NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

ROY COOPER • **Governor**
KODY H. KINSLEY • Secretary
MARK PAYNE • **Director, Division of Health Service Regulation**

VIA EMAIL ONLY

April 1, 2024

Denise M. Gunter
Denise.gunter@nelsonmullins.com

No Review

Record #:	**4401**
Date of Request:	March 20, 2024
Facility Name:	Onslow Memorial Hospital, Inc.
FID #:	923383
Business Name:	Onslow Memorial Hospital, Inc.
Business #:	1354
Project Description:	Convert 4 existing Level III NICU Beds to Level II NICU Beds
County:	Onslow

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request,** the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Gregory F. Yakaboski, Project Analyst

Micheala Mitchell

Micheala Mitchell, Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

NELSON MULLINS

NELSON MULLINS RILEY & SCARBOROUGH LLP
ATTORNEYS AND COUNSELORS AT LAW

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Denise M. Gunter
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March 20, 2024

VIA EMAIL ONLY

Micheala Mitchell, Chief
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Neonatal Intensive Care Unit at Onslow County Hospital Authority/Onslow Memorial Hospital, Inc. (License H0048)
Onslow County
FID#: 923383
Business#: 1354
Health Service Area VI

Dear Ms. Mitchell:

On behalf of Onslow County Hospital Authority and Onslow Memorial Hospital, Inc. (together, "OMH") in Jacksonville, North Carolina, I am writing to request the Agency's written determination that the following reconfiguration of OMH's neonatal intensive care unit ("NICU") does not require a CON. OMH is presently licensed for four Level III NICU beds. OMH also offers a Well-Baby Nursery for routine births with little to no complications and a Level II nursery. The Level II nursery, with fourteen beds, is designated for more comprehensive monitoring and observation of infants born prematurely or those with jaundice, breathing, or feeding problems.

OMH's neonatology group ended its relationship with OMH in January 2024, which required OMH to temporarily close its Level II and Level III beds. OMH has determined that it would be more efficient and would meet patients' needs to have eighteen Level II beds as opposed to four Level III beds and fourteen Level II beds. OMH currently plans to reopen its Level II nursery in June 2024. There are no capital costs associated with this change and the change will not cause OMH to exceed its licensed bed capacity. OMH

will not use the Level II beds to provide Level III services. The Level II beds meet applicable FGI Guidelines, and OMH will ensure that the beds converted from Level III to Level II will also meet applicable FGI Guidelines. *See* 10A NCAC 13B.6228.

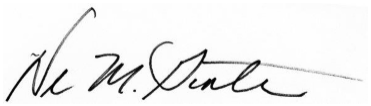
OMH respectfully requests the Agency's written determination that this proposed reconfiguration does not require a CON[1].

If you have any questions or need additional information, please let me know.

Thank you for your time and consideration.

With best personal regards.

Sincerely,



Denise M. Gunter

Enclosure

cc: Azzie Conley, Chief, Acute and Home Care Licensing and Certification (with enclosure)

[1] Attached as Exhibit A to this letter is a CON dated December 21, 2001 which relates to OMH's NICU beds, along with a settlement agreement and rule changes. We believe this is the most recent CON for OMH's NICU. Therefore, to the extent necessary or advisable, we respectfully request that the Agency also treat this letter as a request for material compliance determination pursuant to N.C. Gen. Stat. § 131E-181(b) for Project I.D. No. P-6072-99.

Exhibit A

STATE OF NORTH CAROLINA

Department of Health and Human Services
Division of Facility Services

CERTIFICATE OF NEED
for
Project Identification Number P-6072-99
FID# 923383
REVISED 12/21/2001

ISSUED TO: **Onslow Hospital Authority**
d/b/a Onslow Memorial Hospital
317 Western Boulevard
Jacksonville, NC 28546

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq. the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: **Onslow Memorial Hospital shall add 29 licensed acute care beds by converting 10 LDR rooms to 10 licensed LDRP rooms, adding seven licensed level I neonatal beds and licensing 12 new acute care beds in existing space within existing nursing units for a total of a complement of 162 licensed acute care beds/Onslow County**

CONDITIONS: **See Reverse Side**

PHYSICAL LOCATION: **Onslow Memorial Hospital**
317 Western blvd., Jacksonville, NC 28546

MAXIMUM CAPITAL EXPENDITURE: **$54,000**

TIMETABLE: **See Reverse Side**

FIRST PROGRESS REPORT DUE: **April 15, 2002**

This certificate is effective as of the 21st day of December 2001.

Lee B. Hoffman

Chief, Certificate of Need Section
Division of Facility Services

Exhibit A

Danny

Rec'd 1-28-02

North Carolina Department of Health and Human Services
Division of Facility Services
Certificate of Need Section
2704 Mail Service Center ▪ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor
Carmen Hooker Buell, Secretary

http://facility-services.state.nc.us

Lee Hoffman, Section Chief
Phone: 919-733-6360
Fax: 919-733-8139

January 24, 2002

Douglas W. Kramer, CEO
Onslow Hospital Authority
317 Western Blvd.
Jacksonville, NC 28546

RE: Withdrawal of Original Certificate of Need/ProjectI.D.#P-6072-99/ Onslow Hospital Authority d/b/a Onslow Memorial Hospital/ Add 29 acute care beds for a total of 162 acute care beds/ Onslow County
FID # 923383

Dear Mr. Kramer:

The Certificate of Need Section, Division of Facility Services, Department of Health and Human Services is withdrawing the original certificate of need (CON) issued to Onslow Hospital Authority d/b/a Onslow Memorial Hospital for the above referenced project. This withdrawal is made pursuant to a settlement agreement between the Onslow Hospital Authority and the Division of Facility Services executed December 19, 2001. Additionally, in accordance with that agreement a new certificate of need has been issued and is enclosed with this letter.

Please refer to the Project I.D.# and Facility I.D.# (FID) in all correspondence.

Sincerely,

Lee B. Hoffman

Lee B. Hoffman, Chief
Certificate of Need Section

LBH::mhb

cc: Section Chief, Construction Section, DFS
Section Chief, Licensure and Certification Section, DFS
Jim Keene, Medical Facilities Planning Section, DFS

Exhibit A

BODE, CALL & STROUPE, L.L.P.
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OF COUNSEL

DAVID P. GREEN
(1945 - 1985)

MAILING ADDRESS
POST OFFICE BOX 6338
RALEIGH, NORTH CAROLINA
27628-6338

March 17, 2005

Via Hand Delivery
Lee B. Hoffman, Chief
Certificate of Need Section
701 Barbour Drive
Raleigh, North Carolina 27603

Re: Onslow Memorial Hospital / Designation of Neonatal Beds

Dear Lee:

As you may recall, the above matter was the subject of a contested case [*Onslow Hospital Authority d/b/a Onslow Memorial Hospital v. CON Section,* 01 DHR 0599] which was settled by Settlement Agreement executed December 19, 2001. At that time, our client was authorized to

> develop no more than 29 acute care beds in its existing acute care facility as part of this project, for a total licensed capacity of 162 acute care beds. Of those 29 acute care beds, 10 shall be designated as Labor, Delivery, Recovery and Postpartum ("LDRP") beds, and 7 shall be designated as Level I neonatal beds.

Settlement Agreement, Condition 2 (copy attached as Exhibit A).

This was to occur "after applicable licensure rules become effective." *Id.*, p. 3. At that time, the licensure rules regarding Level I-III neonatal beds were in the process of being amended by Temporary Rule. That Temporary Rule was enacted effective March 15, 2002, in Volume 16, Issue 20 of the NC Register (issued April 15, 2002, copy attached as Exhibit B). Specifically, Level I-III neonatal beds were redefined in 10 N.C.A.C. 3C.4305. Our client licensed and has been operating its neonatal beds pursuant to the provisions of those rules.

However, in 2003, the rules related to neonatal beds changed again. With that change:

(1) services provided in what Onslow has been designating as newborn nursery under the 2002 rules are now Level I services under the 2003 amendments;

(2) services provided in what Onslow has been designating as Level I services under the 2002 rules are now Level II services under the 2003 amendments; and

(3) services provided in what Onslow has been designating as Level II services are now Level III services under the 2003 amendments.

In addition, a fourth category, Level IV, was codified, incorporating Level III services. These changes were as permanent rules effective April 1, 2003, and codified in 10 NCAC 3C.1405 (which subsequently was recodified as 10A NCAC 13B.4305), in Volume 17, Issue 10 of the NC Register (issued November 15, 2002, copy attached as Exhibit C)

Attached as Exhibit D is redlined copy of 10A NCAC 13B.4305, demonstrating the changes in the rule from April 2002 to April 2003. Onslow only recently became aware of this change. The result is that, despite the fact that neonatal services which Onslow is providing have not changed, and are consistent with the conditions placed on Onslow's CON, they are being billed at a level which is lower than the appropriate designation.

I have also discussed this issue with Jeff Horton, Chief of the Licensure and Certification Section. He confirmed the 2003 change in 10 NCAC 3C. 3102(d), as per Exhibit D hereto. He also confirmed that Level I beds no longer need to be licensed, as per that 2003 change in the rule.

By this letter, we are requesting your confirmation that by redesignating on its Hospital License Renewal Application newborn nursery beds as Level I beds, Level I beds as Level II beds, and Level II beds as Level III beds, Onslow will nevertheless remain in compliance with the conditions placed on the CON issued in 2001, pursuant to G.S. 131E-189(b).

We would like to set up a meeting with you at your earliest convenience to confirm with you our understanding of the change in the rules, so that there is no question that Onslow is operating its licensed beds in conformity with its CON.

