STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEDICAL CARE COMMISSION QUARTERLY MEETING
DIVISION OF HEALTH SERVICE REGULATION
1800 UMSTEAD DRIVE, RALEIGH NC 27603
WILLIAMS BUILDING
CONFERENCE ROOM – 123B
OR
TEAMS Video Conference: Join the meeting now
OR
Dial-IN: 1-984-204-1487 / Passcode: 634 608 863#

May 9, 2025 (Friday)
9:00 a.m.

Agenda

I. Meeting Opens – Roll Call

II. Chairman's Comments……Dr. John Meier

III. Public Meeting Statement……Dr. John Meier

This meeting of the Medical Care Commission is open to the public but is not a public hearing. Therefore, any discussion will be limited to members of the Commission and staff unless questions are specifically directed by the Commission to someone in the audience.

IV. Ethics Statement……Dr. John Meier

The State Government Ethics Act requires members to act in the best interest of the public and adhere to the ethical standards and rules of conduct in the State Government Ethics Act, including the duty to continually monitor, evaluate, and manage personal, financial, and professional affairs to ensure the absence of conflicts of interest.

V. Resolution of Appreciation for the following Retiring Member:

- Dr. Robert E. Schaaf

VI. Approval of Minutes (Action Items)……..……..Dr. John Meier

- **February 7, 2025** (Medical Care Commission Quarterly Meeting) (**See Exhibit A**)
- **March 25, 2025** (Executive Committee) **(See Exhibit B/1**)

    - Preliminary Approval for Pennybyrn refunding (Series 2015 - $42,605,000)
    - Approval of technical changes for Adult Care rules (10A NCAC 13F.1604 & 13G.1604)
    - Final Approval for the use of $560,474.91 NCMCC Funds to improve the OEMS Mobile Disaster Hospital (*Preliminary Approval given at 5/19/23 NCMCC meeting*)

- **April 22, 2025** (Executive Committee) **(See Exhibit B/2)**

    - Preliminary Approval for Duke University Health Systems refunding (Series 2005A, 2005B, 2016B, 2016C, 2006A, 2006B, 2006C - $344,645,000)
    - Final Approval of Aldersgate Master Trust Indenture amendment to accommodate recent affiliation with the Givens Estates, Inc.

- **April 30, 2025** (Executive Committee) **(See Exhibit B/3)**

    - Final Approval for Twin Lakes bond sale (Series 2025A, 2025B1, 2025B2 - $35,310,000) (*Preliminary Approval given at 8/19/24 NCMCC meeting*)

VII. NC Hospital Discharge Data Presentation..……..……Dr. Sandra Greene

VIII. Old Business (Discuss rules, fiscal note, & comments submitted) (Action Items)

A. Periodic Review Rules for Approval of Comments and Final Determinations

1. **Hospice Licensing Rules**…….……..……...Shanah Back & Azzie Conley
   Agency Determination of 51 rules 10A NCAC 13K .0102, .0201-.0202, .0206, .0208, .0210, .0301, .0303, .0401-.0402, .0501, .0504-.0505, .0601, .0604-.0605, .0701, .0801-.0802, .0901-.0902, .1001, .1101-.1116, .1201-.1212
   (See Exhibits C–C/2)

2. **Licensing of Ambulatory Surgical Facilities**……Shanah Black & Azzie Conley
   Agency Determination of 44 rules 10A NCAC 13C .0103. .0201-.0206, .0301-.0306, .0401-.0403, .0501-.0504, .0601-.0602, .0701-.0702, .0801-.0802, .0901-.0902, .1001-.1002, .1101-.1102, .1201-.1202, .1301-.1305, .1401-.1404, .1411
   (See Exhibits D– D/1)

3. **Rulemaking and Hearings: Transfers and Discharges**….S. Black & B. Speroff
   Agency Determination of 5 rules 10A NCAC 14A .0101, .0103, .0301, .0302, 0303
   (See Exhibits E–E/1)

4. **Emergency Medical Services and Trauma Rules**……S. Black & W. Ainsworth
Agency Initial Determination of 76 Rules 10A NCAC 13P .0101, .0102, .0201-.0224, .0301-.0305, .0401-.0410, .0501-.0513, .0601-.0605, .0901, .0904, .0905, .1003, .1101-.1103, .1401-.1405, .1501-.1511
(See Exhibits F-F/1)

IX. New Business (Rules for Initiating Rulemaking Approval) (Action Items)

(Discuss rules & fiscal note)

A. Periodic Review Rules for Initial Approval

1. **Licensing of Hospitals**……...……S. Black, A. Conley & G. Hill

Agency Initial Determination and 198 Rules 10A NCAC 13B .1901-.1912, .1915-.1932, .2020, .2033, .2101-.2102, .3001, .3101-.3111, .3201-.3205, .3301-.3303, .3401-.3402, .3405, .3501-.3503, .3601-.3609, .3701, .3703-.3708, .3801-.3804, .3901-.3907, .4001-.4005, .4101-.4110, .4201-.4204, .4301-.4308, .4401-.4403, .4501-.4516, .4601-.4605, .4701-.4705, .4801-.4806, .4901-.4907, .5001-.5005, .5101-.5105, .5201-.5207, .5301, .5401-.5410, .5412-.5414, .5501-.5506, .6003, .6101-.6103, .6105, .6207, .6228
(See Exhibits G-G/2)

2. **Licensing of Home Care Agencies**……...……S. Black, A. Conley & Greta Hill
Agency Initial Determination and 36 Rules 10A NCAC 13J.0901-.0907, .1001-.1007, .1101-.1112, .1201-.1202, .1301-.1302, .1401-.1402, .1501-.1504.
(See Exhibits H-H/1)

X. Bond Program Activities……Geary W. Knapp

A. Quarterly Report on Bond Program (See Exhibit B)
B. Process Discussion

XI. Refunding of Commission Bond Issues (Action Item)……..…..……..….Geary W. Knapp

Recommended:

WHEREAS, the bond market is in a period of generally fluctuating interest rates, and

WHEREAS, in the event of decline of rates during the next quarter, refunding of certain projects could result in significant savings in interest expense thereby reducing the cost of health care to patients, and

WHEREAS, the Commission will not meet again until August 8, 2025 in Raleigh, North Carolina;

THEREFORE, BE IT RESOLVED; that the Commission authorize its Executive Committee to approve projects involving the refunding of existing Commission debt and amend previously approved projects to include refunding components only between this date and August 8, 2025. Refunding projects may include non-Commission debt, and non-material, routine capital improvement expenditures.

XII. Meeting Adjournment

STATE OF NORTH CAROLINA
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Dial-IN: 1-984-204-1487 / Passcode: 958 004 649

FEBRUARY 7, 2025 (Friday)
9:00 a.m.

Minutes

I. Meeting Opens

MEMBERS PRESENT	MEMBERS ABSENT
John J. Meier, IV, M.D., Chairman Joseph D. Crocker, Vice-Chairman Kathy G. Barger Sally B. Cone Paul R.G. Cunningham, M.D. Bryant C. Foriest Linwood B. Hollowell, III Michelle F. Jones, M.D. Eileen C. Kugler, RN, MSN, MPH, FNP Ashley H. Lloyd, D.D.S. David C. Mayer, M.D. Robert E. Schaaf, M.D. Neel G. Thomas, M.D. Lisa A. Tolnitch, M.D. Pascal O. Udekwu, M.D. Timothy D. Weber, RPH Jeffrey S. Wilson **DIVISION OF HEALTH SERVICE REGULATION STAFF**	

Mark Payne, Director, DHSR/Secretary, MCC Emery Milliken, Deputy Director, DHSR Geary W. Knapp, JD, CPA, Assistant Secretary, MCC Eric R. Hunt, Attorney General's Office Jeff Harms, Construction Chief, DHSR Tammy Sylvester, Assistant. Construction Chief, DHSR Shanah F. Black, Rule Making Coordinator, DHSR Megan Lamphere, Chief, ACLS Libby Kinsey, Assistant Chief, ACLS Azzie Conley, Chief, Acute & Home Care Licensure Greta Hill, Assistant Chief, Acute & Home Care Licensure Tom Mitchell, Chief, OEMS Wally Ainsworth, Paramedic Manager, OEMS Jana Busick, Chief, Health Care Personnel Registry, DHSR Rita Horton, Chief, Complaint Intake/ Healthcare Personnel Investigations, DHSR Crystal Abbott, Auditor, MCC Kathy C. Larrison, Auditor, MCC Alice Creech, Executive Assistant, MCC **OTHERS PRESENT** Emma Kate Burns, NC Medical Society Roslyn Cozart, Local Government Commission Donald Houaudev, AGNP Student/University of Cincinnati Christopher McCann, JP Morgan Chase Christopher Taylor Jennifer Wimmer, Local Government Commission Robert Willis, Duke University Hospital	

II. Chairman's Comments……..……..…….……Dr. John Meier

III. Public Meeting Statement…….……..……..……Dr. John Meier

This meeting of the Medical Care Commission is open to the public but is not a public hearing. Therefore, any discussion will be limited to members of the Commission and staff unless questions are specifically directed by the Commission to someone in the audience.

IV. Ethics Statement……..…….Dr. John Meier

The State Government Ethics Act requires members to act in the best interest of the public and adhere to the ethical standards and rules of conduct in the State Government Ethics Act, including the duty to continually monitor, evaluate, and manage personal, financial, and professional affairs to ensure the absence of conflicts of interest.

