1	10A NCAC 14	C .1401 is readopted as published in 38:02 NCR 80-83 as follows:
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3	SECTION	.1400 – CRITERIA AND STANDARDS FOR <u>LEVEL IV</u> NEONATAL <u>INTENSIVE CARE</u>
4		SERVICES
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6	10A NCAC 14	C.1401 DEFINITIONS
7	The definitions	in this Rule shall apply to all rules in this Section:
8	(1)	"Approved neonatal service" means a neonatal service that was not operational prior to the
9		beginning of the review period.
10	(2)	"Existing neonatal service" means a neonatal service in operation prior to the beginning of the
11		review period.
12	(3)	"High risk obstetric patients" means those patients requiring specialized services provided by an
13		acute care hospital to the mother and fetus during pregnancy, labor, delivery and to the mother after
14		delivery. The services are characterized by specialized facilities and staff for the intensive care and
15		management of high risk maternal and fetal patients before, during, and after delivery.
16	(4)	"Level I neonatal services" means services provided by an acute care hospital to full term and pre-
17		term neonates that are stable, without complications, and may include neonates that are small for
18		gestational age or large for gestational age.
19	(5)	"Level II neonatal service" means services provided by an acute care hospital in a licensed acute
20		care bed to neonates and infants that are stable without complications but require special care and
21		frequent feedings; infants of any weight who no longer require Level III or Level IV neonatal
22		services, but still require more nursing hours than normal infants; and infants who require close
23		observation in a licensed acute care bed.
24	(6)	"Level III neonatal service" means services provided by an acute care hospital in a licensed acute
25		care bed to neonates or infants that are high risk, small (approximately 32 and less than 36
26		completed weeks of gestational age) but otherwise healthy, or sick with a moderate degree of illness
27		that are admitted from within the hospital or transferred from another facility requiring intermediate
28		care services for sick infants, but not intensive care. Level III neonates or infants require less
29		constant nursing care than Level IV services, but care does not exclude respiratory support.
30	(7)	"Level IV neonatal service" means neonatal intensive care services provided by an acute care
31		hospital in a licensed acute care bed to high risk medically unstable or critically ill neonates
32		(approximately under 32 weeks of gestational age) or infants requiring constant nursing care or
33		supervision not limited to continuous cardiopulmonary or respiratory support, complicated surgical
34		procedures, or other intensive supportive interventions.
35	(8)	"Neonatal bed" means a licensed acute care bed used to provide Level II, III or IV neonatal services.
36	(9)	"Neonatal intensive care services" shall have the same meaning as defined in G.S. 131E 176(15b).

1	(10)	"Neonatal service area" means a geographic area defined by the applicant from which the patients
2		to be admitted to the service will originate.
3	(11)	"Neonatal services" means any of the Level I, Level II, Level III or Level IV services defined in this
4		Rule.
5	(12)	"Obstetric services" means any normal or high risk services provided by an acute care hospital to
6		the mother and fetus during pregnancy, labor, delivery and to the mother after delivery.
7	(13)	"Perinatal services" means services provided during the period shortly before and after birth.
8	The following d	efinitions shall apply to all rules in this Section:
9	(1)	"Approved neonatal intensive care unit (NICU) beds" means acute care beds in a hospital that were
10		issued a certificate of need to provide Level IV neonatal intensive care services but are not providing
11		those services as of the application deadline for the review period.
12	(2)	"Average daily census (ADC)" means the total number of existing, approved, and proposed NICU
13		days of care provided during a full fiscal year of operation divided by 365 days.
14	(3)	"Existing NICU beds" means acute care beds in a hospital that are providing Level IV neonatal
15		intensive care services as of the application deadline for the review period.
16	(4)	"Level IV neonatal intensive care services" means services provided to high-risk medically unstable
17		or critically ill neonates less than 32 weeks of gestational age, or infants requiring constant nursing
18		care or supervision in NICU beds.
19	(5)	"Occupancy rate" means the ADC divided by the total number of existing, approved, and proposed
20		NICU beds expressed as a percentage.
21	<u>(6)</u>	"Proposed NICU beds" means the acute care beds proposed [to be developed] to provide Level IV
22		neonatal intensive care services in a hospital in the application under review.
23		
24	History Note:	Authority G.S. 131E-177(1); 131E-183; <u>131E-183(b);</u>
25		Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule
26		becomes effective, whichever is sooner;
27		Eff. January 4, 1994;
28		Amended Eff. November 1, 1996;
29		Temporary Amendment Eff. March 15, 2002;
30		Amended Eff. April 1, 2003. 2003:
31		<u>Readopted Eff. January 1, 2024.</u>