Very truly yours,

BODE, CALL & STROUPE, LLP

Robert V. Bode

RVB:sh
cc w/enc.: Fred Carmichael

F:\Onslow Memorial\CON withdrawal\hoffman 03-05.wpd

Exhibit A

A

Exhibit A

STATE OF NORTH CAROLINA

COUNTY OF ONSLOW

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS
01 DHR 0599

EXHIBIT
tabbies A

ONSLOW HOSPITAL AUTHORITY, d/b/a ONSLOW MEMORIAL HOSPITAL,

Petitioner,

N.C. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF FACILITY SERVICES, CERTIFICATE OF NEED SECTION,

Respondent.

SETTLEMENT AGREEMENT

This Agreement is entered into by and between Onslow Hospital Authority, d/b/a Onslow Memorial Hospital ("Onslow Memorial") and the Certificate of Need Section, Division of Facility Services, North Carolina Department of Health and Human Services (the "Agency") (collectively referred to as "the Parties").

RECITALS

WHEREAS, Onslow Memorial filed a certificate of need ("CON") application for review on July 1, 1999, Project I.D. No. P-6072-99 to add 30 existing acute care beds to be purchased and then relocated to Onslow Memorial. The application was disapproved and Onslow Memorial initiated a contested case in the Office of Administrative Hearings. Subsequent to the filing of the contested case, Onslow Memorial filed a CON application for review on March 1, 2000, Project I.D. No. P-6072-99, to add 30 new acute care beds to its existing acute care facility.

WHEREAS, on the basis of information contained in Onslow Memorial's CON application, Project I.D. No. P-6072-99, the need determination in the 2000 State Medical

Facilities Plan ("SMFP"), and information provided in the CON application for Project I.D. No. P-6198-00, the Agency concluded that Project I.D. No. P-6072-99 could be approved, subject to certain conditions.

WHEREAS, On March 3, 2000, the Agency issued a certificate of need ("CON") to Onslow Memorial for Project I.D. No. P-6072-99 to renovate and convert the seventh floor to accommodate twenty four (24) new acute care beds, and distribute six (6) other new acute care beds among available space within existing nursing units for a total of thirty (30) new acute care beds; and

WHEREAS, by letter dated March 26, 2001, the Agency informed Onslow that it had determined that Onslow Memorial had not developed the project in accordance with the approved timetable and had not adequately documented that it had made a good faith effort to meet the timetable for the above project, and that its CON should be withdrawn; and

WHEREAS, Onslow Memorial challenged the Agency's decision, by initiating the above-referenced contested case in the Office of Administrative Hearings; and

WHEREAS, the Agency contends that it properly determined that Onslow Memorial's CON should be withdrawn; and

WHEREAS, the execution of this settlement agreement does not constitute an admission of error by any party; and

WHEREAS, no other parties have sought to intervene in this contested case and none of the parties knows of any person who is interested in intervening; and

WHEREAS, pursuant to N.C. Gen. Stat. §150B-22, it is the policy of the State to settle disputes between State agencies and other persons whenever possible; and

WHEREAS, pursuant to this policy, the parties have discussed settlement of this contested case; and

WHEREAS, during the course of the contested case, Onslow Memorial has determined that it can locate 29 new acute care beds in its existing facility without renovating and converting the seventh floor, as identified in the CON application for Project I.D. No. P-6072-99, by converting 10 unlicensed Labor, Delivery and Recovery ("LDR") beds to 10 licensed Labor, Delivery, Recovery and Postpartum ("LDRP") beds; by adding seven beds as Level I neonatal beds, after applicable licensure rules become effective; and by distributing 12 other new acute care beds within existing nursing units; and

WHEREAS, Onslow has determined that the location of acute care beds in existing space, as set forth above, should shorten the development time and significantly reduce construction costs; and

WHEREAS, during the settlement discussions, Onslow Memorial has submitted information to the Agency in support of this Agreement; and

WHEREAS, after reviewing additional information provided by Onslow Memorial, the Agency has concluded that the location of acute care beds in existing space, as set forth above, is in material compliance with Onslow Memorial's CON application and the certificate of need issued for Project I.D. No. P-6072-99, and that Onslow Memorial can be approved to develop only 29 of the 30 approved acute care beds in its existing acute care facility, subject to the conditions and timetable set out in Exhibits A and B to this agreement;

NOW, THEREFORE, pursuant to N.C.Gen. Stat.§§150B-22 and 31(b), and subject to the approval of Robert J. Fitzgerald, Director of the Division of Facility Services, the parties

have decided to resolve this contested case in the manner set forth below.

TERMS OF AGREEMENT

1. Voluntary Dismissal with Prejudice Within five business days after this agreement is approved and adopted by Robert J. Fitzgerald, Director of the Division of Facility Services, Onslow Memorial shall file a notice of voluntary dismissal, with prejudice, in the above-referenced contested case in the Office of Administrative Hearings.

2. Issuance of New Certificate of Need to Onslow Memorial. Within five business days after it receives the Notice of Voluntary Dismissal in the above contested case, the Agency shall withdraw Onslow Memorial's CON for 30 acute care beds issued March 3, 2000, for Project I.D. No. P-6072-99. Simultaneously therewith, the Agency shall issue a new CON to Onslow Memorial for Project I.D. No. P-6072-99, subject to the conditions and timetable contained in Exhibits A and B to this Settlement Agreement, authorizing the development of 29 acute care beds in its existing acute care facility. By executing this Agreement, Onslow Memorial accepts the conditions and timetable which have been imposed upon its certificate of need as set out in Exhibits A and B to this Settlement Agreement.

3. Effect of Approval. By executing this Settlement Agreement, the Parties acknowledge that, if approved by Robert J. Fitzgerald, Director of the Division of Facility Services, this Agreement shall resolve all issues involved in the contested case initiated by Onslow Memorial.

4. Effect of Disapproval. In the event that this Agreement is not approved by Mr. Fitzgerald, the Parties acknowledge that this Agreement shall be null and void and Onslow Memorial shall be entitled to proceed with the pending contested case. In such event, Mr.

Fitzgerald's consideration of this Agreement for his approval as provided herein shall not prejudice his authority to render the final agency decision in this matter following the hearing in accordance with N.C.G.S. §150B. In addition, if this Agreement is not approved by Mr. Fitzgerald, the Parties agree that it shall be inadmissible for any purpose in the contested case.

5. Release. Onslow Memorial hereby releases the Agency, its officials, employees, and representatives, from any and all liability that has arisen or might arise out of the Agency's review of their certificate of need applications.

6. Expenses. The Parties agree that each shall bear its own expenses. No claim for any other costs or expenses shall be made by one party against the other.

7. Waiver of Right to Appeal Agreement. The parties irrevocably waive any right to initiate an appeal from this Agreement, assuming that any such right exists; provided that nothing in this Agreement shall be construed to waive any claim for enforcement or breach of this Agreement.

8. Merger. The parties further agree and acknowledge that this written agreement sets forth all of the terms and conditions between them concerning the subject matter of this Agreement, superseding all prior oral and written drafts, statements and representations, and that there are no terms or conditions between the Parties except as specifically set forth in this Agreement.

9. Modification or Waiver. No modification or waiver of any provision of this agreement shall be effective unless it is in writing. Any modification or waiver must be signed by authorized representatives of the parties and must be adopted and approved by the Director of the Division of Facility Services.

10. No Strict Interpretation Against Draftsman. Each of the Parties has participated in the drafting of this Agreement and has had the opportunity to consult with counsel concerning its terms. This Agreement shall not be interpreted strictly against any one party on the grounds that it drafted the Agreement.

11. Recitals and Headings. All parts and provisions of this Agreement, including the recitals and paragraph headings, are intended to be material parts of the Agreement.

12. Authority to Settle. The undersigned represent and warrant that they are authorized to enter into this Agreement on behalf of the parties to this Agreement.

13. *Ex Parte* Presentation. Onslow Memorial authorizes counsel for the Agency to present this agreement to Mr. Fitzgerald *ex parte*.

14. Effective Date. This Agreement shall be effective as of the day and year on which it is adopted and approved by the Director of the Division of Facility Services.

15. Successors and Assigns. This agreement shall be binding upon the Parties and their successors and assigns.

This the 19th day of December, 2001.

BODE, CALL & STROUPE, L.L.P.
Attorneys for Petitioner
Onslow Hospital Authority
d/b/a Onslow Memorial Hospital

S. Todd Hemphill
N.C. State Bar No. 10360
Post Office Box 6338
Raleigh, NC 27628
(919) 881-0338

N.C. DEPARTMENT OF HEALTH
AND HUMAN SERVICES,
DIVISION OF FACILITY SERVICES

Lee B. Hoffman, Chief
CON Section

ROY COOPER
Attorney General for the State
of North Carolina

Melissa L. Trippe
Assistant Attorney General
N.C. State Bar No. 13739
Post Office Box 629
Raleigh, NC 27602-0629
(919) 716-6860

Approved and Adopted this the 19th day of December, 2001.

Robert J. Fitzgerald, Director
Division of Facility Services,
Department of Health and Human Services

EXHIBIT A
Onslow Hospital Authority d/b/a Onslow Memorial Hospital
Project I.D. #P-6072-99
Conditions

1. Onslow Memorial shall materially comply with all representations made in its certificate of need application for Project I.D. No. P-6072-99, except as modified by information provided in the application for Project I.D. No. P-6198-00 filed with the Certificate of Need Section on February 15, 2000, and except as further modified by the supplemental documents provided to the Certificate of Need Section on November 7 and December 6, 2001.

2. Onslow Memorial shall develop no more than 29 acute care beds in its existing acute care facility as part of this project, for a total licensed capacity of 162 acute care beds. Of those 29 acute care beds, 10 shall be designated as Labor, Delivery, Recovery and Postpartum ("LDRP") beds, and 7 shall be designated as Level I neonatal beds.

