Amended Eff. November 1, 2005;
6	Temporary Amendment Eff. February 1, 2006,
7	Amended Eff. November 1, 2006. 2006;
8	Readopted Eff. January 1, 2022.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Department of Health and Human Services/ DHSR

RULE CITATION: 10A NCAC 14C .1903

DEADLINE FOR RECEIPT: Friday, December 3, 2021

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

Please provide some language to link (A) through (B) to Item (5).

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1	10A NCAC 14C .1903 is readopted as published in 36:02 NCR 94-108 as follows:	
2		
3	10A NCAC 14C .1903 PERFORMANCE STANDARDS	
4	(a) An applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards we	ill
5	be met:	
6	(1) an applicant's existing linear accelerators located in the proposed radiation therapy service are	ea
7	performed at least 6,750 ESTV treatments per machine or served at least 250 patients per machine	ne
8	in the twelve months prior to the date the application was submitted;	
9	(2) each proposed new linear accelerator will be utilized at an annual rate of 250 patients or 6,750 EST	¥
10	treatments during the third year of operation of the new equipment; and	
11	(3) an applicant's existing linear accelerators located in the proposed radiation therapy service area a	re
12	projected to be utilized at an annual rate of 6,750 ESTV treatments or 250 patients per machin	ne
13	during the third year of operation of the new equipment.	
14	(b) A linear accelerator shall not be held to the standards in Paragraph (a) of this Rule if the applicant provid-	es
15	documentation that the linear accelerator has been or will be used exclusively for clinical research and teaching.	
16	(c) An applicant proposing to acquire radiation therapy equipment other than a linear accelerator shall provide the	he
17	following information:	
18	(1) the number of patients who are projected to receive treatment from the proposed radiation therap	эy
19	equipment, classified by type of equipment, diagnosis, treatment procedure, and county	of
20	residence; and	
21	(2) the maximum number and type of procedures that the proposed equipment is capable of performin	g.
22	(d) The applicant shall document all assumptions and provide data supporting the methodology used to determine	ne
23	projected utilization as required in this Rule.	
24	An applicant proposing to acquire a LINAC pursuant to a need determination in the annual State Medical Facilities	es
25	Plan in effect as of the first day of the review period shall:	
26	(1) identify the existing LINACs owned or operated by the applicant or a related entity and located	in
27	the proposed LINAC service area;	
28	(2) identify the approved LINACs owned or operated by the applicant or a related entity and located	in
29	the proposed LINAC service area;	
30	(3) provide projected utilization of the LINACs identified in Items (1) and (2) of this Rule and the	he
31	proposed LINAC during each of the first three full fiscal years of operation following completic	on
32	of the project;	
33	(4) provide the assumptions and methodology used for the projected utilization required by Item (3)	of
34	this Rule;	
35	(5) project that the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC sha	<u>all</u>
36	perform during the third full fiscal year of operation following completion of the project:	
37	(A) 6,750 or more ESTVs per LINAC; or	

1		(B) serve 250 or more patients per LINAC.
2		
3 <i>H</i> 1	istory Note:	Authority G.S. 131E-177(1); 131E-183(b);
4		Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule
5		becomes effective, whichever is sooner;
6		Eff. January 4, 1994;
7		Amended Eff. November 1, 1996
8		Temporary Amendment Eff. January 1, 1999;
9		Temporary Amendment effective January 1, 1999 expired October 12, 1999;
10		Temporary Amended Eff. January 1, 2000;
11		Temporary Amendment Eff. February 1, 2006;
12		Amended Eff. November 1, 2006.
13		Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking
14		originally proposed to be effective August 2000;
15		Amended Eff. April 1, 2001;
16		Temporary Amendment Eff. March 15, 2002; January 1, 2002; Amended Eff. April 1, 2003;
17		Temporary Amendment Eff. February 1, 2008;
18		Amended Eff. November 1, 2008;
19		Temporary Amendment Eff. February 1, 2009;
20		Amended Eff. November 1, 2009. <u>2009:</u>
21		Readopted Eff. January 1, 2022.