1 2 10A NCAC 14C .1403 is readopted as published in 38:02 NCR 80-83 as follows:

3 10A NCAC 14C .1403 **PERFORMANCE STANDARDS** 4 (a) An applicant shall demonstrate that the proposed project is capable of meeting the following standards: 5 if an applicant is proposing to increase the total number of neonatal beds (i.e., the sum of Level II, (1)6 Level III and Level IV beds), the overall average annual occupancy of the combined number of 7 existing Level II, Level III and Level IV beds in the facility is at least 75 percent, over the 12 months 8 immediately preceding the submittal of the proposal; 9 if an applicant is proposing to increase the total number of neonatal beds (i.e., the sum of Level II, (2)10 Level III and Level IV beds), the projected overall average annual occupancy of the combined number of Level II, Level III and Level IV beds proposed to be operated during the third year of 11 operation of the proposed project shall be at least 75 percent; and 12 13 (3)The applicant shall document the assumptions and provide data supporting the methodology used 14 for each projection in this rule. (b) If an applicant proposes to develop a new Level III or Level IV service, the applicant shall document that an unmet 15 need exists in the applicant's defined neonatal service area, unless the State Medical Facilities Plan includes a need 16 determination for neonatal beds in the service area. The need for Level III and Level IV beds shall be computed for 17 18 the applicant's neonatal service area by: 19 identifying the annual number of live births occurring at all hospitals within the proposed neonatal (1)service area, using the latest available data compiled by the State Center for Health Statistics; 20 21 identifying the low birth weight rate (percent of live births below 2,500 grams) for the births (2)identified in (1) of this Paragraph, using the latest available data compiled by the State Center for 22 23 Health Statistics: dividing the low birth weight rate identified in (2) of this Paragraph by .08 and subsequently 24 (3)multiplying the resulting quotient by four; and 25 determining the need for Level III and Level IV beds in the proposed neonatal service area as the 26 (4)product of: 27 28 (A) - the product derived in (3) of this Paragraph, and the quotient resulting from the division of the number of live births in the initial year of the 29 (B) determination identified in (1) of this Paragraph by the number 1000. 30 31 (a) An applicant proposing to develop a new Level IV neonatal intensive care service without increasing the total 32 number of acute care beds on the hospital license shall: 33 provide projected utilization of the proposed NICU beds during each of the first three full fiscal (1)34 years of operation following completion of the project; 35 (2)document that the occupancy rate for the proposed NICU beds shall be at least 65 percent during 36 the third full fiscal year of operation following completion of the project; and

1	<u>(3)</u>	provide the assumptions and methodology used for the projected utilization and occupancy rate
2		required by Subparagraphs (1) and (2) of this Paragraph.
3	(b) An applicant	t proposing to develop a new Level IV neonatal intensive care service or increase the number of NICU
4	beds on the hosp	vital license shall:
5	<u>(1)</u>	provide projected utilization of all existing, approved, and proposed NICU beds on the hospital
6		license during each of the first three full fiscal years of operation following completion of the
7		project:
8	(2)	document that the occupancy rate for all existing, approved, and proposed NICU beds on the hospital
9		license shall be at least 65 percent during the third full fiscal year of operation following completion
10		of the project; and
11	<u>(3)</u>	provide the assumptions and methodology used for the projected utilization and occupancy rate
12		required by Subparagraphs (1) and (2) of this Paragraph.
13		
14	History Note:	Authority G.S. 131E-177(1); 131E-183(b);
15		Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule
16		becomes effective, whichever is sooner;
17		Eff. January 4, 1994;
18		Temporary Amendment Eff. March 15, 2002;
19		Amended Eff. April 1, 2003;
20		Temporary Amendment Eff. February 1, 2009;
21		Amended Eff. November 1, 2009;
22		Temporary Amendment Eff. February 1, 2010;
23		Amended Eff. November 1, 2010. <u>2010:</u>
24		Temporary Amendment Eff. January 27, 2023. 2023:
25		<u>Readopted Eff. January 1, 2024.</u>

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10A NCAC 14C .2703 is amended as published in 38:02 NCR 80-83 as follows:

	3	10A NCAC 14C .2703	PERFORMANCE STANDARDS
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- (a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State
 Medical Facilities Plan in effect as of the first day of the review period shall:
- 6 (1) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity and 7 located in the proposed fixed MRI scanner service area;
- 8 (2) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity and 9 located in the proposed fixed MRI scanner service area;
- 10(3)identify the existing mobile MRI scanners owned or operated by the applicant or a related entity11that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service12area during the 12 months before the application deadline for the review period;
- (4) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity
 that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service
 area;
- 16(5)provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this17Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years of18operation following completion of the project;
- 19(6)provide the assumptions and methodology used to project the utilization required by Subparagraph20(5) of this Paragraph;
- (7) project that the fixed MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and
 the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following
 completion of the project as follows:
 - (A) 3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more fixed MRI scanners in the fixed MRI scanner service area;
- 26
 (B) 3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI

 27
 scanners in the fixed MRI scanner service area;
- 28 (C)(A) 2,883 3,494 or more adjusted MRI procedures per fixed MRI scanner if there are two or
 29 more fixed MRI scanners in the fixed MRI scanner service area;
- 30(D)(B)2,643 3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed31MRI scanner in the fixed MRI scanner service area; or
 - (E)(C) 1,201 1,310 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area; and
- (8) project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall
 perform 3,328 3,120 or more adjusted MRI procedures per mobile MRI scanner during the third full
 fiscal year of operation following completion of the project.

1	(b) An applica	nt proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State
2	Medical Faciliti	es Plan in effect as of the first day of the review period shall:
3	(1)	identify the existing mobile MRI scanners owned or operated by the applicant or a related entity
4		that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service
5		area during the 12 months before the application deadline for the review period;
6	(2)	identify the approved mobile MRI scanners owned or operated by the applicant or a related entity
7		that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner
8		service area;
9	(3)	identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that
10		are located in the proposed mobile MRI scanner service area;
11	(4)	identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that
12		will be located in the proposed mobile MRI scanner service area;
13	(5)	identify the existing and proposed host sites for each mobile MRI scanner identified in
14		Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner;
15	(6)	provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this
16		Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years of
17		operation following completion of the project;
18	(7)	provide the assumptions and methodology used to project the utilization required by Subparagraph
19		(6) of this Paragraph;
20	(8)	project that the mobile MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and
21		the proposed mobile MRI scanner shall perform 3,328 3,120 or more adjusted MRI procedures per
22		MRI scanner during the third full fiscal year of operation following completion of the project; and
23	(9)	project that the fixed MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall
24		perform during the third full fiscal year of operation following completion of the project as follows:
25		(A) 3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more
26		fixed MRI scanners in the fixed MRI scanner service area;
27		(B) 3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI
28		scanners in the fixed MRI scanner service area;
29		(C)(A) 2,883 3,494 or more adjusted MRI procedures per fixed MRI scanner if there are two or
30		more fixed MRI scanners in the fixed MRI scanner service area;
31		(D)(B) 2,643 3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed
32		MRI scanner in the fixed MRI scanner service area; or
33		(E)(C) 1,201 1,310 or more adjusted MRI procedures per MRI scanner if there are no fixed MRI
34		scanners in the fixed MRI scanner service area.
35		
36	History Note:	Authority G.S. 131E-177(1); 131E-183(b);

1	Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule
2	becomes effective, whichever is sooner;
3	Eff. February 1, 1994;
4	Temporary Amendment Eff. January 1, 1999;
5	Temporary Amendment Eff. January 1, 1999 Expired on October 12, 1999;
6	Temporary Amendment Eff. January 1, 2000;
7	Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking
8	originally proposed to be effective August 2000;
9	Temporary Amendment Eff. January 1, 2001;
10	Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking
11	originally proposed to be effective April 1, 2001;
12	Temporary Amendment Eff. January 1, 2002;
13	Temporary Amendment Eff. January 1, 2002 amends and replaces the permanent rule effective,
14	August 1, 2002;
15	Temporary Amendment Eff. January 1, 2003;
16	Amended Eff. August 1, 2004; April 1, 2003;
17	Temporary Amendment Eff. January 1, 2005;
18	Amended Eff. November 1, 2005;
19	Temporary Amendment Eff. February 1, 2006;
20	Amended Eff. November 1, 2006;
21	Temporary Amendment Eff. February 1, 2008;
22	Amended Eff. November 1, 2008;
23	Readopted Eff. January 1, 2022. 2022:
24	Temporary Amendment Eff. January 27, 2023. <u>2023:</u>
25	Amended Eff. January 1, 2024.