3. Onslow Memorial's approved capital expenditure shall be $54,000.

EXHIBIT B
Onslow Hospital Authority d/b/a Onslow Memorial Hospital
Project I.D. #P-6072-99
Timetable

1.	Certificate of Need		
	(a)	Date of Issuance of Certificate of Need	December 21, 2001
2.	Design		
	(a)	Completion of preliminary drawings	January 15, 2002
	(b)	Completion of final drawings and specifications	January 30, 2002
	(c)	Approval of final drawings and specifications by Construction Section, DFS	January 30, 2002
3.	Construction		
	(a)	Approval of Site by Construction Section, DFS	October 10, 2001
	(b)	Contract Award	March 1, 2002
	(c)	25% completion of construction	April 1, 2002
	(d)	50% completion of construction	May 1, 2002
	(e)	75% completion of construction	May 27, 2002
	(f)	Completion of construction	June 7, 2002
	(g)	Occupancy/offering of service(s)	June 17, 2002
4.	Other Milestones		
	(a)	Licensure of Facility	June 17, 2002
	(b)	Certification	June 17, 2002

Exhibit A

B

NORTH CAROLINA

REGISTER

Volume 16, Issue 20
Pages 2135 - 2232

April 15, 2002

This issue contains documents officially filed through March 22, 2002.

Office of Administrative Hearings
Rules Division
424 North Blount Street (27601)
6714 Mail Service Center
Raleigh, NC 27699-6714
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IN THIS ISSUE

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Reason for Proposed Action: *When the North Carolina Supreme Court issued the March 7, 2002 Order in Stephenson v. Bartlett, it had the effect of holding part of the North Carolina election law invalid. Based upon that fact, the precondition in G.S. 163-22.2 was satisfied, and the State Board had authority to issue temporary rules and regulations to deal with election issues created by the Order. The March 12, 2002 Order of the State Board is to be considered a temporary rule under G.S. 163-22.2.*

Comment Procedures: *The March 12, 2002 Order of the State Board of Elections was issued under authority granted under G.S. 163-22.2. The effect of the Order is to delay all elections, primaries, and referenda that had been set for May 7, 2002.*

CHAPTER 13 – INTERIM RULES

SECTION .0100 – INTERIM RULES

08 NCAC 13 .0101 IN THE MATTER OF THE MAY 7, 2002 PRIMARIES
BEFORE THE STATE BOARD OF ELECTIONS

NORTH CAROLINA
WAKE COUNTY

IN THE MATTER OF THE 2002 PRIMARY ELECTION — ORDER

THIS CAUSE coming before the State Board of Elections at its meeting on March 12, 2002, at its offices in Raleigh, North Carolina.

After discussion and an opportunity for public comment, the State Board, upon motion by Mr. Winfree, seconded by Ms. Sims, and amended at the suggestion of Chairman Leake, with the consent of Mr. Winfree, unanimously voted to delay all primaries, elections, and referenda set for May 7, 2002, and to meet immediately after a ruling is issued by the North Carolina Supreme Court on the constitutionality of the legislative redistricting plans adopted by the General Assembly in 2001.

THEREFORE, it is ordered, adjudged and decreed that primaries, elections, and referenda set for May 7, 2002 are hereby delayed pending action of the North Carolina Supreme Court, in the case of Stephenson v. Bartlett, No. 94 P02. The State Board of Elections will meet as soon as possible after the Court rules to decide what action is appropriate at that time.

This the 12th day of March, 2002.

_____
Larry Leake, Chairman

History Note: *Authority G.S. 163-22.2;*
Temporary Adoption Eff. March 14, 2002, and will become null and void 60 days after the convening of the next regular session of the General Assembly.

TITLE 10 – DEPARTMENT OF HEALTH AND HUMAN SERVICES

Rule-making Agency: *NC Medical Care Commission*

Rule Citation: *10 NCAC 03C .3102, .4305; 03R .1413-.1417*

Effective Date: *March 15, 2002*

Findings Reviewed and Approved by: *Beecher R. Gray*

Authority for the rulemaking: *G.S. 131E-79; S.L. 2001, c. 410*

Reason for Proposed Action:
10 NCAC 03C .3102, .4305 *- The NC General Assembly recently ratified House Bill 1147 (Session Law 2001-410). This legislation amends G.S. 131E-83 and directs the NC Medical Care Commission to adopt temporary rules "setting forth conditions for licensing neonatal care beds." The Commission needs to adopt temporary amendments to rules 10 NCAC 03C .3102 and .4305 to meet this legislative mandate. The public was given prior notice to this rule-making action in three ways: (1) a Notice of Proposed Rule-making Proceedings was published in Volume 16, Issue 08 of the North Carolina Register; and (2) a Notice was published at the Division's website (http://www.facility-services.state.nc.us) under the section titled "What's New;" and (3) the text of the proposed*

rules were published in Volume 16, Issue 14 of the North Carolina Register.

10 NCAC 03R .1413-.1417 – The NC General Assembly recently ratified House Bill 1147 (Session Law 2001-410). This legislation amends G.S. 131E-83 and directs the NC Medical Care Commission to adopt temporary rules "setting forth conditions for licensing neonatal care beds." The Commission needs to adopt temporary amendments to rules 10 NCAC 03C .3102 and .4305 to meet this legislative mandate. Rules 10 NCAC 03R .1413-.1417 are Certificate of Need (CON) rules and must now be amended to conform – and ensure consistency – with the changes to 10 NCAC 03C .3102 and .4305. The public was given prior notice to this rule-making action in three ways: (1) a Notice of Proposed Rule-making Proceedings was published in Volume 16, Issue 08 of the North Carolina Register; and (2) a Notice was published at the Division's website (http://www.facility-services.state.nc.us) under the section titled "What's New;" and (3) the text of the proposed rules were published in Volume 16, Issue 14 of the North Carolina Register.

Comment Procedures: *Written comments concerning this rule-making action must be submitted to Mark Benton, Rule-making Coordinator, NC Division of Facility Services, 2701 Mail Service Center, Raleigh, NC 27699-2701.*

CHAPTER 03 – FACILITY SERVICES

SUBCHAPTER 03C – LICENSING OF HOSPITALS

SECTION .03100 - PROCEDURE

10 NCAC 03C .3102 PLAN APPROVAL

(a) The facility design and construction shall be in accordance with the construction standards of the Division, the North Carolina Building Code, and local municipal codes.

(b) Submission of Plans:

(1) Before construction is begun, color marked plans, and specifications covering construction of the new buildings, alterations or additions to existing buildings, or any change in facilities shall be submitted to the Division for approval.

(2) The Division will review the plans and notify the licensee that said buildings, alterations, additions, or changes are approved or disapproved. If plans are disapproved the Division shall give the applicant notice of deficiencies identified by the Division.

(3) In order to avoid unnecessary expense in changing final plans, a preliminary step, proposed plans in schematic form shall be reviewed by the Division.

(4) The plans shall include a plot plan showing the size and shape of the entire site and the location of all existing and proposed facilities.

(5) Plans shall be submitted in triplicate in order that the Division may distribute a copy to the Department of Insurance for review of State Building Code requirements and to the Department of Environment, Health, and Natural Resources for review under state sanitation requirements.

(c) Location:

(1) The site for new construction or expansion shall be approved by the Division.

(2) Hospitals shall be so located that they are free from undue noise from railroads, freight yards, main traffic arteries, schools and children's playgrounds.

(3) The site shall not be exposed to smoke, foul odors, or dust from nearby industrial plants.

(4) The area of the site shall be sufficient to permit future expansion and to provide adequate parking facilities.

(5) Available paved roads, adequate water, sewage and power lines shall be taken into consideration in selecting the site.

(d) The bed capacity and services provided in a facility shall be in compliance with G.S. 131E, Article 9 regarding Certificate of Need. A facility shall be licensed for no more beds than the number for which required physical space and other required facilities are available. Neonatal Level 1, Level II and III beds are considered part of the licensed bed capacity. ~~beds for licensure purposes, but Level I (bassinets for newborns) are not considered part of licensed bed capacity.~~ Newborn nursery bassinets are not considered part of the licensed bed capacity however, no more bassinets shall be placed in service than the number for which required physical space and other required facilities are available.

History Note: Authority G.S. 131E-79;
Eff. January 1, 1996;
Temporary Amendment Eff. March 15, 2002.

10 NCAC 03C .4305 ORGANIZATION OF NEONATAL SERVICES

(a) The governing body shall approve the scope of all neonatal services and the facility shall classify its capability in providing a range of neonatal services using the following criteria:

(1) ~~LEVEL I or Neonate~~ Newborn Nursery: Full-term and pre-term neonates ~~or infants~~ that are stable without complications; may include ~~premature~~, small for gestational age or large for gestational age neonates;

(2) ~~LEVEL II~~LEVEL I: ~~Ill neonates or infants requiring less constant nursing care but does not exclude respiratory support~~ Neonates or infants that are stable without complications but require special care and frequent feedings; infants of any weight who no longer require Level II or Level III neonatal services, but who still require more nursing hours than normal infants; and infants who require close observation in a licensed acute care bed;~~may serve as "step-down" unit from LEVEL III; and~~

(3) ~~LEVEL III~~LEVEL II: ~~Medically unstable or critically ill neonates or infants requiring constant nursing care or supervision involving complicated surgical procedures, continual respiratory or other intensive interventions.~~

Neonates or infants that are high-risk, small (or approximately 32 and less than 36 completed weeks of gestational age) but otherwise healthy, or sick with a moderate degree of illness that are admitted from within the hospital or transferred from another facility requiring intermediate care services for sick infants, but not requiring intensive care; may serve as a "step-down" unit from Level III. Level II neonates or infants require less constant nursing care, but care does not exclude respiratory support; and

(4) LEVEL III (Neonatal Intensive Care Services): High-risk, medically unstable or critically ill neonates approximately under 32 weeks of gestational age, or infants, requiring constant nursing care or supervision not limited to continuous cardiopulmonary or respiratory support, complicated surgical procedures, or other intensive supportive interventions.