V. Introduction of New Commission Member & State Ethics Letter…….Dr. John Meier

Introduction of Dr. Michelle F. Jones who was appointed to the Commission by Governor Cooper on December 31, 2024. We received an *Evaluation of Statement of Economic Interest* letter from the State Ethics Commission for Dr. Jones, which stated no actual conflict of interest but found the potential for a conflict of interest. The potential conflict identified does not prohibit service on this entity. **(See Exhibit A/1)**

VI. Approval of Minutes (Action Items)……..……..Dr. John Meier

- **November 22, 2024** (Medical Care Commission Quarterly Meeting) (**See Exhibit A**)

COMMISSION ACTION: *A motion was made to approve the minutes by Mrs. Kathy Barger, seconded by Dr. Robert Schaaf, and unanimously approved.*

VII. Bond Program Activities……...……Geary W. Knapp

A. Quarterly Report on Bond Program (**See Exhibit B**)
B. Notices & Non-Action Items & Technical Rule Changes

VIII. Bond Projects- (Action Item)

A. Duke University Health System, Inc. (Cary, Charlotte)..…...….Geary W. Knapp

Resolution: The Commission grants preliminary approval to a transaction for Duke University Health System, Inc. to provide funds, to be used, together with other available funds to **1)** partially refinance the acquisition costs of Lake Norman Regional Medical Center and **2)** construct the following:

- 111,000 sq. ft. building located in Wake County
  - Free-standing emergency department
  - 6 room ambulatory surgical center
  - 4 gastrointestinal endoscopy rooms
  - 30,000 sq. ft. of clinical infusion space

Capital expenditures for the new construction shall be included as listed below, all in accordance with a preliminary application, plans and specifications and participation as follows:

ESTIMATED SOURCES OF FUNDS

Principal Amount of Bonds to be Issued	$	435,535,000
Premium on Bond Issuance	$	22,968,249
Total Sources	**$**	**458,503,249**

ESTIMATED USE OF FUNDS

Construction Cost	$	122,796,545
Loan Payoff (Lake Norman)	$	280,000,000
Architect Fees	$	12,995,777
Architect Reimbursables	$	616,543
Contingency	$	1,239,990
Moveable Equipment	$	34,305,761
Surveys	$	3,045,384
Underwriter Placement Fee	$	2,182,749
Accountant Fee	$	175,000
Corporate Counsel	$	100,000
Bond Counsel	$	200,000
Trustee Fee	$	2,000
Trustee Counsel	$	7,500
Underwriter Counsel	$	140,000
Local Government Commission Fee	$	20,000
Financial Advisor Fee	$	225,000
Rating Agencies Fee	$	426,000
Printing Costs	$	25,000
Total Uses	**$**	**458,503,249**

Tentative approval is given with the understanding that the governing board of Duke University Health System accepts the following conditions:

1. The project will continue to be developed pursuant to the applicable Medical Care Commission guidelines.

2. Any required certificate of need must be in effect at the time of the issuance of the bonds or notes.

3. Final financial feasibility must be determined prior to the issuance of bonds.

4. The project must, in all respects, meet requirements of G.S. § 131A (Health Care Facilities Finance Act).

5. The Executive Committee of the Commission is delegated the authority to approve the issuance of bonds for this project and may approve the issuance of such greater principal amount of the loan as shall be necessary to finance the project; provided, however, that the amount set forth above shall not be increased by more than ten percent (10%).

6. The bonds or notes shall be sold in such a manner and upon such terms and conditions as will, in the sole judgment of the Executive Committee of the Commission, result in the lowest cost to the facility and its patients.

7. If public approval of the bonds is required for the purpose of Section 147(f) of the Internal Revenue Code of 1986, as amended ("Section 147(f)"), this tentative approval shall constitute the recommendation of the Commission that the Governor of the State of North Carolina (the "Governor") approve the issuance of such bonds, subject to the satisfaction of the requirements of Section 147(f) concerning the holding of a public hearing prior to the submission of such recommendation to the Governor.

8. The borrower will provide the Commission annually a copy of Schedule H of the IRS form 990 to demonstrate community benefits provided by the borrower.

9. The borrower will furnish, prior to the sale of or issuance of the bonds or notes or execution of the leases, evidence that it is in compliance with the covenants of all of its outstanding Medical Care Commission debt.

10. All health care facilities and services directly or indirectly owned or controlled by the health care organization, including physician practices, shall be available to Medicare and Medicaid patients with no limitations imposed as a result of the source of reimbursement.

Based on information furnished by applicant, the project is:

Financially Feasible: **YES**
Construction & Related Costs are Reasonable: **YES**

See **Exhibit J** and **Exhibit K** for selected application information and presentation

COMMISSION ACTION: *A motion was made to approve the preliminary project for Duke University Health System, Inc. by Dr. Robert Schaaf, seconded by Mr. Linwood Hollowell, and unanimously approved.*

IX. OLD BUSINESS (Discuss Rules, Fiscal Note, & Comments Submitted) (Action Items)

A. Periodic Review Rules for Approval of Comments and Final Determinations

1. Nursing Pool Licensure……..…..…….Shanah Black & Azzie Conley

Agency Determination of 8 rules 10A NCAC 13L .0101, .0201 - .0204, .0301 - .0303

(See Exhibits C-C/2)

2. Mammogram and Pap Smear Certification……....…S. Black & A. Conley

Agency Determination of 2 rules 10A NCAC 13M .0101 and .0201

(See Exhibits D-D/1)

3. **Healthcare Personnel Registry**……..…... S. Black, J. Busick & R. Horton

   Agency Determination of 5 rules 10A NCAC 13O .0101, .0102, .0201, 0202, .0301

   (See Exhibits E-E/1)

COMMISSION ACTION: *A motion was made to approve the Nursing Pool Licensure Rules, Mammogram and Pap Smear Certification Rules, & Healthcare Personnel Registry Rules by Dr. Robert Schaaf, seconded by Mrs. Kathy Barger, and unanimously approved.*

X. NEW BUSINESS (Discuss rules & fiscal note) (Action Items)

A. Periodic Review Rules for Initial Approval

1. **Rulemaking & Hearings: Transfers & Discharges**.....S. Black & B. Speroff

   Agency Determination and 5 Rules 10A NCAC 14A .0101, .0103, .0301, .0302, .0303

   (See Exhibits F-F/2)

2. **Emergency Medical Services & Trauma Rules**…...S. Black & W. Ainsworth

   Agency Initial Determination of 76 Rules 10A NCAC 13P .0101, .0102, .0201-.0224, .0301-.0305, .0401-.0410, .0501-.0513, .0601-.0605, .0901, .0904, .0905, .1003, .1101-.1103, .1401-.1405, .1501-.1511

   (See Exhibits G-G/1)

3. **Licensing of Ambulatory Surgical Facilities**…….....S. Black & A. Conley

   Agency Initial Determination of 44 Rules 10A NCAC 13C .0103. .0201-.0206, .0301-.0306, .0401-.0403, .0501-.0504, .0601-.0602, .0701-.0702, .0801-.0802, .0901-.0902, .1001-.1002, .1101-.1102, .1201-.1202, .1301-.1305, .1401-.1404, .1411

   (See Exhibits H-H/1)

4. **Hospice Licensing Rules**……..……..…...S. Black & A. Conley

   Agency Initial Determination of 51 Rules 10A NCAC 13K .0102, .0201-.0202, .0206, .0208, .0210, .0301, .0303, .0401-.0402, .0501, .0504-.0505, .0601,

.0604-.0605, .0701, .0801-.0802, .0901-.0902, .1001, .1101-.1116, .1201-.1212

(See Exhibits I-I/1)

COMMISSION ACTION: *A motion was made to approve the Nursing Home Transfer & Discharge Rules, Emergency Medical Services & Trauma Rules, Licensing of Ambulatory Surgical Facilities Rules, and Hospice Licensing Rules by Dr. Paul Cunningham, seconded by Mrs. Eileen Kugler, and unanimously approved.*

XI. Refunding of Commission Bond Issues (Action Item).....Geary W. Knapp

Recommended:
WHEREAS the bond market is in a period of generally fluctuating interest rates, and

WHEREAS, in the event of decline of rates during the next quarter, refunding of certain projects could result in significant savings in interest expense thereby reducing the cost of health care to patients, and

WHEREAS, the Commission will not meet again until May 9, 2025 in Raleigh, North Carolina;

THEREFORE, BE IT RESOLVED; that the Commission authorize its Executive Committee to approve projects involving the refunding of existing Commission debt and amend previously approved projects to include refunding components only between this date and May 9, 2025. Refunding projects may include non-Commission debt, and non-material, routine capital improvement expenditures.

COMMISSION ACTION: *A motion was made to authorize the Executive Committee to approve projects involving the refunding of existing debt between this date and the next full Commission meeting by Dr. Robert Schaaf, seconded by Mrs. Kathy Barger, and unanimously approved.*

XII. Meeting Adjournment

There being no further business the meeting was adjourned at 10:40 a.m.

Respectfully Submitted,

Geary W. Knapp, JD, CPA
Assistant Secretary

NC Medical Care Commission

Quarterly Report on **Outstanding Debt** (End: 3rd Quarter FYE 2025)

Program Measures	FYE 2024 Ending: 6/30/2024	FYE 2025 Ending: 3/31/2025
Outstanding Debt	**$4,677,104,694**	**$4,728,674,780**
Outstanding Series	**114**[1]	**115**[1]

Detail of Program Measures	Ending: 6/30/2024	Ending: 3/31/2025
Outstanding Debt per Hospitals and Healthcare Systems	$3,088,410,639	$3,020,035,000
Outstanding Debt per CCRCs	$1,588,694,055	$1,708,639,780
Outstanding Debt per Other Healthcare Service Providers	$0	$0
Outstanding Debt Total	**$4,677,104,694**	**$4,728,674,780**
Outstanding Series per Hospitals and Healthcare Systems	50	49
Outstanding Series per CCRCs	64	66
Outstanding Series per Other Healthcare Service Providers	0	0
Series Total	**114**	**115**
Number of Hospitals and Healthcare Systems with Outstanding Debt	10	10
Number of CCRCs with Outstanding Debt	20	22
Number of Other Healthcare Service Providers with Outstanding Debt	0	0
Facility Total	30	32

Note 1: For FYE 2025, NCMCC closed 11 **Bond Series**. Out of the closed Bond Series: 4 conversions, 6 were new money projects, 0 combination of new money project and refunding, and 1 refunding. The Bond Series outstanding from FYE 2025 to current represents all new money projects, refundings, conversions, and redemptions.