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1	10A NCAC 14C	2.2301 is repealed through readoption as published in 36:02 NCR 94-108 as follows:
2		
3	SECTION .2	300 – CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY EQUIPMENT
4		
5	10A NCAC 140	C.2301 DEFINITIONS
6		
7	History Note:	Authority G.S. 131E-177(1); 131E-183(b);
8		Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule
9		becomes effective, whichever is sooner;
10		Eff. February 1, 1994;
11		Amended Eff. February 1, 2008. <u>2008;</u>
12		Repealed Eff. January 1, 2022.

1	10A NCAC 14C	2.2303 is repealed through readoption as published in 36:02 NCR 94-108 as follows:
2		
3	10A NCAC 140	C.2303 PERFORMANCE STANDARDS
4		
5	History Note:	Authority G.S. 131E-177(1); 131E-183(b);
6		Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule
7		becomes effective, whichever is sooner;
8	Eff. February 1, 1994;	
9		Amended Eff. February 1, 2008. <u>2008:</u>
10		Repealed Eff. January 1, 2022.

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1 10A NCAC 14C .2401 is readopted as published in 36:02 NCR 94-108 as follows: 2 3 SECTION .2400 - CRITERIA AND STANDARDS FOR INTERMEDIATE CARE FACILITIES FOR 4 INDIVIDUALS WITH INTELLECTUAL DISABILITIES 5 6 10A NCAC 14C .2401 **DEFINITIONS** 7 The definitions in this Rule shall apply to all rules in this Section: 8 "Intermediate care facility for the mentally retarded (ICF/MR)" shall have the same meaning as 9 defined in G.S. 131E-176(14a). 10 "Active treatment" means: (2)11 regular participation in professionally developed and supervised activities, experiences, or therapies in accordance with an individual plan of care; 12 13 an individual plan of care which is a written plan that is based on individual choice and 14 sets forth measurable goals or behaviorally stated objectives and prescribes an integrated program of individually designed activities, experiences or therapies necessary to achieve 15 16 such goals or objectives; an interdisciplinary professional evaluation consisting of complete medical, social, or 17 18 psychological diagnosis and an evaluation of the individual's need for the facility's care, 19 prior to admission but not to exceed three months before admission to the facility or, in the 20 case of individuals who make application while in such facility, before requesting payment 21 under the plan; re evaluation medically, socially, and psychologically, at least annually by the staff 22 (d) involved in carrying out the resident's individual plan of care, including review of the 23 individual's progress toward meeting the plan of care, assessment of continuing need for 24 facility care, and consideration of alternate methods of care; and 25 26 (e) an individual plan (as part of the individual's total plan of care) developed prior to discharge that is based on individual choice by a qualified developmental disabilities professional 27 28 and other appropriate professionals, which includes the present residence, specifying the type of care and services that will be needed to enable the individual to function in a 29 different environment and also includes provisions for protective supervision. 30 "Qualified Developmental Disabilities Professional" means a staff person in an ICF/MR facility 31 (3)designated to be responsible for supervising the implementation of each resident's individual plan 32 33 of care, integrating the various aspects of the facility's program, recording each resident's progress and initiating periodic review of each individual plan of care. A Qualified Developmental 34 Disabilities Professional shall meet the minimum qualifications for employment as defined in the 35 36 42 CFR 483.430 which is incorporated by reference including all subsequent amendments.