(b) The facility shall provide for the availability of equipment, supplies, and clinical support services.

(c) The medical and nursing staff shall develop and approve policies and procedures for the provision of all neonatal services.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Temporary Amendment Eff. March 15, 2002.

SUBCHAPTER 03R – CERTIFICATE OF NEED REGULATIONS

SECTION .1400 - CRITERIA AND STANDARDS FOR NEONATAL SERVICES

10 NCAC 03R .1413 DEFINITIONS

The definitions in this Rule shall apply to all rules in this Section:

(1) "Approved neonatal service" means a neonatal service that was not operational prior to the beginning of the review ~~period but that had been issued a certificate of need or for which development had been initiated prior to March 18, 1993 in accordance with 1993 N.C. Sess. Laws c. 7, s. 12.~~period.

(2) "Existing neonatal service" means a neonatal service in operation prior to the beginning of the review period.

(3) "High-risk obstetric patients" means those patients requiring specialized services provided by an acute care hospital to the mother and fetus during pregnancy, labor, delivery and to the mother after delivery. The services are characterized by specialized facilities and staff for the intensive care and management of high-risk maternal and fetal patients before, during, and after delivery.

(4) "Level I neonatal service" means ~~those routine~~ services provided by an acute care hospital in a licensed acute care bed to ~~normal full-term and pre-term infants weighing at least 2000 grams at birth or infants of any weight who are convalescing from Level II or Level III services. Level I neonatal services include the observation, screening, and stabilization of: infants following birth who are served in a bassinet; infants who are not sick but who~~ neonates and infants that are stable without complications but require special care and frequent feedings; infants of any weight who no longer require Level II or Level III neonatal services, but still require more nursing hours than normal infants; and infants who require close observation in a licensed acute care bed.

(5) "Level II neonatal service" means services provided by an acute care hospital in a licensed acute care bed to ~~the performance of Level I neonatal services, plus the management of~~ neonates or infants that are high-risk, ~~small, and~~ small (approximately 32 and less than 36 completed weeks of gestational age) but otherwise healthy, or sick ~~neonates~~ with a moderate degree of illness that are admitted from within the hospital or transferred from another ~~facility. Level II neonatal services involve the management of newborns weighing between approximately 1,500-2,500 grams (or approximately 32 and less than 36 completed weeks of gestational age) that are relatively healthy, or involve~~ facility requiring intermediate care services for sick ~~infants~~ infants, but~~who do~~ not ~~require~~ intensive ~~care but who do require six to twelve nursing hours per day. Level II neonatal services are provided in a licensed acute care bed.~~ care. Level II neonates or infants require less constant nursing care than Level III services, but care does not exclude respiratory support.

(6) "Level III neonatal service" means ~~the performance of Level I and Level II neonatal services plus the management of high-risk newborns weighing less than 1,500 grams (or approximately under 32 weeks of gestational age), which requires neonatal expertise. Level III neonates require constant nursing care, including but~~ neonatal intensive care services provided by an acute care hospital in a licensed acute care bed to high-risk medically unstable or critically ill neonates (approximately under 32 weeks of gestational age) or infants requiring constant nursing care or supervision not limited to continuous cardiopulmonary ~~and other supportive care, care required for neonatal surgery patients and other intensive care services. Level III neonatal services are provided in a licensed acute care bed.~~ or respiratory support, complicated surgical procedures, or other intensive supportive interventions.

(7) "Neonatal bed" means a licensed acute care bed used to provide Level I, II , or III neonatal services.

~~(7)~~(8) "Neonatal intensive care services" shall have the same meaning as defined in G.S. 131E-176(15b).

~~(8)~~(9) "Neonatal service area" means a geographic area defined by the applicant from which the patients to be admitted to the service will originate.

~~(9)~~(10) "Neonatal services" means any of the Level I, Level II or Level III services defined in this Rule.

(11) "Newborn nursery services" means services provided by an acute care hospital to full term and pre-term neonates that are stable, without complications, and may include neonates that are small for gestational age or large for gestational age.

~~(10)~~(12) "Obstetric services" means any normal or high-risk services provided by an acute care hospital to the mother and fetus during pregnancy, labor, delivery and to the mother after delivery.

~~(11)~~(13) "Perinatal services" means services provided during the period shortly before and after birth.

~~(12) "Perinatal region" means a geographic area of the state as established by the Perinatal Council. A copy of the perinatal regions may be obtained from the Division of Maternal and Child Health, Department of Environment, Health and Natural Resources, 1330 St. Mary's Street, Raleigh, NC, 27605-3248.~~)

History Note: Authority G.S. 131E-177(1); 131E-183;
Filed as a Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. January 4, 1994;
Amended Eff. November 1, 1996;
Temporary Amendment Eff. March 15, 2002.

10 NCAC 03R .1414 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to develop a new ~~neonatal service or to add a bed to an existing neonatal service~~ newborn nursery service or increase the number of Level I, II, or III neonatal beds shall use the Acute Care Facility/Medical Equipment application form.

(b) ~~The~~ An applicant proposing to develop a new newborn nursery service or increase the number of Level I, II, or III neonatal beds shall provide the following additional information:

(1) the current number of ~~Level I~~ newborn nursery bassinets, Level I beds, Level II beds and Level III beds operated by the applicant;

(2) the proposed number of ~~Level I~~ newborn nursery bassinets, Level I beds, Level II beds and Level III beds to be operated following completion of the proposed project;

(3) evidence of the applicant's experience in treating the following patients at the facility during the past twelve months, including:

(A) the number of obstetrical patients treated at the acute care facility;

(B) the number of neonatal patients treated in ~~Level I~~ newborn nursery bassinets, Level I beds, Level II beds and Level III beds, respectively;

(C) the number of inpatient days at the facility provided to obstetrical patients;

(D) the number of inpatient days provided in Level I beds, Level II beds and Level III beds, respectively;

(E) the number of high-risk obstetrical patients treated at the applicant's facility and the number of high-risk obstetrical patients referred from the applicant's facility to other facilities or programs; and

(F) the number of neonatal patients referred to other facilities for services, identified by required level of neonatal service (i.e. Level I, Level II or Level III);

(4) the projected number of neonatal patients to be served identified by newborn nursery,Level I, Level II and Level III neonatal services ~~and by county of residence~~ for each of the first ~~twelve quarters~~ three years of operation following the completion of the project, including the methodology and assumptions used for the projections;

(5) the projected ~~utilization of the Level I bassinets,~~ number of patient days of care to be provided in the newborn nursery bassinets,Level I beds, Level II beds and Level III beds, respectively, ~~by county of residence~~ for each of the first ~~twelve quarters~~ three years of operation following completion of the project, including the methodology and assumptions used for the projections;

(6) if proposing to provide new newborn nursery or Level I neonatal services, documentation that at least 90 percent of the anticipated patient population is within 30 minutes driving time one-way from the facility;

(7) if proposing to provide new newborn nursery or Level I neonatal services, documentation of a written plan to transport infants to Level II or Level III neonatal services as the infant's care requires;

~~(8) if proposing to provide new Level II or Level III neonatal services, documentation that at least 90 percent of the anticipated patient population is within 90 minutes driving time one-way from the facility, with the exception that there shall be a variance from the 90 percent standard for facilities which demonstrate that they provide very specialized~~

levels of neonatal care to a large and geographically diverse population, or facilities which demonstrate the availability of air ambulance services for neonatal patients; (9) evidence that existing and approved neonatal services and obstetric services in the applicant's perinatal region and in the applicant's defined neonatal service area are unable to accommodate the applicant's projected need for additional Level II and Level III services;

(10) documentation of the availability of existing obstetric services; identification of all obstetrics programs and neonatal services which currently serve patients from the applicant's primary service area; and for those applicants proposing to establish or expand Level II and III neonatal services, the availability of high risk OB services at the site of the applicant's planned neonatal service;

(11) an analysis of the proposal's impact upon existing and approved neonatal services in the same perinatal region(s) and those perinatal regions adjacent to the perinatal region(s) in which the applicant proposes to provide services, including but not limited to the proposal's effect on the utilization of existing neonatal services, except when an applicant demonstrates that they provide very specialized levels of neonatal care to a large and geographically diverse population;

(12) evidence that the applicant shall have access to a transport service with at least the following components:

(A) trained personnel;

(B) transport incubator;

(C) emergency resuscitation equipment;

(D) oxygen supply, monitoring equipment and the means of administration;

(E) portable cardiac and temperature monitors; and

(F) a mechanical ventilator;

(13) documentation that the new or additional neonatal service shall be coordinated with the existing statewide perinatal network, including but not limited to:

(A) the Division of Maternal and Child Health of the Department of Environment, Health and Natural Resources.

(B) the physicians' statewide neonatal bed locator system.

(C) existing neonatal services,

(D) existing obstetrical services,

(E) home health care agencies,

(F) other hospitals, and

(G) local Departments of Social Services;

(14) copies of written policies which provide for parental participation in the care of their infant, as the infant's condition permits, in order to facilitate family adjustment and continuity of care following discharge; and

(15) copies of written policies and procedures regarding the scope and provision of care within the neonatal service, including but not limited to the following:

(A) the admission and discharge of patients;

(B) infection control;

(C) pertinent safety practices;

(D) the triaging of patients requiring consultations, including the transfer of patients to another facility; and

(E) the protocol for obtaining emergency physician care for a sick infant.