GENERAL NOTES: Facility Totals represent a parent entity total and do not represent each individual facility owned/managed by the parent entity. CCRCs are licensed by the NC Department of Insurance. "Other Healthcare Service Providers" would include nursing homes, rehabilitation facilities, assisted living, blood donation centers, and hospice facilities. The following parent entities represent the current "other healthcare service providers" with outstanding NC MCC debt: NONE AT THIS TIME

NC Medical Care Commission

Quarterly Report on **History** of NC MCC Finance Act Program (End: 3rd Quarter FYE 2025)

Program Measures	FYE 2024 Ending: 6/30/2024	FYE 2025 Ending: 3/31/2025
Total PAR Amount of Debt Issued	**$29,378,557,997**	**$29,688,247,997**
Total Project Debt Issued (excludes refunding/conversion proceeds)[1]	**$13,828,615,223**	**$14,003,390,223**
Total Series Issued	**715**	**726**

Detail of Program Measures	Ending: 6/30/2024	Ending: 3/31/2025
PAR Amount of Debt per Hospitals and Healthcare Systems	$23,116,044,855	$23,233,174,855
PAR Amount of Debt per CCRCs	$5,888,217,912	$6,080,777,912
PAR Amount of Debt per Other Healthcare Service Providers	$374,295,230	$374,295,230
Par Amount Total	**$29,378,557,997**	**$29,688,247,997**
Project Debt per Hospitals and Healthcare Systems	$10,273,019,674	$10,273,019,674
Project Debt per CCRCs	$3,308,581,635	$3,483,356,635
Project Debt per Other Healthcare Service Providers	$247,013,915	$247,013,915
Project Debt Total	**$13,828,615,223**	**$14,003,390,223**
Series per Hospitals and Healthcare Systems	433	437
Series per CCRCs	243	250
Series per Other Healthcare Service Providers	39	39
Series Total	**715**	**726**
Number of Hospitals and Healthcare Systems issuing debt	99	99
Number of CCRCs issuing debt	42	42
Number of Other Healthcare Service Providers issuing debt	46	46
Facility Total	187	187

Note 1: Project Debt excludes bond proceeds that directly refunded prior NCMCC outstanding issues and conversion par amounts. Project Debt is an accumulation of all new project money, issuance costs (including issuance costs for refundings/conversions (if any)), and refundings of non-NCMCC debt.

GENERAL NOTES: Facility Totals represent each individual facility and do not represent parent entity totals. CCRCs are licensed by the NC Department of Insurance. "Other Healthcare Service Providers" would include nursing homes, rehabilitation facilities, assisted living, blood donation centers, and hospice facilities.

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES

The North Carolina Medical Care Commission
809 Ruggles Drive
Raleigh, North Carolina

MINUTES

CALLED MEETING OF THE EXECUTIVE COMMITTEE CONFERENCE TELEPHONE MEETING ORIGINATING FROM THE COMMISSION'S OFFICE MARCH 25, 2025 11:30 A.M.

Members of the Executive Committee Present:

John J. Meier, IV, M.D., Chairman
Paul R.G. Cunningham, M.D.
Bryant C. Foriest
Eileen C. Kugler, RN, MSN, MPH, FNP
David C. Mayer, M.D.
Neel G. Thomas, M.D.

Members of the Executive Committee Absent:

Joseph D. Crocker, Vice-Chairman

Members of Staff Present:

S. Mark Payne, Director, DHSR/Secretary, MCC
Emery E. Milliken, Deputy Director, DHSR
Geary W. Knapp, JD, CPA, Assistant Secretary, MCC
Shanah F. Black, Rules Review Coordinator, DHSR
Eric R. Hunt, Attorney General's Office
Megan Lamphere, Chief, Adult Care Licensure Section, DHSR
Kathy C. Larrison, Auditor, MCC
Crystal Watson-Abbott, Auditor, MCC
Kimberly Clement, Program Manager, Healthcare Preparedness Program, OEMS

Others Present:

Loretta Long, Pennybyrn at Maryfield
Rich Newman, Pennybyrn at Maryfield
Tad Melton, Ziegler

1. Purpose of Meeting

To approve a refunding for Pennybyrn at Maryfield (preliminary), an amendment of 2 Adult Care Rules for technical changes, and an OEMS Mobile Disaster Hospital purchase (final approval).

2. Refunding for Pennbyrn at Maryfield

Resolution: The Commission grants preliminary approval to a transaction for Maryfield Inc. d/b/a Pennybyrn to (1) provide funds, to be used, together with other available funds, to refund the North Carolina Medical Care Commission $66,135,000 Retirement Facilities First Mortgage Revenue Refunding Bonds, Series 2015, outstanding as of the date of the refunding in the amount of $42,605,000, (2) provide funds, to be used, together with other available funds, to refund an existing line of credit ($800,000), and (3) fund routine capital expenditures ($4,200,000) that include paving projects, roofing projects, HVAC improvements, acquisition of equipment, acquisition of vehicles, refurbishment projects, and construction of a maintenance building among other capital improvements. The proposed 2025 Bond Issue is estimated to generate $1,695,595 in net present value savings, as well as generate cash flow savings. The proposed transaction is in accordance with an application received as follows:

ESTIMATED SOURCES OF FUNDS		
Principal Amount of Bonds to be Issued	$	48,100,000.00
Prior Debt Service Reserve Fund	$	5,070,600.00
Bond Fund Principal Account Balance	$	164,400.00
Total Sources	**$**	**53,335,000.00**

ESTIMATED USE OF FUNDS		
NCMCC Series 2015	$	42,605,000.00
Routine Capital Expenditures	$	4,200,000.00
Line of Credit Payor	$	800,000.00
Debt Service Reserve Fund	$	4,775,500.00
Underwriter Placement Fee	$	650,000.00
Accountant Fee	$	50,000.00
Corporate Counsel	$	25,000.00
Bond Counsel	$	90,000.00
Trustee Fee	$	7,500.00
Trustee Counsel	$	7,500.00
Underwriter Counsel	$	75,000.00
Local Government Commission Fee	$	8,750.00
Printing Costs	$	7,500.00
Real Estate/Title/Recording	$	33,250.00
Total Uses	**$**	**53,335,000.00**

Tentative approval is given with the understanding that the governing board of Pennbyrn accepts the following conditions:

1. The project will continue to be developed pursuant to the applicable Medical Care Commission guidelines.

2. Final financial feasibility must be determined prior to the issuance of bonds.

3. The project must, in all respects, meet requirements of G.S. § 131A (Health Care Facilities Finance Act).

4. The Executive Committee of the Commission is delegated the authority to approve the issuance of bonds for this project and may approve the issuance of such greater principal amount of the loan as shall be necessary to finance the project; provided, however, that the amount set forth above shall not be increased by more than ten percent (10%).

5. The bonds or notes shall be sold in such a manner and upon such terms and conditions as will, in the sole judgment of the Executive Committee of the Commission, result in the lowest cost to the facility and its residents.

6. If public approval of the bonds is required for the purpose of Section 147(f) of the Internal Revenue Code of 1986, as amended ("Section 147(f)"), this tentative approval shall constitute the recommendation of the Commission that the Governor of the State of North Carolina (the "Governor") approve the issuance of such bonds, subject to the satisfaction of the requirements of Section 147(f) concerning the holding of a public hearing prior to the submission of such recommendation to the Governor.

7. The borrower will comply with the Commission's Resolution: Community Benefits/Charity Care Agreement and Program Description for CCRCs as adopted.

8. The borrower will furnish, prior to the sale of or issuance of the bonds or notes or execution of the leases, evidence that it is in compliance with the covenants of all of its outstanding Medical Care Commission debt.

Based on information furnished by applicant, the project is:

Financially Feasible: YES
Construction Costs are Reasonable: N/A

(See **Exhibit A** for selected application information)

COMMISSION ACTION: *A motion was made to approve the resolution by Mrs. Eileen Kugler, seconded by Dr. Paul Cunningham, and unanimously approved.*

3. OEMS Mobile Disaster Hospital Purchase

RESOLUTION AUTHORIZING THE USE OF $560,474.91 OF FUNDS REMAINING IN A NORTH CAROLINA MEDICAL CARE COMMISSION ACCOUNT FOLLOWING THE REPAYMENT OF ALL OBLIGATIONS UNDER THE 1985 AND 1986 POOLED LOAN PROGRAMS BY THE NORTH CAROLINA OFFICE OF EMERGENCY MEDICAL SERVICES (NCOEMS).