1	(4)—	"Catchment area" means the geographic part of the State served by a specific area authority ("Area
2		authority" means the Mental Health, Developmental Disabilities, and Substance Abuse Authority.)
3	The following d	efinitions shall apply to all rules in this Section:
4	<u>(1)</u>	"Catchment area" means as defined in G.S. 122C-3(4).
5	<u>(2)</u>	"Intermediate care facility for individuals with intellectual disabilities" means as defined in G.S.
6		<u>131E-176(14a).</u>
7		
8	History Note:	Authority G.S. 131E-177(1), (5); <u>131E-177(1); 131E-177(5);</u> 131E-183;
9		Eff. December 1, 1981;
10		Amended Eff. November 1, 1996; September 1, 1989. <u>1989;</u>
11		Readopted Eff. January 1, 2022.

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1	10A NCAC 14C	.2403 is readopted as published in 36:02 NCR 94-108 as follows:
2		
3	10A NCAC 14C	.2403 PERFORMANCE STANDARDS
4	(a) An applicant	t proposing to add ICF/MR intermediate care facility for individuals with intellectual disabilities
5	(ICF/IID) beds to	o an existing facility shall not be approved unless the average occupancy, over the six months
6	immediately prec	eding the submittal of the application, of the total number of ICF/MR ICF/IID beds within the facility
7	in which the new	beds are to be operated was at least 90 percent.
8	(b) An applican	t proposing to establish new ICF/IID beds shall not be approved unless occupancy is
9	projected to be at	least 90 percent for the total number of $\frac{ICF/MR}{ICF/IID}$ beds proposed to be operated in the entire
10	facility, no later to	han one year following the completion of the proposed project.
11	(c) An applicant	proposing to establish new ICF/MR ICF/IID beds shall comply with one of the following models:
12	(1)	a residential community based freestanding facility with six beds or less, i.e., group home model; $\underline{\text{or}}$
13	(2)	a community-based facility with 7 to 15 beds if documentation is provided that a facility of this size
14		is necessary because adequate residential community based freestanding facilities are not available
15		in the Area Authority catchment area to meet the needs of the population to be served; or served.
16	(3)	a facility with greater than 15 beds if the proposed new beds are to be established in response to an
17		adjusted need determination contained in the 2003 State Medical Facilities Plan.
18	(d) No more that	n three intermediate care facilities for the mentally retarded ICF/IID facilities housing a combined
19	total of 18 person	s shall be developed on contiguous pieces of property, with the exception that this standard shall be
20	waived for beds p	proposed to be established in response to an adjusted need determination contained in the 2003 State
21	Medical Facilities	: Plan. property.
22		
23	History Note:	Authority G.S. 131E-177(1), (5); <u>131E-177(1);</u> 131E-177(5); 131E-183;
24		Eff. November 1, 1996;
25		Temporary Amendment Eff. January 1, 2003;
26		Amended Eff. August 1, 2004. <u>2004:</u>
27		Readopted Eff. January 1, 2022.

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1	10A NCAC 140	C .2501 is repealed through readoption as published in 36:02 NCR 94-108 as follows:
2		
3	SECTION.	2500 – CRITERIA AND STANDARDS FOR SUBSTANCE USE DISORDER (CHEMICAL
4		DEPENDENCY TREATMENT) BEDS
5		
6	10A NCAC 14	C .2501 DEFINITIONS
7		
8	History Note:	Authority G.S. 131E-177(1); 131E-183;
9		Eff. March 1, 1983;
10		Amended Eff. November 1, 1996; October 1, 1984.
11		Temporary Amendment Eff. January 1, 2001;
12		Amended Eff. August 1, 2002. <u>2002;</u>
13		Repealed Eff. January 1, 2022.

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1	10A NCAC 140	C .2503 is repealed through readoption as published in 36:02 NCR 94-108 as follows:
2		
3	10A NCAC 14	C .2503 PERFORMANCE STANDARDS
4		
5	History Note:	Authority G.S. 131E-177(1); 131E-183(b);
6		Eff. November 1, 1996;
7		Temporary Amendment Eff. January 1, 2002;
8		Amended Eff. April 1, 2003;
9		Temporary Amendment Eff. February 1, 2006;
10		Amended Eff. January 1, 2007. <u>2007;</u>
11		Repealed Eff. January 1, 2022.