(c) An applicant proposing to provide new or additional neonatal services shall provide the following:

(1) documentation that the proposed service shall be operated in an area organized as a physically and functionally distinct entity with controlled access;

(2) documentation to show that the new or additional Level I, Level II or Level III neonatal services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;

(3) a detailed floor plan of the proposed area drawn to scale;

(4) documentation of direct or indirect visual observation by unit staff of all patients from one or more vantage points; and

(5) documentation that the floor space allocated to each bed and bassinet shall accommodate equipment and personnel to meet anticipated contingencies.

(8) evidence that the applicant shall have access to a transport service with at least the following components:

(A) trained personnel;

(B) transport incubator;

(C) emergency resuscitation equipment;

(D) oxygen supply, monitoring equipment and the means of administration;

(E) portable cardiac and temperature monitors; and

(F) a mechanical ventilator;

(9) documentation that the proposed service shall be operated in an area organized as a physically and functionally distinct entity with controlled access;

(10) documentation to show that the new or additional Level I, Level II or Level III neonatal services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;

(11) a detailed floor plan of the proposed area drawn to scale;

(12) documentation of direct or indirect visual observation by unit staff of all patients from one or more vantage points; and

(13) documentation that the floor space allocated to each bed and bassinet shall accommodate equipment and personnel to meet anticipated contingencies.

(c) If proposing to provide new Level II or Level III neonatal services the applicant shall also provide the following information:

(1) documentation that at least 90 percent of the anticipated patient population is within 90 minutes driving time one-way from the facility, with the exception that there shall be a variance from the 90 percent standard for facilities which demonstrate that they provide very specialized levels of neonatal care to a large and geographically diverse population, or facilities which demonstrate the availability of air ambulance services for neonatal patients;

(2) evidence that existing and approved neonatal services in the applicant's defined neonatal service area are unable to accommodate the applicant's projected need for additional Level II and Level III services;

(3) an analysis of the proposal's impact on existing Level II and Level III neonatal services which currently serve patients from the applicant's primary service area;

(4) the availability of high risk OB services at the site of the applicant's planned neonatal service;

(5) copies of written policies which provide for parental participation in the care of their infant, as the infant's condition permits, in order to facilitate family adjustment and continuity of care following discharge; and

(6) copies of written policies and procedures regarding the scope and provision of care within the neonatal service, including but not limited to the following:

(A) the admission and discharge of patients;

(B) infection control;

(C) pertinent safety practices;

(D) the triaging of patients requiring consultations, including the transfer of patients to another facility; and

(E) the protocols for obtaining emergency physician care for a sick infant.

History Note: Authority G.S. 131E-177(1); 131E-183;
Filed as a Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. January 4, 1994;
Amended Eff. November 1, 1996;
Temporary Amendment Eff. March 15, 2002.

10 NCAC 03R .1415 REQUIRED PERFORMANCE STANDARDS

(a) An applicant shall demonstrate that the proposed project is capable of meeting the following standards:

~~(1) applicants proposing new or additional Level I services shall perform or project to perform, at least 500 deliveries per year, except that a variance from this standard shall be allowed to the extent that a major portion of the population to be served residemore than 45 minutes automobile driving time one way from existing inpatient neonatal services;~~

~~(2) applicants proposing new or additional Level I services shall demonstrate that the following standards will be met:~~

~~(A) the occupancy of the applicant's total number of neonatal beds is projected to be 50% or more during the first year of operation following completion of the proposed project. Provide all assumptions and data supporting the methodology used for the projections;~~

~~(B) if an applicant is proposing additional Level I services and does not currently provide Level II or Level III services, the projected occupancy of the proposed service shall be at least 75% after the second year of operation following completion of the proposed project and provide all assumptions and data supporting the methodology used for the projections;~~

~~(C) if an applicant is proposing additional Level I services and currently provides Level II or Level III services, the projected occupancy of all neonatal services in the facility shall be at least 65% after the second year of operation following completion of the proposed project, and provide all assumptions and data supporting the methodology used for the projections;~~

~~(D) the total number of Level I neonatal bassinets and Level I neonatal beds projected to be operated in the facility shall exceed the number of obstetric beds in the facility by at least 25%; and(E) the total number of Level I neonatal bassinets and Level I neonatal beds projected to be operated in the facility shall exceed the number of obstetric beds in the facility by at least 35% if Level II or Level III services will be provided in the facility;~~

(1) an applicant proposing a new newborn nursery, new Level I services, or additional Level I beds shall demonstrate that the occupancy of the applicant's total number of neonatal beds is projected to be at least 50% during the first year of operation and at least 65% during the third year of operation following completion of the proposed project;

~~(3)~~(2) if an applicant proposes an increase in the number of the facility's existing Level II or

Level III beds, the overall average annual occupancy of the total number of existing Level II and Level III beds in the facility is at least 75%, over the 12 months immediately preceding the submittal of the proposal; and

~~(4)~~(3) if an applicant is proposing to develop new or additional Level II or Level III beds, the projected occupancy of the total number of Level II and Level III beds proposed to be operated ~~after the second~~ during the third year of operation of the proposed project shall be at least 75%. ~~The applicant shall document the assumptions and provide data supporting the methodology used for the projections.~~

(4) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

(b) If an applicant proposes to develop a new Level II or Level III ~~service~~ service, the applicant shall document that an unmet need exists ~~in the perinatal region or~~ in the applicant's defined neonatal service area. The need for Level II and Level III beds shall be computed for ~~each of the perinatal regions in North Carolina or in~~ the applicant's neonatal service area by:

(1) identifying the annual number of live births occurring at all hospitals within the ~~perinatal region or~~ proposed neonatal service area, using the latest available data compiled by the State Center for Health ~~and Environmental~~ Statistics;

(2) identifying the low birth weight rate (percent of live births below 2,500 grams) for the births identified in (1) of this Paragraph, using the latest available data compiled by the State Center for Health ~~and Environmental~~ Statistics;

(3) dividing the low birth weight rate identified in (2) of this Paragraph by .08 and subsequently multiplying the resulting quotient by four; and

(4) determining the need for Level II and Level III beds in the ~~perinatal region or~~ proposed neonatal service area as the product of:

(A) the product derived in (3) of this Paragraph, and

(B) the quotient resulting from the division of the number of live births in the initial year of the determination identified in (1) of this Paragraph by the number 1000.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Filed as a Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Temporary Amendment Eff. March 15, 2002.

10 NCAC 03R .1416 REQUIRED SUPPORT SERVICES

(a) An applicant proposing to provide new ~~or additional~~ Level I, Level II or Level III services shall document that the following items shall be available, unless an item shall not be available, then documentation shall be provided obviating the need for that item:

(1) competence to manage uncomplicated labor and delivery of normal term newborn;

(2) capability for continuous fetal monitoring;

(3) a continuing education program on resuscitation to enhance competence among all delivery room personnel in the immediate evaluation and resuscitation of the newborn and of the mother;

(4) obstetric services;

(5) anesthesia services;

(6) capability of cesarean section within 30 minutes at any hour of the day; and

(7) twenty-four hour on-call blood bank, radiology, and clinical laboratory services.

(b) An applicant proposing to provide new ~~or additional~~ Level II or Level III services shall document that the following items shall be available, unless any item shall not be available, then documentation shall be provided obviating the need for that item:

(1) competence to manage labor and delivery of premature newborns and newborns with complications;

(2) twenty-four hour availability of microchemistry hematology and blood gases;

(3) twenty-four hour coverage by respiratory therapy;

(4) twenty-four hour radiology coverage with portable radiographic capability;

(5) oxygen and air and suction capability;

(6) electronic cardiovascular and respiration monitoring capability;

(7) vital sign monitoring equipment which has an alarm system that is operative at all times;

(8) capabilities for endotracheal intubation and mechanical ventilatory assistance;

(9) cardio-respiratory arrest management plan;

(10) isolation capabilities;

(11) social services staff;

(12) occupational or physical therapies with neonatal expertise; and

(13) a registered dietician or nutritionist with training to meet the special needs of neonates.

(c) An applicant proposing to provide new ~~or additional~~ Level III services shall document that the following items shall be available, unless any item shall not be available, then documentation shall be provided obviating the need for that item:

(1) pediatric surgery services;

(2) ophthalmology services;

(3) pediatric neurology services;

(4) pediatric cardiology services;

(5) on-site laboratory facilities;

(6) computed tomography and pediatric cardiac catheterization services;

(7) emergency diagnostic studies available 24 hours per day;

(8) designated social services staff; and

(9) serve as a resource center for the statewide perinatal network.

History Note: *Authority G.S. 131E-177(1); 131E-183(b); Filed as a Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Temporary Amendment Eff. March 15, 2002.*

10 NCAC 03R .1417 REQUIRED STAFFING AND STAFF TRAINING

An applicant shall demonstrate that the following staffing requirements for hospital care of newborn infants shall be met:

(1) If proposing to provide new ~~or additional~~ Level I services the applicant shall provide documentation to demonstrate that:
   (a) the nursing care shall be supervised by a registered nurse in charge of perinatal facilities;
   (b) a physician is designated to be responsible for neonatal care; and
   (c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.

(2) If proposing to provide new ~~or additional~~ Level II services the applicant shall provide documentation to demonstrate that:
   (a) the nursing care shall be supervised by a registered nurse;
   (b) the service shall be staffed by a board certified pediatrician; and
   (c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.

(3) If proposing to provide new ~~or additional~~ Level III services the applicant shall provide documentation to demonstrate that:
   (a) the nursing care shall be supervised by a registered nurse with educational preparation and advanced skills for maternal-fetal and neonatal services;
   (b) the service shall be staffed by a full-time board certified pediatrician with certification in neonatal medicine; and
   (c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.