WHEREAS, the North Carolina Medical Care Commission (Commission) has funds remaining in an account associated with its 1985 and 1986 Pooled Loan programs, and

WHEREAS, all obligations of the Commission under the terms of the bond issues under the 1985 and 1986 Pooled Loan programs have been discharged, and

WHEREAS, the terms of the Trust Agreements under both the 1985 and 1986 Pooled Loan programs provided that any remaining funds belong to the Commission, and

WHEREAS, the Commission is authorized by the Health Care Facility Finance Act to finance, acquire, construct, equip, provide, operate, own, repair, maintain, extend, improve, rehabilitate, renovate and furnish any health care facilities and to pay all or any part of the cost thereof from the proceeds of bonds or notes or from any contribution, gift or donation, or other funds available to the Commission for such purpose, and

WHEREAS, the North Carolina Office of Emergency Medical Services (NCOEMS), a section of the North Carolina Division of Health Service Regulation, under the North Carolina Department of Health and Human Services, operates a mobile disaster hospital, within the statutory meaning of a health care facility, and

WHEREAS, the mobile disaster hospital operated by the NCOEMS is in need of funds to make improvements; and

WHEREAS, the Commission has determined that the public will be best served by providing the proposed funds, and by a resolution adopted on May 19, 2023, has approved the providing of funds, subject to compliance by the NCOEMS with the conditions set forth in such resolution, and the NCOEMS has complied with such conditions to the satisfaction of the Commission.

WHEREAS, the NCOEMS has provided and addressed to staff of the Commission appropriate quotes, bids, and contracting considerations with regards to the specific improvements for the mobile disaster hospital of (1) stretchers, (2) generators, (3) transfer switch, and (4) soft-sided structures;

NOW THEREFORE, THE COMMISSION HEREBY RESOLVES: that $560,474.91 of the funds remaining in its account associated with the 1985 and 1986 Pooled Loan programs be provided to the NCOEMS to make improvements to its mobile disaster hospital; and

BE IT FURTHER RESOLVED, that the Chairman, Vice-Chairman, Secretary or Assistant Secretary be authorized to execute any and all documents required to carry out the purposes of this resolution, in accordance with North Carolina purchasing and contracting rules and policies.

(See **Exhibit B** for invoices)

COMMISSON ACTION: *A motion was made to approve the resolution by Dr. Paul Cunningham, seconded by Mr. Bryant Foriest, and unanimously approved.*

4. Rules for Adoption

1. **Adult Care Home Rules**
   Amendment of two Rules for Technical Changes:
   - 10A NCAC 13F.1604
   - 10A NCAC 13G.1604

(See **Exhibits C thru C/2**)

COMMISSION ACTION: *A motion was made to approve the amended rules by Mr. Bryant Foriest, seconded by Mrs. Eileen Kugler, and unanimously approved.*

5. Adjournment

There being no further business, the meeting was adjourned at 11:54 a.m.

Respectfully submitted,

Geary W. Knapp, JD, CPA
Assistant Secretary

EXHIBIT A

Compliance Summary:

- **No Violation of MCC Compliance policy**

1) Does Organization have a formal post tax issuance compliance policy?

   No; Developing a policy

2) Who in the Organization will be designated to ensure appropriate compliance with the issuance?

   CFO

3) What is the Organization's compliance monitoring plan?

   Compliance checklist

4) How will the Organization report compliance deficiencies to leadership and the Board?

   Compliance deficiencies are reported immediately to leadership and the Board.

Selected Application Information:

1) Information from period ending 9/30/24:

Net Income	$ 2,114,647
Operating Revenue	$ 36,629,548
Operating Expenses	($ 37,680,389)
Net Cash from Operating Activities	$ 6,535,648
Cash	$ 3,396,537

2) Ratings:

No Ratings

3) Community Benefits:

- Total Community Benefits and Charity Care - $1,700,454
- Eligible for property tax exclusion – 5.34% of resident revenue

4) Long-Term Debt Service Coverage Ratios:

Actual FYE 2024	1.87
Forecasted FYE 2025	1.41
Forecasted FYE 2026	1.46
Forecasted FYE 2027	1.51
Forecasted FYE 2028	1.58
Forecasted FYE 2029	1.63

5) Transaction Participants:

Bond Counsel:	Womble Bond Dickinson
Underwriter:	B.C. Ziegler and Company
Underwriter Counsel:	Haynsworth Sinkler Boyd
Corporate Counsel:	Keziah Gates
Accountant (AUP Forecast):	Forvis
Trustee:	Bank of New York
Trustee Counsel:	TBD

6) Board Diversity:

Male:	15	Caucasian:	16
Female:	3	African American:	2
Total:	**18**	**Total:**	**18**

Resident Diversity:

Male:	146
Women:	286
Total:	**432**

Caucasian:	419
African American:	13
Total:	**432**

7) Fee Schedule: See Page A-3 thru A-6

8) Bond Sale Approval Form: See Page A-7

Entrance Fees in effect for the independent living unit options are outlined below:

Unit Type		Plan A 0% Amortizing	Plan B 50% Refundable	Plan C 90% Refundable
Apartments: [1]				
1 Bedroom, 1 Bath	Dogwood	$170,000	$247,000	$315,000
1 Bedroom, 1 Bath, Den	Redbud	210,000	305,000	389,000
1 Bedroom, 1 Bath, Den	Periwinkle	246,000	357,000	455,000
1 Bedroom, 1.5 Bath, Den	Periwinkle Enhanced	257,000	372,000	475,000
2 Bedroom, 2 Bath	Magnolia	261,000	378,000	483,000
2 Bedroom, 2 Bath	Camellia	281,000	407,000	519,000
2 Bedroom, 2 Bath	Wisteria	281,000	407,000	519,000
2 Bedroom, 2 Bath, Den	Azalea	305,000	441,000	563,000
3 Bedroom, 2 Bath, Den	Azalea Deluxe	352,000	510,000	650,000
2 Bedroom, 2 Bath, Den	Rose	312,000	452,000	577,000
2 Bedroom, 2 Bath, Den	Holly	360,000	522,000	666,000
2 Bedroom, 2.5 Bath, Den	Jasmine	373,000	541,000	690,000
Total / Weighted Average Apartments		**$267,519**	**$384,115**	**$490,214**
Cottages:				
2 Bedroom, 2 Bath	Standard	$293,000	$425,000	$542,000
2 Bedroom, 2.5 Bath, Den	Enhanced/Deluxe	324,000	470,000	599,000
Total / Weighted Average Cottages		**$322,450**	**$467,750**	**$596,150**

Average Entrance Fees in effect for the Heritage Cottage independent living unit options are as follows:

Unit Type		Plan A 0% Amortizing	Plan B 50% Refundable	Plan C 90% Refundable
Independent Living Heritage Cottages Residences: [2]				
3 Bedroom, 2 Bath	A1	$ 415,000	$ 601,667	$ 767,667
2 Bedroom, 2 Bath	A2	286,750	415,500	530,000
2 Bedroom, 2 Bath	B	201,857	292,571	373,000
1 Bedroom, 1 Bath	C	129,800	187,800	239,400
1 Bedroom, 1 Bath	D	134,000	194,000	247,000
Total / Weighted Average Existing		$ 241,931	$ 350,552	$ 447,069

[1] The above Entrance Fees are those in effect as of October 1, 2024, and are subject to change.
[2] The Entrance Fees for the Heritage Residences are a weighted average based upon the grouping of similar-sized floor plans. The above Entrance Fees are those in effect as of October 1, 2024, and are subject to change.

B. Monthly Service Fees

Monthly Service Fees for the project independent living unit options are as follows:

Unit Type		Number Of Units	Approximate Square Feet	Monthly Service Fees
Apartments:				
1 Bedroom, 1 Bath	Dogwood	10	770	$3,719
1 Bedroom, 1 Bath, Den	Redbud	9	908	$4,110
1 Bedroom, 1 Bath, Den	Periwinkle	35	937	$4,320
2 Bedroom, 2 Bath	Magnolia	41	1,055	$4,728
2 Bedroom, 2 Bath	Camellia	3	1,181	$5,288
2 Bedroom, 2 Bath	Wisteria	2	1,178	$5,288
2 Bedroom, 2 Bath, Den	Azalea	11	1,333	$5,686
2 Bedroom, 2 Bath, Den	Rose	8	1,386	$5,812
2 Bedroom, 2 Bath, Den	Holly	3	1,580	$5,834
2 Bedroom, 2.5 Bath, Den	Jasmine	9	1,600	$6,318
Total / Weighted Average Apartments		**131**	**1,089**	**$4,802**
Cottages:				
2 Bedroom, 2 Bath	Standard	1	1,458	$5,097
2 Bedroom, 2.5 Bath, Den	Enhanced/Deluxe	19	1,693	$5,931
Total / Weighted Average Apartments		**20**	**1,681**	**$5,889**
Heritage:				
1 Bedroom, 1 Bath	Heritage D	2	778	$3,255
1 Bedroom, 1 Bath	Heritage C	5	775	$3,171
2 Bedroom, 2 Bath	Heritage B	7	1,162	$4,706
2 Bedroom, 2 Bath	Heritage A2	12	1,650	$5,544
3 Bedroom, 2 Bath	Heritage A1	3	2,595	$6,549
Total / Weighted Average Cottages		**49**	**1,412**	**4,879**

[1] FY 2024/25 is from (10/01/24 to 9/30/25). Monthly service fees for a second person are $1,493 for all project independent living cottages and apartments. All fees are subject to periodic increases.

Below is a table that reflects Entrance Fees and Monthly Service Fess for the 42 New Expansion Residences:

Expansion Apartments:		Units	Square Footage	Average Entrance Fees(1)(2)	Monthly Fees (1)
1 Bedroom, 1 Bath	Elm	3	895	$216,000	$4,283
1 Bedroom, Den	Mulberry	8	1,008	$248,000	$4,702
1 Bedroom, Den	Cherry	3	1,260	$292,000	$5,664
2 Bedroom	Hickory	3	1,274	$303,000	$5,736
2 Bedroom	Willow	8	1,367	$316,000	$5,968
2 Bedroom, Den	Birch	4	1,382	$320,000	$6,029
2 Bedroom, Den	Maple	3	1,492	$335,000	$6,139
2 Bedroom, Den	Pine	6	1,504	$338,000	$6,173
2 Bedroom, Den	Cedar	4	1,700	$387,000	$6,602
Total / Weighted Average Apartments		**42**	**1,312**	**304,905**	**5,676**
Second person fee – IL					$1,493

Source Management

(1) Entrance Fees and Monthly Fees shown are effective as of October 1, 2024.
(2) The Corporation will offer several refundable Entrance Fee plans. Fee shown are a based on the Traditional Amortizing Entrance Fee Plan.