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1	10A NCAC 14C .2601 is repealed through readoption as published in 36:02 NCR 94-108 as follows
2	
3	SECTION .2600 – CRITERIA AND STANDARDS FOR PSYCHIATRIC BEDS
4	
5	10A NCAC 14C .2601 DEFINITIONS
6	
7	History Note: Authority G.S. 131E-177(1); 131E-183(b);
8	Eff. May 1, 1983;
9	Amended Eff. August 1, 2009; November 1, 1989. <u>1989:</u>
10	Repealed Eff. January 1, 2022.

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1	10A NCAC 140	C.2603 is repealed through readoption as published in 36:02 NCR 94-108 as follows
2		
3	10A NCAC 140	C .2603 PERFORMANCE STANDARDS
4		
5	History Note:	Authority G.S. 131E-177(1); 131E-183;
6		Eff. November 1, 1996. <u>1996;</u>
7		Repealed Eff. January 1, 2022.

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1	10A NCAC 14C	.2701 is readopted as published in 36:02 NCR 94-108 as follows:
2		
3	SECTION .270	0 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER
4		
5	10A NCAC 140	C.2701 DEFINITIONS
6	The following de	efinitions 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 scanne
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 MR
12		procedures outside the norm. Annual capacity of a fixed MRI scanner is 6,864 weighted MR
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 scanne
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 MR
18		procedures outside the norm. Annual capacity of a mobile MRI scanner is 4,160 weighted MR
19		procedures, which assumes two weighted MRI procedures are performed per hour and the scanne
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 breas
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 scanne
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 in
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

26 1 of 4

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 d	efinitions shall apply to all rules in this Section:
33	<u>(1)</u>	"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.

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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	<u>(4)</u>	"Fixed MRI scanner" means an MRI scanner that is not a mobile MRI scanner.
4	<u>(5)</u>	"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	<u>(6)</u>	"Host site" means the location where the mobile MRI scanner provides services.
7	<u>(7)</u>	"Magnetic resonance imaging (MRI) scanner" shall have the same meaning as defined in G.S. 131E-
8		<u>176(14m).</u>
9	(8)	"Mobile MRI scanner" means an MRI scanner that is moved weekly to provide services at two or
10		more host sites.
11	<u>(9)</u>	"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	<u>(10)</u>	"Proposed MRI scanner" means the MRI scanner proposed in the application under review.
14		
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;

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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. <u>2010:</u>
6	Readopted Eff. January 1, 2022.

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REQUEST FOR TECHNICAL CHANGE

AGENCY: Department of Health and Human Services/ DHSR

RULE CITATION: 10A NCAC 14C .2703

DEADLINE FOR RECEIPT: Friday, December 3, 2021

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

Please provide some language to link (A) through (E) to (a)(7). Perhaps end (a)(7) with something like "as follows:"? Please do the same for (b)(9).

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

10A NCAC 14C .2703 is readopted as published in 36:02 NCR 94-108 as follows:

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:

- demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which the proposed equipment will be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in the event an existing mobile MRI scanner has been in operation less than 12 months at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;
- demonstrate annual utilization in the third year of operation is reasonably projected to be at least 3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which the proposed equipment will be located [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; and
- (3) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.
- (b) An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:
 - (1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;
 - demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];
 - (3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:
 - (A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,