(4) All applicants shall submit documentation which demonstrates the availability of appropriate inservice training or continuing education programs for neonatal staff.

(5) All applicants shall submit documentation which demonstrates the proficiency and ability of the nursing staff in teaching parents how to care for neonatal patients following discharge to home.

(6) All applicants shall submit documentation to show that the proposed neonatal services will be provided in conformance with the requirements of federal, state and local regulatory bodies.

History Note: *Authority G.S. 131E-177(1); 131E-183(b); Filed as a Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Temporary Amendment Eff. March 15, 2002.*

* *

Rule-making Agency: *Division of Facility Services*

Rule Citation: *10 NCAC 03R .1914, .6374, .6383*

Effective Date: *March 15, 2002*

Findings Reviewed and Approved by: *Beecher R. Gray*

Authority for the rulemaking: *G.S. 131E-176(25); 131E-177(1); 131E-183(b)*

Reason for Proposed Action:

10 NCAC 03R.1914 *- A technical change is needed to eliminate conflicting references to ESTV treatment utilization. When this temporary amendment was adopted in January 1, 2002 (as part of the 2002 State Medical Facilities Plan), we failed to replace all three references of "250 patients or 6,500 ESTV treatments" with "6,750 ESTV treatments." Subsections (1) and (3) were correctly amended, however we failed to make the same change to (2). This amendment will correct that oversight, eliminate any confusion regarding utilization rates, and ensure consistency with the 2002 State Medical Facilities Plan.*

10 NCAC 03R .6374, .6383 *- The annual State Medical Facilities Plan (SMFP) contains an inventory of facilities/beds/equipment in addition to varying methodologies. That information is used to determine the "need" for new health care facilities and services each year. As the inventory of facilities, beds and equipment is updated throughout the year, amendments to the temporary rules are sometimes necessary. 10 NCAC 03R .6374 is being amended to reflect a change in the inventory of adult care home beds in Madison county, and 10 NCAC 03R .6383 is being amended to reflect a change in chemical dependency detox-only beds in Mental Health Planning Area 17.*

Comment Procedures: *Questions or comments concerning the rules should be directed to Mark Benton, Rule-making Coordinator, Division of Facility Services, 701 Barbour Drive, 2701 Mail Service Center, Raleigh, NC 27699-2701.*

CHAPTER 03 – FACILITY SERVICES

SUBCHAPTER 03R – CERTIFICATE OF NEED REGULATIONS

SECTION .1900 – CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT

Exhibit A

C

NORTH CAROLINA

REGISTER

Volume 17, Issue 10
Pages 933 - 1013

November 15, 2002

This issue contains documents officially filed through October 25, 2002.

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IN THIS ISSUE

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*This Section includes the Register Notice citation to Rules approved by the Rules Review Commission (RRC) at its meeting October 17, 2002, pursuant to G.S. 150B-21.17(a)(1) and reported to the Joint Legislative Administrative Procedure Oversight Committee pursuant to G.S. 150B-21.16. The full text of rules is published below when the rules have been approved by RRC in a form different from that originally noticed in the Register or when no notice was required to be published in the Register. The rules published in full text are identified by an * in the listing of approved rules. Statutory Reference: G.S. 150B-21.17.*

These rules, unless otherwise noted, will become effective on the 31st legislative day of the 2002 Session of the General Assembly or a later date if specified by the agency unless a bill is introduced before the 31st legislative day that specifically disapproves the rule. If a bill to disapprove a rule is not ratified, the rule will become effective either on the day the bill receives an unfavorable final action or the day the General Assembly adjourns. Statutory reference: G.S. 150B-21.3.

APPROVED RULE CITATION				REGISTER CITATION TO THE NOTICE OF TEXT
05	NCAC	02B	.0109-.0114*	G.S. 150B-1(d)(6), Effective October 18, 2002.
10	NCAC	03C	.3102*	17:01 NCR
10	NCAC	03C	.4305*	17:01 NCR
10	NCAC	03D	.0801-.0805	16:21 NCR
10	NCAC	03D	.0807-.0808	16:21 NCR
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10	NCAC	03R	.3303-.3305	17:04 NCR
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10	NCAC	03U	.2410-.2411*	17:03 NCR
10	NCAC	03U	.2703	17:03 NCR
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10	NCAC	26H	.0212-.0213	17:01 NCR
10	NCAC	41I	.0303	17:03 NCR
10	NCAC	41I	.0304-.0306*	17:03 NCR
10	NCAC	41I	.0311-.0312*	17:03 NCR
10	NCAC	41J	.0204	17:03 NCR
10	NCAC	41J	.0205*	17:03 NCR
10	NCAC	41J	.0501*	17:03 NCR
15A	NCAC	02B	.0303	16:15 NCR
15A	NCAC	02H	.0106*	16:19 NCR
15A	NCAC	02R	.0402*	16:24 NCR
15A	NCAC	18A	.1001*	G.S. 150B-21.5, Effective November 1, 2002
15A	NCAC	18A	.1501*	G.S. 150B-21.5, Effective November 1, 2002
15A	NCAC	18A	.1601*	G.S. 150B-21.5, Effective November 1, 2002
15A	NCAC	18A	.2201*	G.S. 150B-21.5, Effective November 1, 2002
15A	NCAC	18A	.2401*	G.S. 150B-21.5, Effective November 1, 2002
15A	NCAC	18A	.2701*	G.S. 150B-21.5, Effective November 1, 2002

15A	NCAC	18A	.3001*	G.S. 150B-21.5, Effective November 1, 2002
15A	NCAC	18A	.3201*	G.S. 150B-21.5, Effective November 1, 2002
18	NCAC	06	.1417*	16:22 NCR
18	NCAC	06	.1702*	16:22 NCR
18	NCAC	06	.1703	16:22 NCR
18	NCAC	06	.1706-.1707*	16:22 NCR
18	NCAC	06	.1710-.1711	16:22 NCR
18	NCAC	06	.1712	16:22 NCR
18	NCAC	06	.1713*	16:22 NCR
18	NCAC	06	.1714	16:22 NCR
18	NCAC	06	.1716*	16:22 NCR
18	NCAC	06	.1717	16:22 NCR
19A	NCAC	02D	.0532*	17:03 NCR
19A	NCAC	02F	.0101	17:02 NCR
19A	NCAC	02F	.0102-.0103*	17:02 NCR
21	NCAC	04B	.0202*	16:22 NCR
21	NCAC	04B	.0801-.0802*	16:22 NCR
21	NCAC	04B	.0804*	16:22 NCR
21	NCAC	32H	.0102	16:21 NCR
21	NCAC	32H	.0201-.0203	16:21 NCR
21	NCAC	32H	.0301-.0303	16:21 NCR
21	NCAC	32H	.0401-.0405	16:21 NCR
21	NCAC	32H	.0407-.0409	16:21 NCR
21	NCAC	32H	.0501-.0503	16:21 NCR
21	NCAC	32H	.0505-.0508	16:21 NCR
21	NCAC	32H	.0601-.0602	16:21 NCR
21	NCAC	32H	.0701	16:21 NCR
21	NCAC	32H	.0801-.0802	16:21 NCR
21	NCAC	32H	.0901-.0903	16:21 NCR
21	NCAC	32H	.1001-.1004	16:21 NCR
21	NCAC	32I	.0101-.0104	16:21 NCR
21	NCAC	48C	.0101*	17:02 NCR

TITLE 5 – DEPARTMENT OF CORRECTION

05 NCAC 02B .0109 SCOPE
05 NCAC 02B .0110 DEFINITIONS
05 NCAC 02B .0111 GOOD TIME
05 NCAC 02B .0112 GAIN TIME
05 NCAC 02B .0113 EARNED TIME
05 NCAC 02B .0114 MERITORIOUS TIME

History Note: Authority G.S. 5A-12(c); 15A-1340.7; 15A-1340.13; 15A-1340.20; 15A-1355; 130A-25; 148-11; 148-13;
Temporary Adoption Eff. November 15, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. February 1, 1995;
Repealed Eff. October 18, 2002.

TITLE 10 – DEPARTMENT OF HEALTH AND HUMAN SERVICES

10 NCAC 03C .3102 PLAN APPROVAL

(a) The facility design and construction shall be in accordance with the construction standards of the Division, the North Carolina Building Code, and local municipal codes.

(b) Submission of Plans:

(1) Before construction is begun, color marked plans and specifications covering construction of the new buildings, alterations or additions to existing buildings, or any change in facilities shall be submitted to the Division for approval.

(2) The Division shall review the plans and notify the licensee that said buildings, alterations, additions, or changes are approved or disapproved. If plans are disapproved the Division shall give the applicant notice of deficiencies identified by the Division.

(3) In order to avoid unnecessary expense in changing final plans, as a preliminary step, proposed plans in schematic form shall be submitted by the applicant to the Division for review.

(4) The plans shall include a plot plan showing the size and shape of the entire site and the location of all existing and proposed facilities.

(5) Plans shall be submitted in triplicate in order that the Division may distribute a copy to the Department of Insurance for review of State Building Code requirements and to the Department of Environment, Health, and Natural Resources for review under state sanitation requirements.

(c) Location:

(1) The site for new construction or expansion shall be approved by the Division.

(2) Hospitals shall be so located that they are free from noise from railroads, freight yards, main traffic arteries, schools and children's playgrounds.

(3) The site shall not be exposed to smoke, foul odors, or dust from industrial plants.

(4) The area of the site shall be sufficient to permit future expansion and to provide parking facilities.

(5) Available paved roads, water, sewage and power lines shall be taken into consideration in selecting the site.