C. Health Center Fees

Licensed Nursing

The Health Center provides services to private-pay, Medicaid and Medicare Residents. The per diem charges currently in effect for the respective payor are presented in the following table.

Payor Type	
Private pay	Rate per Day
Private Room	$418
Semi-private room	372
Medicare	553
Medicaid	276

Daily rates 10/1/2024 to 9/30/2025

Assisted Living

Assisted living Residents will be charged a base monthly fee for services provided. For Residents who require additional services, there are additional levels of care provided. Services not included in the base monthly fee will be an additional charge. Additional levels of care include such services as: verbal instruction on activities of daily living; physical assistance with bathing or showering; periodic use of a hydro-tub; dressing, clothes selection and orientation; grooming, including but not limited to hair and teeth brushing, etc.; eating; walking, wheelchair propelling, and prescribed exercises; laundry services that are needed more often than one time a week (both personal and/or linen); and assistance with bladder and/or bowel incontinence. The cost of incontinence supplies will be billed separately to the Resident.

For Assisted Living, Pennybyrn agrees to provide services to Residents as outlined in either the **Multi-Unit Assisted Housing with Services Agreement** attached to this Disclosure Statement as **Exhibit B** or the **Licensed Assisted Living Agreement** attached to this Disclosure Statement as **Exhibit C** (depending on choice and availability of program).

Residents directly admitted from outside the community must pay, prior to move-in, an initial one-time Entrance Fee of $16,380 or $25,225 for a one or two-bedroom accommodation, respectively. This fee amortizes straight-line over one year (365 days) so that after one year of occupancy, no refund is paid.

Base level monthly fees for assisted living Residents are presented in the following table:

Assisted Living Units and Monthly Fee Rates		
Unit Type	**Number of Units**	**Monthly Fee**
1 Bedroom – Multi-Unit with Services	12	$7,205
1 Bedroom, 1 Bath	10	7,581
2 Bedroom	2	9,087
Total / Weighted Average	24	$7,519

Monthly fees for memory support Residents are presented in the following table:

Memory Support Units and Monthly Fee Rates		
Unit Type	**Number of Units**	**Monthly Fee**
1 Bedroom Dementia Care	24	$8,979

[1] FY 2023/24 is from (10/01/23 to 9/30/24). All fees are subject to periodic increases. For a complete fee schedule for Multi-Unit Assisted Housing with Services and Licensed Assisted Living see the last pages of Exhibits B and C, respectively.

NC MCC Bond Sale Approval Form	
Facility Name: Pennybyrn	
	Time of Preliminary Approval
SERIES:	
PAR Amount	$47,770,000.00
Estimated Interest Rate	4.36%
All-in True Interest Cost	4.67%
Maturity Schedule (Interest) - Date	10/1/2025 - 10/1/2055
Maturity Schedule (Principal) - Date	10/1/2025 - 10/1/2055
Bank Holding Period (if applicable) - Date	N/A
Estimated NPV Savings ($) (if refunded bonds)	$1,695,509
Estimated NPV Savings (%) (if refunded bonds)	3.98%
NOTES:	

McKESSON

Invoice

McKesson Medical-Surgical
Government Solutions LLC
9954 Mayland Drive Suite 5176
Henrico, VA 23233

Bill To: 20086441

NC DHHS DIV OF PUBLC
2019 MAIL SERVICE
HEALTH/ AP PUB HLTH
RALEIGH NC 27699-0001

Danielle Rusnak

APPROVED
By Danielle Rusnak at 10:37 am, Apr 17, 2024

Shipped From: MMSE1DPD01
MCKESSON MEDICAL-SURGICAL INC
885 PARAGON WAY
ROCK HILL,SC 29730
SHIPPED FROM LICENSE: 1345

Shipped To: 70950697
OEMS WAREHOUSE
140 LIONHEART DR
HEALTH/ AP PUB HLTH
MOCKSVILLE NC 27028-9440
Ordered By: DANIELLE R

TIN: 20-2046702
DUNS: 05-142-0107

Payment / Account Balance Inquires: 1-800-453-5180
Customer Service: 1-833-343-2700

Sales Order Number	**12208106**	**Invoice Number**	**21952420**
Sales Order Date	**12/28/2023**	**Invoice Date**	**04/09/2024**
PO Number	**NC493155**	**Payment Due Date**	**05/09/2024**
Sales Rep Name	**PIERCE, JAMES**	**Invoice Amount**	**$18,360.00**

Notes: By doing business with McKesson, Customer acknowledges that it is familiar with McKesson's Terms of Sale and is responsible for reviewing in full the complete Terms of Sale that apply to this purchase, located at https://mms.mckesson.com/content/terms-of-sale-government-solutions. McKesson's acceptance of Customer's order was expressly conditioned upon Customer's assent to the complete Terms of Sale.

Please consider paying online or setting up Autopay at pay.mms.mckesson.com

Invoice Detail

Item Number	Vendor / Vendor Cat #	Description	Ordered	Unit	Shipped	Unit Price	Amount	Sales Tax	Codes (*)
1103077	Vendor: SOMTEC Vend Cat#: HIL-005	STRETCHER, HILLROM P-8000 REFU PO LN 1	8	EA	8	2295.00	18360.00	.00	
	Tracking # 010001715346								
	Shipped: 04/09/2024 From: Charlotte Via: UPS GROUND Broker Lic: 1752								

SUB TOTAL	FREIGHT	TAX	AMOUNT
$18,360.00	$0.00	$0.00	$18,360.00

The prices on this invoice may be subject to rebates, credits and other price adjustments. You are obligated to properly disclose and appropriately reflect all discounts, including rebates, in claims and costs submitted to federal and state government health care programs (including Medicare and Medicaid) and to provide this invoice and other discount documentation to government authorities on request, in accordance with all applicable laws and regulations, including 42 USC 1320a-7b(b) and the discount safe harbor. In addition, the purchase of products hereunder may qualify customer for discounts on certain purchases made under a distribution agreement between customer and McKesson Corporation.
PRICING IS CONFIDENTIAL AND PROPRIETARY.

Invoice

McKESSON

McKesson Medical-Surgical
Government Solutions LLC
9954 Mayland Drive Suite 5176
Henrico, VA 23233

NC DHHS DIV OF PUBLC
2019 MAIL SERVICE
RALEIGH NC 27699-0001

MMSE1DPD01

Account Number	**20086441**		
Document Number	**21952420**	**Date**	**04/09/2024**
Terms			**AR NET 30 DAYS**
Pay This Amount Before	**05/09/2024**		**$18,360.00**

Please consider paying online or setting up Autopay at pay.mms.mckesson.com

Please Remit To:
MCKESSON MEDICAL - SURGICAL
PO BOX 936279
ATLANTA GA 31193-6279

Ascendum Machinery, Inc.
3561 Jones Sausage Road
Garner, NC 27529

INVOICE

Invoice	Date	Customer
E113002956A	10/16/2024	117067
2136244		

☎ P: (919) 661-8710
F: (919) 661-9038

Sold to :

NC DHHS Health Service Regulation AP
2019 Mail Service Center
Raleigh, NC 27699-2019

Shipped to :

NC Healthcare Supply
140 Lionheart Drive
Mocksville, NC 27028

Registration :
Notes :

Salesperson : Matt Marion

Quantity	PMF Product - Description	Unit Price	Total Price
	Order : M113003369 03/29/2024		
	Cust PO# : NC498037		
	Sale of Doosan		
1	2024 Doosan Portable - G325WCU-T4F - Doosan Portable Generator	203,250.69	203,250.69
	S/N: 513180UAHH12 Dealer ID: 61100358 Plate No: 513180UAHH12 Meter : 1.00		

Due Date	Payment	Amount	Paid
4/28/2024	On Account	203,250.69	114,683.69
10/16/2024	On Account	88,567.00	

Tax	Basis	Tax rate	Tax Amount
Exempt-Tax Exempt	0.00	0.0000 %	0.00

Detach at line and return with payment

ASCENDUM

Total Amount :	203,250.69
Sales Tax :	0.00
Total :	203,250.69
Payment :	114,683.69
To pay :	**88,567.00**

Approved for Payment
NC498037 - Pay from Line 2

Danielle Rusnak
Reviewed and Approved 10/17/2024

Ascendum Machinery, Inc.
PO Box 534366
Atlanta, GA 30353

Invoice	E113002956A
Date	10/16/2024
Customer	117067

All amounts are in US Dollars ($)

Accounts over 30 days are subject to a 1.5 % service charge (annual rate 18 %), and all costs of collection including reasonable attorney's fee.