1	(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixe
2	MRI scanner is located,
3	(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixe
4	MRI scanners are located,
5	(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixe
6	MRI scanners are located, or
7	(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four of
8	more fixed MRI scanners are located;
9	(4) if the proposed MRI scanner will be located at a different site from any of the existing or approve
10	MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of
11	the proposed fixed MRI scanner is reasonably expected to perform the following number of
12	weighted MRI procedures, whichever is applicable, in the third year of operation followin
13	completion of the proposed project:
14	(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixe
15	MRI scanners are located,
16	(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixe
17	MRI scanner is located,
18	(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixe
19	MRI scanners are located,
20	(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixe
21	MRI scanners are located, or
22	(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four of
23	more fixed MRI scanners are located;
24	(5) demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanne
25	which the applicant or a related entity owns a controlling interest in and locates in the proposed MR
26	service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of
27	operation following completion of the proposed project [Note: This is not the average number of
28	weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and
29	(6) document the assumptions and provide data supporting the methodology used for each projection
30	required in this Rule.
31	(c) An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which
32	the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the
33	need determination shall:
34	(1) demonstrate annual utilization of the proposed MRI scanner in the third year of operation
35	reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure
36	per hour times 40 hours per week times 52 weeks per year; and

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1	(2)	document the assumptions and provide data supporting the methodology used for each projection
2		required in this Rule.
3	(d) An applican	t proposing to acquire a fixed extremity MRI scanner for which the need determination in the State
4	Medical Facilitie	es Plan was based on an approved petition for an adjustment to the need determination shall:
5	(1)	demonstrate annual utilization of the proposed MRI scanner in the third year of operation is
6		reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to
7		10A NCAC 14C .2702(f)(7); and
8	(2)	document the assumptions and provide data supporting the methodology used for each projection
9		required in this Rule.
10	(e) An applican	t proposing to acquire a fixed multi position MRI scanner for which the need determination in the
11	State Medical Fa	ncilities Plan was based on an approved petition for a demonstration project shall:
12	(1)	demonstrate annual utilization of the proposed multi position MRI scanner in the third year of
13		operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant
14		in response to 10A NCAC 14C .2702(g)(7); and
15	(2)	document the assumptions and provide data supporting the methodology used for each projection
16		required in this Rule.
17	(a) An applicar	at proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State
18	Medical Facilitie	es Plan in effect as of the first day of the review period shall:
19	(1)	identify the existing fixed MRI scanners owned or operated by the applicant or a related entity and
20		located in the proposed fixed MRI scanner service area;
21	(2)	identify the approved fixed MRI scanners owned or operated by the applicant or a related entity and
22		located in the proposed fixed MRI scanner service area;
23	(3)	identify the existing mobile MRI scanners owned or operated by the applicant or a related entity
24		that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service
25		area during the 12 months before the application deadline for the review period;
26	(4)	identify the approved mobile MRI scanners owned or operated by the applicant or a related entity
27		that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service
28		area;
29	<u>(5)</u>	provide projected utilization of the MRI scanners identified in Subparagraphs (a)(1) through (a)(4)
30		of this Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years
31		of operation following completion of the project;
32	(6)	provide the assumptions and methodology used to project the utilization required by Subparagraph
33		(a)(5) of this Paragraph;
34	<u>(7)</u>	project that the fixed MRI scanners identified in Subparagraphs (a)(1) and (a)(2) of this Paragraph
35		and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation
36		following completion of the project:

1		(A) 3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more
2		fixed MRI scanners in the fixed MRI scanner service area;
3		(B) 3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI
4		scanners in the fixed MRI scanner service area;
5		(C) 2,883 or more adjusted MRI procedures per fixed MRI scanner if there are two fixed MRI
6		scanners in the fixed MRI scanner service area;
7		(D) 2,643 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI
8		scanner in the fixed MRI scanner service area; or
9		(E) 1,201 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI
10		scanners in the fixed MRI scanner service area; and
11	(8)	project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall
12		perform 3,328 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal
13		year of operation following completion of the project.
14	(b) An applican	at proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State
15	Medical Facilitie	es Plan in effect as of the first day of the review period shall:
16	<u>(1)</u>	identify the existing mobile MRI scanners owned or operated by the applicant or a related entity
17		that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service
18		area during the 12 months before the application deadline for the review period;
19	<u>(2)</u>	identify the approved mobile MRI scanners owned or operated by the applicant or a related entity
20		that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner
21		service area;
22	<u>(3)</u>	identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that
23		are located in the proposed mobile MRI scanner service area;
24	<u>(4)</u>	identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that
25		will be located in the proposed mobile MRI scanner service area;
26	<u>(5)</u>	identify the existing and proposed host sites for each mobile MRI scanner identified in
27		Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner;
28	<u>(6)</u>	provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4)
29		of this Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years
30		of operation following completion of the project;
31	<u>(7)</u>	provide the assumptions and methodology used to project the utilization required by Subparagraph
32		(b)(6) of this Paragraph;
33	(8)	project that the mobile MRI scanners identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph
34		and the proposed mobile MRI scanner shall perform 3,328 or more adjusted MRI procedures per
35		MRI scanner during the third full fiscal year of operation following completion of the project; and
36	(9)	project that the fixed MRI scanners identified in Subparagraphs (b)(3) and (b)(4) of this Paragraph
37		shall perform during the third full fiscal year of operation following completion of the project:

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1		(A)	3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more
2			fixed MRI scanners in the fixed MRI scanner service area;
3		<u>(B)</u>	3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI
4			scanners in the fixed MRI scanner service area;
5		<u>(C)</u>	2,883 or more adjusted MRI procedures per fixed MRI scanner if there are two fixed MRI
6			scanners in the fixed MRI scanner service area;
7		(D)	2,643 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI
8			scanner in the fixed MRI scanner service area; or
9		<u>(E)</u>	1,201 or more adjusted MRI procedures per MRI scanner if there are no fixed MRI scanners
10			in the fixed MRI scanner service area.
11			
12	History Note:	Autho	rity G.S. 131E-177(1); 131E-183(b);
13		Тетр	orary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule
14		becon	nes effective, whichever is sooner;
15		Eff. F	ebruary 1, 1994;
16		Тетр	orary Amendment Eff. January 1, 1999;
17		Тетр	orary Amendment Eff. January 1, 1999 Expired on October 12, 1999;
18		Тетр	orary Amendment Eff. January 1, 2000;
19		Тетр	orary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking
20		origin	ally proposed to be effective August 2000;
21		Тетро	orary Amendment Eff. January 1, 2001;
22		Тетро	orary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking
23		origin	ally proposed to be effective April 1, 2001;
24		Тетр	orary Amendment Eff. January 1, 2002;
25		Тетр	orary Amendment Eff. January 1, 2002 amends and replaces the permanent rule effective,
26		Augus	st 1, 2002;
27		Тетро	orary Amendment Eff. January 1, 2003;
28		Amen	ded Eff. August 1, 2004; April 1, 2003;
29		Тетро	orary Amendment Eff. January 1, 2005;
30		Amen	ded Eff. November 1, 2005;
31		Тетро	orary Amendment Eff. February 1, 2006;
32		Amen	ded Eff. November 1, 2006;
33		Тетро	orary Amendment Eff. February 1, 2008;
34		Amen	ded Eff. November 1, 2008. <u>2008;</u>
35		Reado	opted Eff. January 1, 2022.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Department of Health and Human Services/ DHSR

RULE CITATION: 10A NCAC 14C .3701

DEADLINE FOR RECEIPT: Friday, December 3, 2021

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In Item (8) please consider changing "PET scanner" to "Positron emission tomography scanner" since that it what is actually defined in G.S. 131E-176(19a). You've done something similar for MRI scanners in .2701 (7).