(d) The bed capacity and services provided in a facility shall be in compliance with G.S. 131E, Article 9 regarding Certificate of Need. A facility shall be licensed for no more beds than the number for which required physical space and other required facilities are available. Neonatal Level II, III and IV beds are considered part of the licensed bed capacity. Level I bassinets are not considered part of the licensed bed capacity however, no more bassinets shall be placed in service than the number for which required physical space and other required facilities are available.

History Note: Authority G.S. 131E-79;
Eff. January 1, 1996;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, 2003.

10 NCAC 03C .4305 ORGANIZATION OF NEONATAL SERVICES

(a) The governing body shall approve the scope of all neonatal services and the facility shall classify its capability in providing a range of neonatal services using the following criteria:

(1) LEVEL I: Full-term and pre-term neonates that are stable without complications. This may include, small for gestational age or large for gestational age neonates.

(2) LEVEL II: Neonates or infants that are stable without complications but require special care and frequent feedings; infants of any weight who no longer require Level III or LEVEL IV neonatal services, but who still require more nursing hours than normal infant. This may include infants who require close observation in a licensed acute care bed

(3) LEVEL III: Neonates or infants that are high-risk, small (or approximately 32 and less than 36 completed weeks of gestational age) but otherwise healthy, or sick with a moderate degree of illness that are admitted from within the hospital or transferred from another facility requiring intermediate care services for sick infants, but not requiring intensive care. The beds in this level may serve as a "step-down" unit from Level IV. Level III neonates or infants require less constant nursing care, but care does not exclude respiratory support.

(4) LEVEL IV (Neonatal Intensive Care Services): High-risk, medically unstable or critically ill neonates approximately under 32 weeks of gestational age, or infants, requiring constant nursing care or supervision not limited to continuous cardiopulmonary or respiratory support, complicated surgical procedures, or other intensive supportive interventions.

(b) The facility shall provide for the availability of equipment, supplies, and clinical support services.

(c) The medical and nursing staff shall develop and approve policies and procedures for the provision of all neonatal services.

History Note: Authority G.S. 131E-79;
Eff. January 1, 1996;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, 2003.

10 NCAC 03R .1413 DEFINITIONS

The definitions in this Rule shall apply to all rules in this Section:

(1) "Approved neonatal service" means a neonatal service that was not operational prior to the beginning of the review period.

(2) "Existing neonatal service" means a neonatal service in operation prior to the beginning of the review period.

(3) "High-risk obstetric patients" means those patients requiring specialized services provided by an acute care hospital to the mother and fetus during pregnancy, labor, delivery and to the mother after delivery. The services are characterized by specialized facilities and staff for the intensive care and management of high-risk maternal and fetal patients before, during, and after delivery.

(4) "Level I neonatal services" means services provided by an acute care hospital to full term and pre-term neonates that are stable, without complications, and may include neonates that are small for gestational age or large for gestational age.

(5) "Level II neonatal service" means services provided by an acute care hospital in a licensed acute care bed to neonates and infants that are stable without complications but require special care and frequent feedings; infants of any weight who no longer require Level III or Level IV neonatal services, but still require more nursing hours than normal infants; and infants who require close observation in a licensed acute care bed.

(6) "Level III neonatal service" means services provided by an acute care hospital in a licensed acute care bed to neonates or infants that are high-risk, small (approximately 32 and less than 36 completed weeks of gestational age) but otherwise healthy, or sick with a moderate degree of illness that are admitted from within the hospital or transferred from

another facility requiring intermediate care services for sick infants, but not intensive care. Level III neonates or infants require less constant nursing care than Level IV services, but care does not exclude respiratory support.

(7) "Level IV neonatal service" means neonatal intensive care services provided by an acute care hospital in a licensed acute care bed to high-risk medically unstable or critically ill neonates (approximately under 32 weeks of gestational age) or infants requiring constant nursing care or supervision not limited to continuous cardiopulmonary or respiratory support, complicated surgical procedures, or other intensive supportive interventions.

(8) "Neonatal bed" means a licensed acute care bed used to provide Level II, III or IV neonatal services.

(9) "Neonatal intensive care services" shall have the same meaning as defined in G.S. 131E-176(15b).

(10) "Neonatal service area" means a geographic area defined by the applicant from which the patients to be admitted to the service will originate.

(11) "Neonatal services" means any of the Level I, Level II, Level III or Level IV services defined in this Rule.

(12) "Obstetric services" means any normal or high-risk services provided by an acute care hospital to the mother and fetus during pregnancy, labor, delivery and to the mother after delivery.

(13) "Perinatal services" means services provided during the period shortly before and after birth.

History Note: Authority G.S. 131E-177(1); 131E-183; Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. November 1, 1996; Temporary Amendment Eff. March 15, 2002; Amended Eff. April 1, 2003.

10 NCAC 03R .1414 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to develop a new Level I nursery or increase the number of Level II, III or IV neonatal beds shall use the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to develop a new Level I nursery service or to increase the number of Level II, III or IV neonatal beds shall provide the following additional information:

(1) the current number of Level I nursery bassinets, Level II beds, Level III beds and Level IV beds operated by the applicant;

(2) the proposed number of Level I nursery bassinets, Level II beds, Level III beds and Level IV beds to be operated following completion of the proposed project;

(3) evidence of the applicant's experience in treating the following patients at the facility during the past twelve months, including:

(A) the number of obstetrical patients treated at the acute care facility;

(B) the number of neonatal patients treated in Level I nursery bassinets, Level II beds, Level III beds and Level IV beds, respectively;

(C) the number of inpatient days at the facility provided to obstetrical patients;

(D) the number of inpatient days provided in Level II beds, Level III beds and Level IV beds, respectively;

(E) the number of high-risk obstetrical patients treated at the applicant's facility and the number of high-risk obstetrical patients referred from the applicant's facility to other facilities or programs; and

(F) the number of neonatal patients referred to other facilities for services, identified by required level of neonatal service (i.e. Level II, Level III or Level IV);

(4) the projected number of neonatal patients to be served identified by Level I, Level II, Level III and Level IV neonatal services for each of the first three years of operation following the completion of the project, including the methodology and assumptions used for the projections;

(5) the projected number of patient days of care to be provided in Level I bassinets, Level II beds, Level III beds, and Level IV beds, respectively, for each of the first three years of operation following completion of the project, including the methodology and assumptions used for the projections;

(6) if proposing to provide Level I or Level II neonatal services, documentation that at least 90 percent of the anticipated patient population is within 30 minutes driving time one-way from the facility;

(7) if proposing to provide new Level I or Level II neonatal services, documentation of a written plan to transport infants to Level III or Level IV neonatal services as the infant's care requires;

(8) evidence that the applicant shall have access to a transport service with at least the following components:

(A) trained personnel;

(B) transport incubator;

(C) emergency resuscitation equipment;

(D) oxygen supply, monitoring equipment and the means of administration;

(E) portable cardiac and temperature monitors; and

(F) a mechanical ventilator;

(9) documentation that the proposed service shall be operated in an area organized as a physically and functionally distinct entity with controlled access;

(10) documentation to show that the new or additional Level I, Level II, Level III or Level IV neonatal services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;

(11) a detailed floor plan of the proposed area drawn to scale;

(12) documentation of direct or indirect visual observation by unit staff of all patients from one or more vantage points; and

(13) documentation that the floor space allocated to each bed and bassinet shall accommodate equipment and personnel to meet anticipated contingencies.

(c) If proposing to provide new Level III or Level IV neonatal services the applicant shall also provide the following information:

(1) documentation that at least 90 percent of the anticipated patient population is within 90 minutes driving time one-way from the facility, with the exception that there shall be a variance from the 90 percent standard for facilities which demonstrate that they provide very specialized levels of neonatal care to a large and geographically diverse population, or facilities which demonstrate the availability of air ambulance services for neonatal patients;

(2) evidence that existing and approved neonatal services in the applicant's defined neonatal service area are unable to accommodate the applicant's projected need for additional Level III and Level IV services;

(3) an analysis of the proposal's impact on existing Level III and Level IV neonatal services which currently serve patients from the applicant's primary service area;

(4) the availability of high risk OB services at the site of the applicant's planned neonatal service;

(5) copies of written policies which provide for parental participation in the care of their infant, as the infant's condition permits, in order to facilitate family adjustment and continuity of care following discharge; and

(6) copies of written policies and procedures regarding the scope and provision of care within the neonatal service, including but not limited to the following:

(A) the admission and discharge of patients;

(B) infection control;

(C) pertinent safety practices;

(D) the triaging of patients requiring consultations, including the transfer of patients to another facility; and

(E) the protocols for obtaining emergency physician care for a sick infant.

History Note: Authority G.S. 131E-177(1); 131E-183; Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. November 1, 1996; Temporary Amendment Eff. March 15, 2002; Amended Eff. April 1, 2003.