Ed Browning
Digitally signed by Ed Browning
Date: 2024.10.17 09:14:12 -04'00'

541.357.5978 // DEPLOYEDLOGIX.COM

DLX Enterprises, LLC
Deployed Logix
1075 Arrowsmith St.
Eugene, OR 97402

Invoice

DATE	INVOICE #
6/5/2024	5261R
TERMS	**DUE DATE**
Net 30	7/5/2024

Invoice Currency: USD

BILL TO
Paul King NC // Department of Health and Human Services // Office of Emergency Medical Services 1201 Umstead Drive Wright Building 2707 Mail Service Center Raleigh, NC 27699-2707

SHIP TO
Paul King MDH 315 Bethel Church Road Mocksville, NC 27018 Paul.King@dhhs.nc.gov 803 242-7938

Item	Description	Qty	Rate	Amt
SXMRP32HCT	X-32 // TAN // MISSION READY PACKAGE • X-32 Aircraft grade aluminum frame 20 x 32 ft (6.10 x 9.75 m) • Mil Spec blackout vinyl • LED stringable lights • Protective vinyl carry bags • Wiring Harness (110V) • ATLAS® Anchors • (2) Side walls • (2) End walls • (1) Roof • (1) Insulation liner w/ radiant barrier aluminized backing • (1) Waterproof vinyl floor • (1) Stake kit • (1) Repair kit • (2) Best Case by DLX™ Earth w/ table kit 101 x 25 x 24 in (256.86 x 63.50 x 60.96 cm) S/N: 10006808	1	$29,896.15	$29,896.15
SXMRP16HCT	X-16 // TAN // MISSION READY PACKAGE • X-16 Aircraft grade aluminum frame 20 x 16 ft (6.10 x 4.88 m) • Mil Spec blackout vinyl • LED stringable lights • Protective vinyl carry bags • Wiring Harness (110V) • ATLAS® Anchors • (2) Side walls • (2) End walls • (1) Roof • (1) Insulation liner w/ radiant barrier aluminized backing • (1) Waterproof vinyl floor • (1) Stake kit	1	$19,888.59	$19,888.59

	• (1) Repair kit • (1) Best Case by DLX™ Earth w/ table kit 101 x 25 x 24 in (256.86 x 63.50 x 60.96 cm) S/N: 10006445			
SXMRPHUBHCT	MRP // ASAP -HUB // TAN • MRP ASAP-HUB Tan Shelter 17 x 17 ft (5.18 x 5.18 m) • Mil Spec blackout vinyl • LED stringable lights • Wiring Harness (110V) • ATLAS® Anchors • (1) Roof • (2) Removable End walls (1) Insulation liner w/ radiant barrier aluminized backing • (1) Waterproof vinyl floor • (1) Stake kit • (4) ASAP Connector w/ peak, floor, insulation connecting strip • (1) Best Case by DLX™ Earth w/ table kit 101 x 25 x 24 in (256.86 x 63.50 x 60.96 cm) • (1) Best Case by DLX™ Earth 50.13 x 25 x 24 in (127.33 x 63.50 x 60.96 cm) S/N: 10006030	1	$34,316.56	$34,316.56
SOXWSC	X-SERIES // WESTERN SHELTER CONNECTOR	1	$1,272.61	$1,272.61
SORD1T	RIGID DOOR TAN • Removable privacy panels • Comes with hard door insert vinyl package • Interchangeable with ASAP & X-SERIES shelters	8	$3,484.4775	$27,875.82
SOSD1	RIGID DOUBLE SWINGING DOOR • Removable privacy panels • Comes with hard door insert vinyl package • Interchangeable with ASAP & X-SERIES shelters	1	$3,843.21	$3,843.21
CCX16AP	X-16 AIR PLENUM • Air Plenum, 16 ft (4.88 m) • Carry Bag	2	$1,180.24	$2,360.48
HC1002524 Earth	Best Case by DLX™, Earth, 101.13 x 25 x 24 in (256.87 x 63.50 x 60.96 cm)	3	$2,660.22	$7,980.66
CUSTOM	Custom Trailer Boot Adapter w/ floor, insulation. and divider	1	$5,698.75	$5,698.75
Shipping and Handling	Charges are for transportation, packaging materials and handling May or may not include the following incidental costs: Freight costs, pallets, crates, plastic wrap, custom straps, etc	1	$2,480.70	$2,480.70

SUBTOTAL	$135,613.53
DISCOUNT	$0.00
TAX	$0.00
TOTAL	$135,613.53
DEPOSITS	$0.00
BALANCE **	$135,613.53

**** 3% credit card processing fee will be charged if Balance is paid by credit card, please contact AR for details before submitting credit card payments.**

--- Customer PO: NC505864

Customer Purchase Order: NC505864

Approved for Payment NC505864

Ed Browning

Digitally signed by Ed Browning
Date: 2024.06.12 09:31:26 -04'00'

ASCENDUM

16810 Kenton Drive, Suite 300
Huntersville, NC 28078

Remit to: Ascendum Machinery, Inc.
PO Box 534366
Atlanta, GA 30353

DATE	Invoice
3/6/2024	JK003717

Bill To:	Acct# :		Ship To:
NC DHHS Health Service Regulation AP 2019 Mail Service Center Raleigh, NC 27699-2019			NC Healthcare Supply 140 Lionheart Drive Mocksville, NC 27029 Ship To Code: 6343488
PURCHASE ORDER:	NC498037	SALESMAN:	Matt Marion

INVOICE DETAIL

	Amount
Sale of Doosan Generator Model: G324WXU-T4F s/n: 513180UAHH12	$ 158,967.19
Sale of Doosan Generator Model: G324WXU-T4F s/n: 508100UIAGH12	$ 158,967.19
Delivered 2/28/24	$ -

Net: 30 Days

Danielle Rusnak

APPROVED
By Danielle Rusnak at 10:59 am, Mar 13, 2024

TERMS:NET RECEIPT OF INVOICE

Sub Total	$	317,934.38
Sales Tax: Exempt	$	-
	$	-
Balance Due	$	317,934.38

10A NCAC 13F .1604 is proposed for amendment as follows:

10A NCAC 13F .1604 RATING CALCULATION

(a) Ratings shall be based on:

(1) Inspections completed pursuant to G.S. 131D-2.11(a) and (a1);

(2) Statutory and Rule requirements listed in Rule .1603 of this Section;

(3) Type A1, Type A2, or uncorrected Type B penalty violations identified pursuant to G.S. 131D-34; and

(4) Other items listed in Subparagraphs (c)(1) and (c)(2) of this Rule.

(b) The initial rating a facility receives shall remain in effect until the next inspection. If an activity occurs which results in the assignment of additional merit or demerit points, a new certificate shall be issued pursuant to Rule .1602(a) of this Section.

(c) The rating shall be based on a 100 point scale. Beginning with the initial rating and repeating with each annual or biennial inspection, the facility shall be assigned 100 points and shall receive merits or demerits, which shall be added or subtracted from the 100 points, respectively. The merits and demerits shall be assigned as follows:

(1) Merit Points

(A) If the facility corrects a standard deficiency of noncompliance with the statutes or rules listed in Rule .1603 of this Subchapter, the facility shall receive 1.25 merit points for each corrected deficiency;

(B) If the facility corrects a citation for which a Type B violation was identified, the facility shall receive 1.75 merit points;

(C) If the facility corrects a previously uncorrected Type B violation, the facility shall receive 1.75 merit points;

(D) If the facility corrects the citation for which a Type A1 or Type A2 violation was identified, the facility shall receive 5 merit points;

(E) If the facility corrects a previously uncorrected Type A1 or Type A2 violation, the facility shall receive 5 merit points;

(F) If the facility's admissions have been ~~suspended,~~ suspended pursuant to 131D-2.7, the facility shall receive 5 merit points if the suspension is removed;

(G) If the facility's license is restored to a full license after being downgraded to a provisional license, the facility shall receive 5 merit points;

(H) If the facility participates in any quality improvement program pursuant to G.S. 131D-10, the facility shall receive 2.5 merit points;

(I) If the facility establishes an ongoing resident council which meets at least quarterly, the facility shall receive .5 merit point;

(J) If the facility establishes an ongoing family council which meets at least quarterly, the facility shall receive .5 merit point;

(K) If the facility's designated on-site staff member who directs the facility's infection control activities in accordance with G.S. 131D-4.4A has completed the "Infection Control in Long Term Care Facilities" course offered by the University of North Carolina Statewide Program for Infection Control and Epidemiology (SPICE) every two years, the facility shall receive .5 merit point;

(L) If the facility permanently installs a generator or has a contract with a generator provider to provide emergency power for essential functions of the facility, the facility shall receive 2 merit points. For purposes of this Rule, essential functions mean those functions necessary to maintain the health or safety of residents during power outages greater than 6 hours and include the fire alarm system, heating, lighting, refrigeration for medication storage, minimal cooking, elevators, medical equipment, computers, door alarms, special locking systems, sewage and well operation where applicable, sprinkler system, and telephones. If the facility has an existing permanently installed generator or an existing contract with a generator provider, the facility shall receive 1 merit point for maintaining the generator in working order or continuing the contract with a generator provider;

(M) If the facility installs automatic sprinklers in compliance with the North Carolina Building Code, and maintains the system in working order, the facility shall receive 3 merit points. If the facility has an existing automatic sprinkler, the facility shall receive 2 merit points for subsequent ratings for maintaining the automatic sprinklers in working order; and

(N) If the facility engages the services of a third-party company to conduct resident and family satisfaction surveys at least annually for the purpose of improving resident care, the facility shall receive 1 merit point. Resident and family satisfaction surveys shall not be conducted by any employees of the facility, or a third-party company affiliated with the facility. The satisfaction survey results shall be made available upon request and in a location accessible to residents and visitors in the facility.