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amber May
Commission Counsel
Date submitted to agency: November 17, 2021

1	10A NCAC 14C	.3701 is readopted as published in 36:02 NCR 94-108 as follows:
2		
3	SECTION	.3700 - CRITERIA AND STANDARDS FOR POSITRON EMISSION TOMOGRAPHY
4		SCANNER
5		
6	10A NCAC 14C	2.3701 DEFINITIONS
7	The following de	efinitions shall apply to all rules in this Section:
8	(1)	"Approved positron emission tomography (PET) scanner" means a PET scanner which was not
9		operational prior to the beginning of the review period but which had been issued a certificate of
10		need.
11	(2)	"Cyclotron" means an apparatus for accelerating protons or neutrons to high energies by means of
12		a constant magnet and an oscillating electric field.
13	(3)	"Dedicated PET Scanner" means PET Scanners as defined in the applicable State Medical Facilities
14		Plan.
15	(4)	"Existing PET scanner" means a PET scanner in operation prior to the beginning of the review
16		period.
17	(5)	"Mobile PET Scanner" means a PET scanner and transporting equipment that is moved, at least
18		weekly, to provide services at two or more host facilities.
19	(6)	"PET procedure" means a single discrete study of one patient involving one or more PET scans.
20	(7)	"PET scan" means an image scanning sequence derived from a single administration of a PET
21		radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise
22		a PET procedure.
23	(8)	"PET scanner service area" means the PET Scanner Service Area as defined in the applicable State
24		Medical Facilities Plan.
25	(9)	"Positron emission tomographic scanner" (PET) is defined in G.S. 131E-176(19a).
26	(10)	"Radioisotope" means a radiochemical which directly traces biological processes when introduced
27		into the body.
28	The following de	efinitions shall apply to all rules in this Section:
29	<u>(1)</u>	"Approved PET scanner" means a positron emission tomography (PET) scanner that was issued a
30		certificate of need but is not being used to provide services as of the application deadline for the
31		review period.
32	<u>(2)</u>	"Existing PET scanner" means a PET scanner that is being used to provide services as of the
33		application deadline for the review period.
34	(3)	"Fixed PET scanner" means a PET scanner that is not mobile.
35	(4)	"Fixed PET scanner service area" shall have the same meaning as defined in the annual State
36	, ,	Medical Facilities Plan in effect as of the first day of the review period.
37	(5)	"Host site" means the location where the mobile PET scanner provides services.

1	(6)	"Mobile PET scanner" means a PET scanner that is moved weekly to provide services at two or
2		more host sites.
3	<u>(7)</u>	"Mobile PET scanner service area" shall have the same meaning as defined in the annual State
4		Medical Facilities Plan in effect as of the first day of the review period.
5	<u>(8)</u>	"PET scanner" shall have the same meaning as defined in G.S. 131E-176(19a).
6	(9)	"Proposed PET scanner" means the PET scanner proposed in the application under review.
7		
8	History Note:	Authority G.S. 131E-177(1); 131E-183(b);
9		Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule
10		becomes effective, whichever is sooner;
11		Eff. January 4, 1994;
12		Temporary Amendment Eff. January 1, 2001;
13		Temporary Amendment Eff. January 1, 2002;
14		Amended Eff. August 1, 2002;
15		Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective
16		August 1, 2002;
17		Temporary Amendment Eff. January 1, 2003;
18		Amended Eff. August 1, 2004; April 1, 2003. <u>2003;</u>
19		Readopted Eff. January 1, 2022.