10 NCAC 03R .1415 REQUIRED PERFORMANCE STANDARDS

(a) An applicant shall demonstrate that the proposed project is capable of meeting the following standards:

(1) an applicant proposing new Level I or Level II services, or additional Level II beds shall demonstrate that the occupancy of the applicant's total number of neonatal beds is projected to be at least 50% during the first year of operation and at least 65% during the third year of operation following completion of the proposed project;

(2) if an applicant proposes an increase in the number of the facility's existing Level III or Level IV beds, the overall average annual occupancy of the total number of existing Level III and Level IV beds in the facility is at least 75%, over the 12 months immediately preceding the submittal of the proposal;

(3) if an applicant is proposing to develop new or additional Level III or Level IV beds, the projected occupancy of the total number of Level III and Level IV beds proposed to be operated during the third year of operation of the proposed project shall be at least 75%; and

(4) The applicant shall document the assumptions and provide data supporting the methodology used 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 need exists in the applicant's defined neonatal service area. The need for Level III and Level IV beds shall be computed for the applicant's neonatal service area by:

(1) identifying the annual number of live births occurring at all hospitals within the proposed neonatal service area, using the latest available data compiled by the State Center for Health Statistics;

(2) identifying the low birth weight rate (percent of live births below 2,500 grams) for the births identified in (1) of this Paragraph, using the latest available data compiled by the State Center for Health Statistics;

(3) dividing the low birth weight rate identified in (2) of this Paragraph by .08 and subsequently multiplying the resulting quotient by four; and

(4) determining the need for Level III and Level IV beds in the proposed neonatal service area as the product of:

(A) the product derived in (3) of this Paragraph, and

(B) the quotient resulting from the division of the number of live births in the initial year of the determination identified in (1) of this Paragraph by the number 1000.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Temporary Amendment Eff. March 15, 2002; Amended Eff. April 1, 2003.

10 NCAC 03R .1416 REQUIRED SUPPORT SERVICES

(a) An applicant proposing to provide new Level I, Level II, Level III or Level IV services shall document that the following items shall be available, unless an item shall not be available, then documentation shall be provided obviating the need for that item:

(1) competence to manage uncomplicated labor and delivery of normal term newborn;
(2) capability for continuous fetal monitoring;
(3) a continuing education program on resuscitation to enhance competence among all delivery room personnel in the immediate evaluation and resuscitation of the newborn and of the mother;
(4) obstetric services;
(5) anesthesia services;
(6) capability of cesarean section within 30 minutes at any hour of the day; and
(7) twenty-four hour on-call blood bank, radiology, and clinical laboratory services.

(b) An applicant proposing to provide new Level III Level IV services shall document that the following items shall be available, unless any item shall not be available, then documentation shall be provided obviating the need for that item:

(1) competence to manage labor and delivery of premature newborns and newborns with complications;
(2) twenty-four hour availability of microchemistry hematology and blood gases;
(3) twenty-four hour coverage by respiratory therapy;
(4) twenty-four hour radiology coverage with portable radiographic capability;
(5) oxygen and air and suction capability;
(6) electronic cardiovascular and respiration monitoring capability;
(7) vital sign monitoring equipment which has an alarm system that is operative at all times;
(8) capabilities for endotracheal intubation and mechanical ventilatory assistance;
(9) cardio-respiratory arrest management plan;
(10) isolation capabilities;
(11) social services staff;
(12) occupational or physical therapies with neonatal expertise; and
(13) a registered dietician or nutritionist with training to meet the special needs of neonates.

(c) An applicant proposing to provide new Level IV services shall document that the following items shall be available, unless any item shall not be available, then documentation shall be provided obviating the need for that item:

(1) pediatric surgery services;
(2) ophthalmology services;
(3) pediatric neurology services;
(4) pediatric cardiology services;
(5) on-site laboratory facilities;
(6) computed tomography and pediatric cardiac catheterization services;
(7) emergency diagnostic studies available 24 hours per day;
(8) designated social services staff; and
(9) serve as a resource center for the statewide perinatal network.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Temporary Amendment Eff. March 15, 2002: Amended Eff. April 1, 2003.

10 NCAC 03R .1417 REQUIRED STAFFING AND STAFF TRAINING

An applicant shall demonstrate that the following staffing requirements for hospital care of newborn infants shall be met:

(1) If proposing to provide new Level I or II services the applicant shall provide documentation to demonstrate that:
  (a) the nursing care shall be supervised by a registered nurse in charge of perinatal facilities;
  (b) a physician is designated to be responsible for neonatal care; and
  (c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.
(2) If proposing to provide new Level III services the applicant shall provide documentation to demonstrate that:
  (a) the nursing care shall be supervised by a registered nurse;
  (b) the service shall be staffed by a pediatrician certified by the American Board of Pediatrics; and
  (c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.
(3) If proposing to provide new Level IV services the applicant shall provide documentation to demonstrate that:
  (a) the nursing care shall be supervised by a registered nurse with educational

preparation and advanced skills for maternal-fetal and neonatal services;

(b) the service shall be staffed by a full-time board certified pediatrician with certification in neonatal medicine; and

(c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.

(4) All applicants shall submit documentation which demonstrates the availability of appropriate inservice training or continuing education programs for neonatal staff.

(5) All applicants shall submit documentation which demonstrates the proficiency and ability of the nursing staff in teaching parents how to care for neonatal patients following discharge to home.

(6) All applicants shall submit documentation to show that the proposed neonatal services will be provided in conformance with the requirements of federal, state and local regulatory bodies.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. January 4, 1994;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, 2003.

10 NCAC 03R .3301 DEFINITIONS

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

(1) "Air ambulance" as defined in G.S. 131E-176(1a).

(2) "Air ambulance service" means an entity engaged in the operation of an air ambulance transporting patients.

(3) "Air ambulance service area" means a geographic area defined by the applicant from which the project's patients originate.

(4) "Approved air ambulance" means either a rotary air ambulance or a fixed wing air ambulance that was not operational prior to the beginning of the review period but which had been acquired prior to March 18, 1993 in accordance with 1993 N.C. Sess. Laws c. 7, s. 12.

(5) "Capacity of fixed wing air ambulance" means the maximum number of hours the aircraft can be operated as defined by the aircraft manufacturer.

(6) "Existing air ambulance" means either a rotary air ambulance or a fixed wing air ambulance in operation prior to the beginning of the review period.

(7) "Inter-facility patient transport" means the transport of a patient from one facility to another facility.

(8) "Level 2 trauma center" as defined in North Carolina's Trauma Center Criteria developed by the OEMS pursuant to 10 NCAC 03D .3201(16).

(9) "Patient" as defined in G.S. 131E-155(16).

(10) "Scene transport" means the transport of a patient from the scene of a medical emergency.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. February 1, 1994;
Temporary Amendment Eff. May 15, 2002;
Amended Eff. April 1, 2003.

10 NCAC 03R .3302 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire an air ambulance shall use the Acute Care Facility/Medical Equipment Application Form.

(b) The applicant shall also provide the following additional information:

(1) the number of air ambulance aircraft by type and make currently operated and to be operated in the "air ambulance" service area following completion of the proposed project;

(2) if the applicant is a current air ambulance service provider, documentation of the applicant's experience in transporting patients via air ambulance during the past 12 months, including:

(A) the number of scene transports by air ambulance by type of air ambulance (i.e., fixed wing and rotary wing); and

(B) the number of inter-facility patient transports by air ambulance by type of air ambulance (i.e., fixed wing and rotary wing);

(3) if the applicant is a health service facility proposing to establish a new air ambulance service, the applicant shall provide documentation of:

(A) the number of scene transports to their facility by air ambulance by type of air ambulance (i.e., fixed wing and rotary wing) during the past 12 months; and

(B) the number of inter-facility patient transports during the past 12 months by air ambulance by type of air ambulance (i.e., fixed wing and rotary wing) to their facility from other facilities and from their facility to other facilities;

(4) the number of patients from the proposed air ambulance service area that are projected to require air ambulance service by type of aircraft and the patients' county of residence and county from which transported in each of the first 12 calendar quarters of operation

Exhibit A

D

EXHIBIT D

COMPARISON OF
10 N.C.A.C. 3R.4305(a) (Eff. 4/15/02) and
10A N.C.A.C. 13B.4305(a) (Eff. 4/1/03)
REGARDING LEVEL I, II, II AND IV SERVICES

10A NCAC ~~03C~~ 13B.4305 ~~.~~ , ORGANIZATION OF NEONATAL SERVICES

(a) ~~—~~ The governing body shall approve the scope of all neonatal services and the facility shall classify its capability in providing a range of neonatal services using the following criteria:

(1) ~~—~~ ~~Newborn Nursery~~ LEVEL I: Full-term and pre-term neonates that are stable without complications~~;~~. This may include, small for gestational age or large for gestational age neonates~~;~~,

(2) ~~—~~ LEVEL ~~II~~: Neonates or infants that are stable without complications but require special care and frequent feedings; infants of any weight who no longer require Level III or ~~Level~~LEVEL ~~II~~V neonatal services, but who still require more nursing hours than normal ~~infants; and~~infant. This may include infants who require close observation in a licensed acute care bed~~;~~

(3) ~~—~~ LEVEL III: Neonates or infants that are high-risk, small (or approximately 32 and less than 36 completed weeks of gestational age) but otherwise healthy, or sick with a moderate degree of illness that are admitted from within the hospital or transferred from another facility requiring intermediate care services for sick infants, but not requiring intensive care~~;~~. The beds in this level may serve as a ~~"step-down"~~"step-down" unit from Level ~~II~~V.~~-~~ Level ~~II~~III neonates or infants require less constant nursing care, but care does not exclude respiratory support~~; and~~ .

(4) ~~—~~ LEVEL ~~II~~V (Neonatal Intensive Care Services): High-risk, medically unstable or critically ill neonates approximately under 32 weeks of gestational age, or infants, requiring constant nursing care or supervision not limited to continuous cardiopulmonary or respiratory support, complicated surgical procedures, or other intensive supportive interventions.

From: Denise Gunter
To: Stancil, Tiffany C; Waller, Martha K
Subject: [External] No Review Letter for Onslow Memorial Hospital
Date: Wednesday, March 20, 2024 3:13:25 PM
Attachments: March 20 22024 Onslow Material Compliance Letter.docx
OMH CON for NICU.pdf

Hi, Tiffany and Martha,

Hope you're well.

Attached for processing is a no review letter for Onslow Memorial Hospital. Could you please confirm that you have received this?

Thanks.

DENISE M. GUNTER PARTNER
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