(2) Demerit Points

(A) For each standard deficiency of noncompliance with the statutes or rules listed in Rule .1603 of this Subchapter, the facility shall receive a demerit of 2 points. The facility shall receive demerit points only once for citations in which the findings are identical to those findings used for another citation;

(B) For each citation of a Type A1 or Type A2 violation, the facility shall receive a demerit of 10 points, and if the Type A1 or Type A2 violation remains uncorrected as result of a follow-up inspection, the facility shall receive an additional demerit of 10 points;

(C) For each citation of a Type B violation, the facility shall receive a demerit of 3.5 points and if the Type B violation remains uncorrected as the result of a follow-up inspection, the facility shall receive an additional demerit of 3.5 points;

(D) If the facility's admissions are ~~suspended,~~ suspended pursuant to G.S. 131D-2.7, the facility shall receive a demerit of 10 points; however, if the facility's admissions are suspended pursuant to ~~G.S. 131D-2.7,~~ G.S. 131D-4.2, the facility shall not receive any demerit points;

(E) If the facility's license is downgraded to a provisional license pursuant to G.S. 131D-2.7, the facility shall receive a demerit of 10 points;

(F) If the facility receives a notice of revocation against its license pursuant to G.S. 131D-2.7, the facility shall receive a demerit of 31 points; and

(G) If the facility's license is summarily suspended pursuant to G.S. 131D-2.7, the facility shall receive a demerit of 31 points.

(d) Facilities shall be given a rating of zero to four stars depending on the score assigned pursuant to Paragraph (a), (b) or (c) of this Rule. Ratings shall be assigned as follows:

(1) Four stars shall be assigned to any facility whose score is 100 points or greater on two consecutive annual or biennial inspections;

(2) Three stars shall be assigned for scores of 90 to 99.9 points, or for any facility whose score is 100 points or greater on one annual or biennial inspection;

(3) Two stars shall be assigned for scores of 80 to 89.9 points;

(4) One star shall be assigned for scores of 70 to 79.9 points; and

(5) Zero stars shall be assigned for scores of 69.9 points or lower.

History Note: *Authority G.S. 131D-4.5; 131D-10;*
Eff. July 3, 2008;
Readopted Eff. ~~August 1, 2025.~~ August 1, 2025;
Amended Eff. August 1, 2025.

10A NCAC 13G .1604 is proposed for amendment as follows:

10A NCAC 13G .1604 RATING CALCULATION

(a) Ratings shall be based on:

(1) Inspections completed pursuant to G.S. 131D-2.11(a) and (a1);

(2) Statutory and Rule requirements listed in Rule .1603 of this Section;

(3) Type A1, Type A2, or uncorrected Type B penalty violations identified pursuant to G.S. 131D-34; and

(4) Other items listed in Subparagraphs (c)(1) and (c)(2) of this Rule.

(b) The initial rating a facility receives shall remain in effect until the next inspection. If an activity occurs which results in the assignment of additional merit or demerit points, a new certificate shall be issued pursuant to Rule .1602(a) of this Section.

(c) The rating shall be based on a 100 point scale. Beginning with the initial rating and repeating with each annual or biennial inspection, the facility shall be assigned 100 points and shall receive merits or demerits, which shall be added or subtracted from the 100 points, respectively. The merits and demerits shall be assigned as follows:

(1) Merit Points

(A) If the facility corrects a standard deficiency of noncompliance with the statutes or rules listed in Rule .1603 of this Subchapter, the facility shall receive 1.25 merit points for each corrected deficiency;

(B) If the facility corrects a citation for which a Type B violation was identified, the facility shall receive 1.75 merit points;

(C) If the facility corrects a previously uncorrected Type B violation, the facility shall receive 1.75 merit points;

(D) If the facility corrects the citation for which a Type A1 or Type A2 violation was identified, the facility shall receive 5 merit points;

(E) If the facility corrects a previously uncorrected Type A1 or A2 violation, the facility shall receive 5 merit points;

(F) If the facility's admissions have been ~~suspended,~~ suspended pursuant to 131D-2.7, the facility shall receive 5 merit points if the suspension is removed;

(G) If the facility's license is restored to a full license after being downgraded to a provisional license, the facility shall receive 5 merit points;

(H) If the facility participates in any quality improvement program pursuant to G.S. 131D-10, the facility shall receive 2.5 merit points;

(I) If the facility establishes an ongoing resident council which meets at least quarterly, the facility shall receive .5 merit point;

(J) If the facility establishes an ongoing family council which meets at least quarterly, the facility shall receive .5 merit point;

(K) If the facility's designated on-site staff member who directs the facility's infection control activities in accordance with G.S. 131D-4.4A has completed the "Infection Control in Long Term Care Facilities" course offered by the University of North Carolina Statewide Program for Infection Control and Epidemiology (SPICE) every two years, the facility shall receive .5 merit point;

(L) If the facility permanently installs a generator or has a contract with a generator provider to provide emergency power for essential functions of the facility, the facility shall receive 2 merit points. For purposes of this Rule, essential functions mean those functions necessary to maintain the health or safety of residents during power outages greater than 6 hours and include the fire alarm system, heating, lighting, refrigeration for medication storage, minimal cooking, elevators, medical equipment, computers, door alarms, special locking systems, sewage and well operation where applicable, sprinkler system, and telephones. If the facility has an existing permanently installed generator or an existing contract with a generator provider, the facility shall receive 1 merit point for maintaining the generator in working order or continuing the contract with a generator provider;

(M) If the facility installs automatic sprinklers in compliance with the North Carolina Building Code, and maintains the system in working order, the facility shall receive 3 merit points. If the facility has an existing automatic sprinkler, the facility shall receive 2 merit points for subsequent ratings for maintaining the automatic sprinklers in working order; and

(N) If the facility engages the services of a third-party company to conduct resident and family satisfaction surveys at least annually for the purpose of improving resident care, the facility shall receive 1 merit point. Resident and family satisfaction surveys shall not be conducted by any employees of the facility, or a third-party company affiliated with the facility. The satisfaction survey results shall be made available upon request and in a location accessible to residents and visitors in the facility.

(2) Demerit Points

(A) For each standard deficiency of noncompliance with the statutes or rules listed in Rule .1603 of this Subchapter, the facility shall receive a demerit of 2 points. The facility shall receive demerit points only once for citations in which the findings are identical to those findings used for another citation;

(B) For each citation of a Type A1 or Type A2 violation, the facility shall receive a demerit of 10 points, and if the Type A1 or Type A2 violation remains uncorrected as result of a follow-up inspection, the facility shall receive an additional demerit of 10 points;

(C) For each citation of a Type B violation, the facility shall receive a demerit of 3.5 points and if the Type B violation remains uncorrected as the result of a follow-up inspection, the facility shall receive an additional demerit of 3.5 points;

(D) If the facility's admissions are ~~suspended,~~ suspended pursuant to G.S. 131D-2.7, the facility shall receive a demerit of 10 points; however, if the facility's admissions are suspended pursuant to ~~G.S. 131D-2.7,~~ G.S. 131D-4.2, the facility shall not receive any demerit points;

(E) If the facility's license is downgraded to a provisional license pursuant to G.S. 131D-2.7, the facility shall receive a demerit of 10 points;

(F) If the facility receives a notice of revocation against its license pursuant to G.S. 131D-2.7, the facility shall receive a demerit of 31 points; and

(G) If the facility's license is summarily suspended pursuant to G.S. 131D-2.7, the facility shall receive a demerit of 31 points.

(d) Facilities shall be given a rating of zero to four stars depending on the score assigned pursuant to Paragraph (a), (b) or (c) of this Rule. Ratings shall be assigned as follows:

(1) Four stars shall be assigned to any facility whose score is 100 points or greater on two consecutive annual or biennial inspections;

(2) Three stars shall be assigned for scores of 90 to 99.9 points, or for any facility whose score is 100 points or greater on one annual or biennial inspection;

(3) Two stars shall be assigned for scores of 80 to 89.9 points;

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(5) Zero stars shall be assigned for scores of 69.9 points or lower.

History Note: *Authority G.S. 131D-4.5; 131D-10;*
Eff. July 3, 2008;
Readopted Eff. ~~August 1, 2025.~~ August 1, 2025;
Amended Eff. August 1, 2025.

DHSR Adult Care Licensure Section
Fiscal Impact Analysis
Permanent Rule Amendment without Substantial Economic Impact

Agency: North Carolina Medical Care Commission

Contact Persons: Shanah Black, DHSR Rules Review Manager, (919) 855-3481
Megan Lamphere, Adult Care Licensure Section Chief, (919) 855-3784
Shalisa Jones, Regulatory Analyst, (704) 589-6214

Impact Summary:

Federal Government:	No
State Government:	No
Local Government:	No
Private Entities:	No
Substantial Impact:	No

N.C. Administrative Code Citations: 10A NCAC 13F .1604 Rating Calculation
10A NCAC 13G .1604 Rating Calculation
See Appendix for the proposed rule text.

Authority: G.S. 131D-4.5; 131D-10

Necessity: This rulemaking is necessary to correct technical errors identified after the recent readoption of these two rules.

1. Background

These two rules outline the standards for how the star rating is calculated for North Carolina's adult care home (13F .1604) and family care home (13G .1604) facilities pursuant to the N.C. Star Rated Certificate Program. These rules were approved for readoption by the Rules Review Commission on January 30, 2025, to become effective August 1, 2025. After approval of the rules, an error was identified in each of these rules whereby the incorrect general statute was referenced for specific situations in which a facility with suspended admissions would not receive any demerit points or merit points. The proposed changes will correct the error, thereby clarifying the circumstances for which demerit and merit points will or will not be imposed. The changes will revert this portion of the rule back to the original language. Specifically, the rule changes will make it clear that:

- Demerit points will not be deducted when admissions are suspended pursuant to G.S. 131D-4.2 (failure to submit a report of actual costs "cost report" in a timely manner).
- A demerit of 10 points will be imposed when admissions are suspended pursuant to G.S. 131D-2.7 (NC DHHS has determined that conditions in the facility are detrimental to the health or safety of the residents). *Note this is separate from the demerit of 31 points that would be deducted for license revocation or "summary suspension" pursuant to G.S. 131D-2.7.*

These errors were unintended and as such, they were not accounted for in the Fiscal Impact Analysis approved for this rule in 2024.