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1	10A NCAC 14C .3703 is readopted as published in 36:02 NCR 94-108 as follows:
2	
3	10A NCAC 14C .3703 PERFORMANCE STANDARDS
4	(a) An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, sha
5	demonstrate that:
6	(1) the proposed dedicated PET scanner, including a proposed mobile dedicated PET scanner, shall b
7	utilized at an annual rate of at least 2,080 PET procedures by the end of the third year followin
8	completion of the project;
9	(2) if an applicant operates an existing dedicated PET scanner, its existing dedicated PET scanner
10	excluding those used exclusively for research, performed an average of at least 2,080 PE
11	procedures per PET scanner in the last year; and
12	(3) its existing and approved dedicated PET scanners shall perform an average of at least 2,080 PE
13	procedures per PET scanner during the third year following completion of the project.
14	(b) The applicant shall describe the assumptions and provide data to support and document the assumptions an
15	methodology used for each projection required in this Rule.
16	(a) An applicant proposing to acquire a fixed PET scanner pursuant to a need determination in the annual Stat
17	Medical Facilities Plan in effect as of the first day of the review period shall:
18	(1) identify the existing fixed PET scanners owned or operated by the applicant or a related entity an
19	located in the proposed fixed PET scanner service area;
20	(2) identify the approved fixed PET scanners owned or operated by the applicant or a related entity an
21	located in the proposed fixed PET scanner service area;
22	(3) identify the existing mobile PET scanners owned or operated by the applicant or a related entity that
23	provided services at host sites located in the proposed fixed PET scanner service area during the 1
24	months before the application deadline for the review period;
25	(4) identify the approved mobile PET scanners owned or operated by the applicant or a related entit
26	that will provide services at host sites located in the proposed fixed PET scanner service area;
27	(5) provide projected utilization of the PET scanners identified in Subparagraphs (a)(1) through (a)(4)
28	of this Paragraph and the proposed fixed PET scanner during each of the first three full fiscal year
29	of operation following completion of the project;
30	(6) provide the assumptions and methodology used to project the utilization required by Subparagrap
31	(a)(5) of this Paragraph; and
32	(7) project that the PET scanners identified in Subparagraphs (a)(1) through (a)(4) of this Paragrap
33	and the proposed fixed PET scanner shall perform 2,080 or more procedures per PET scanner durin
34	the third full fiscal year of operation following completion of the project.
35	(b) An applicant proposing to acquire a mobile PET scanner pursuant to a need determination in the annual State
36	Medical Facilities Plan in effect as of the first day of the review period shall:

1	(1)	identify the existing mobile PET scanners owned or operated by the applicant or a related entity that
2		provided services at host sites located in the proposed mobile PET scanner service area during the
3		12 months before the application deadline for the review period;
4	<u>(2)</u>	identify the approved mobile PET scanners owned or operated by the applicant or a related entity
5		that will provide services at host sites located in the proposed mobile PET scanner service area
6		during the first three full fiscal years following completion of the project;
7	<u>(3)</u>	identify the existing fixed PET scanners owned or operated by the applicant or a related entity and
8		located in the proposed mobile PET scanner service area;
9	<u>(4)</u>	identify the approved fixed PET scanners owned and operated by the applicant or a related entity
10		and located in the proposed mobile PET scanner service area;
11	<u>(5)</u>	identify the existing and proposed host sites for each mobile PET scanner identified in
12		Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile PET scanner;
13	<u>(6)</u>	provide projected utilization of the PET scanners identified in Subparagraphs (b)(1) through (b)(4)
14		of this Paragraph and the proposed mobile PET scanner during each of the first three full fiscal years
15		of operation following completion of the project:
16	<u>(7)</u>	provide the assumptions and methodology used to project the utilization required by Subparagraph
17		(b)(6) of this Paragraph; and
18	(8)	project that the PET scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph
19		and the proposed mobile PET scanner shall perform 2,080 or more procedures per PET scanner
20		during the third full fiscal year of operation following completion of the project.
21		
22	History Note:	Authority G.S. 131E-177(1); 131E-183(b);
23		Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule
24		becomes effective, whichever is sooner;
25		Eff. January 4, 1994;
26		Temporary Amendment Eff. January 1, 2002; January 1, 2001;
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29		August 1, 2002;
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31		Amended Eff. August 1, 2004; April 1, 2003;
32		Temporary Amendment Eff. January 1, 2005;
33		Amended Eff. November 1, 2005;
34		Temporary Amendment Eff. February 1, 2006;
35		Amended Eff. November 1, 2006. 2006;
36		Readopted Eff. January 1, 2022.

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