2. Impact Analysis

State and Local Government

The proposed changes are limited to those changes necessary to correct technical errors. None of these changes will require the State implementing agency (DHHS Adult Care Licensure Section) or local governments (county Departments of Social Services) to revise their existing procedures or to procure additional staff. As such, there will be no economic cost or benefit to state agencies or local governments.

Regulated Community

The regulated community includes licensed adult care home and family care home facilities. The proposed changes are limited to those changes necessary to correct technical errors. As measured from the baseline conditions, none of these changes will require the regulated community to deviate from current practices. As such, there will be no economic costs for facilities due to these proposed changes. It is possible that the regulated community could benefit from the improved regulatory clarity. The likelihood of realizing this benefit is small, however, as the recently readopted rules containing the errors have not yet gone into effect. The proposed corrected version of these rules is anticipated to be adopted by August 1, 2025.

3. Summary

There are no anticipated economic costs or benefits associated with this proposed rulemaking other than minimal benefits from improved rule clarity. Consequently, there were no specific costs or benefit estimations to report in this analysis.

Appendix

10A NCAC 13F .1604 is proposed for amendment as follows:

10A NCAC 13F .1604 RATING CALCULATION

(a) Ratings shall be based on:

(1) Inspections completed pursuant to G.S. 131D-2.11(a) and (a1);

(2) Statutory and Rule requirements listed in Rule .1603 of this Section;

(3) Type A1, Type A2, or uncorrected Type B penalty violations identified pursuant to G.S. 131D-34; and

(4) Other items listed in Subparagraphs (c)(1) and (c)(2) of this Rule.

(b) The initial rating a facility receives shall remain in effect until the next inspection. If an activity occurs which results in the assignment of additional merit or demerit points, a new certificate shall be issued pursuant to Rule .1602(a) of this Section.

(c) The rating shall be based on a 100 point scale. Beginning with the initial rating and repeating with each annual or biennial inspection, the facility shall be assigned 100 points and shall receive merits or demerits, which shall be added or subtracted from the 100 points, respectively. The merits and demerits shall be assigned as follows:

(1) Merit Points

(A) If the facility corrects a standard deficiency of noncompliance with the statutes or rules listed in Rule .1603 of this Subchapter, the facility shall receive 1.25 merit points for each corrected deficiency;

(B) If the facility corrects a citation for which a Type B violation was identified, the facility shall receive 1.75 merit points;

(C) If the facility corrects a previously uncorrected Type B violation, the facility shall receive 1.75 merit points;

(D) If the facility corrects the citation for which a Type A1 or Type A2 violation was identified, the facility shall receive 5 merit points;

(E) If the facility corrects a previously uncorrected Type A1 or Type A2 violation, the facility shall receive 5 merit points;

(F) If the facility's admissions have been ~~suspended,~~ suspended pursuant to 131D-2.7, the facility shall receive 5 merit points if the suspension is removed;

(G) If the facility's license is restored to a full license after being downgraded to a provisional license, the facility shall receive 5 merit points;

(H) If the facility participates in any quality improvement program pursuant to G.S. 131D-10, the facility shall receive 2.5 merit points;

(I) If the facility establishes an ongoing resident council which meets at least quarterly, the facility shall receive .5 merit point;

(J) If the facility establishes an ongoing family council which meets at least quarterly, the facility shall receive .5 merit point;

(K) If the facility's designated on-site staff member who directs the facility's infection control activities in accordance with G.S. 131D-4.4A has completed the "Infection Control in Long Term Care Facilities"

course offered by the University of North Carolina Statewide Program for Infection Control and Epidemiology (SPICE) every two years, the facility shall receive .5 merit point;

(L) If the facility permanently installs a generator or has a contract with a generator provider to provide emergency power for essential functions of the facility, the facility shall receive 2 merit points. For purposes of this Rule, essential functions mean those functions necessary to maintain the health or safety of residents during power outages greater than 6 hours and include the fire alarm system, heating, lighting, refrigeration for medication storage, minimal cooking, elevators, medical equipment, computers, door alarms, special locking systems, sewage and well operation where applicable, sprinkler system, and telephones. If the facility has an existing permanently installed generator or an existing contract with a generator provider, the facility shall receive 1 merit point for maintaining the generator in working order or continuing the contract with a generator provider;

(M) If the facility installs automatic sprinklers in compliance with the North Carolina Building Code, and maintains the system in working order, the facility shall receive 3 merit points. If the facility has an existing automatic sprinkler, the facility shall receive 2 merit points for subsequent ratings for maintaining the automatic sprinklers in working order; and

(N) If the facility engages the services of a third-party company to conduct resident and family satisfaction surveys at least annually for the purpose of improving resident care, the facility shall receive 1 merit point. Resident and family satisfaction surveys shall not be conducted by any employees of the facility, or a third-party company affiliated with the facility. The satisfaction survey results shall be made available upon request and in a location accessible to residents and visitors in the facility.

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(A) For each standard deficiency of noncompliance with the statutes or rules listed in Rule .1603 of this Subchapter, the facility shall receive a demerit of 2 points. The facility shall receive demerit points only once for citations in which the findings are identical to those findings used for another citation;

(B) For each citation of a Type A1 or Type A2 violation, the facility shall receive a demerit of 10 points, and if the Type A1 or Type A2 violation remains uncorrected as result of a follow-up inspection, the facility shall receive an additional demerit of 10 points;

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(5) Zero stars shall be assigned for scores of 69.9 points or lower.

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Eff. July 3, 2008;
Readopted Eff. ~~August 1, 2025.~~ August 1, 2025;
Amended Eff. August 1, 2025.

10A NCAC 13G .1604 is proposed for amendment as follows:

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History Note: *Authority G.S. 131D-4.5; 131D-10;*
Eff. July 3, 2008;
Readopted Eff. ~~August 1, 2025.~~ August 1, 2025;
Amended Eff. August 1, 2025.

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES

The North Carolina Medical Care Commission
809 Ruggles Drive
Raleigh, North Carolina

MINUTES

CALLED MEETING OF THE EXECUTIVE COMMITTEE CONFERENCE TELEPHONE MEETING ORIGINATING FROM THE COMMISSION'S OFFICE APRIL 22, 2025 4:30 P.M.

Members of the Executive Committee Present:

John J. Meier, IV, M.D., Chairman
Joseph D. Crocker, Vice-Chairman
Paul R.G. Cunningham, M.D.
Bryant C. Foriest
Eileen C. Kugler, RN, MSN, MPH, FNP
David C. Mayer, M.D.
Neel G. Thomas, M.D.

Members of the Executive Committee Absent:

None

Members of Staff Present:

S. Mark Payne, Director, DHSR/Secretary, MCC
Geary W. Knapp, JD, CPA, Assistant Secretary, MCC
Kathy C. Larrison, Auditor, MCC
Crystal Watson-Abbott, Auditor, MCC
Alice S. Creech, Executive Assistant, MCC

Others Present:

Cherie Grisso, Aldersgate
Alan Squires, Givens Estates
Jeff Poley, Hawkins Delafield & Wood, LLP
Alice Adams, Robinson Bradshaw
Allen Robertson, Robinson Bradshaw
Jon Mize, Womble Bond Dickinson (US) LLP

1. Purpose of Meeting

To approve an amendment of the Aldersgate United Methodist Retirement Community, Inc.'s Master Trust Indenture and to approve a refunding for Duke University Health Systems, Inc. (preliminary), which will be included with a portion of a new money project previously approved (preliminary) by the North Carolina Medical Care Commission on February 7, 2025.

2. Resolution of the North Carolina Medical Care Commission Consenting to the Amendment of Aldersgate United Methodist Retirement Community, Inc.'s Master Trust Indenture.

Executive Committee Action: *A motion was made to approve the resolution by Dr. Paul Cunningham, seconded by Mr. Joe Crocker, and unanimously approved.*

WHEREAS, the North Carolina Medical Care Commission (the "Commission") is a commission of the Department of Health and Human Services of the State of North Carolina and is authorized under Chapter 131A of the General Statutes of North Carolina, as amended (the "Act"); and

WHEREAS, Aldersgate United Methodist Retirement Community, Inc. (the "Corporation") is a nonprofit corporation duly incorporated and validly existing under and by virtue of the laws of the State of North Carolina and is a "nonprofit agency" within the meaning of the Act; and

WHEREAS, the Commission has issued its retirement facilities first mortgage revenue bonds (the "Bonds") on behalf of the Corporation, four series of which are outstanding; and

WHEREAS, the Corporation desires to amend its Master Trust Indenture, dated as of October 1, 2013 (as previously amended, the "Master Indenture"), by and between the Corporation and The Bank of New York Mellon Trust Company, N.A., as master trustee (the "Master Trustee") to facilitate its proposed affiliation with The Givens Estates, Inc. and its affiliates (known as Givens Communities); and

WHEREAS, the Executive Committee of the Commission has received a copy of Corporation's April, 2025 EMMA filing containing, among other items, the proposed Second Amendment to Master Trust Indenture (the "Amendment"); an explanation of the Amendment and a letter from the North Carolina Department of Insurance consenting to the Amendment; and

WHEREAS, pursuant to the Master Indenture and the loan agreements related to the Bonds, the Commission, among others, must consent to the Amendment; and

WHEREAS, the Executive Committee of the Commission has determined it is in the best interest of Corporation, and the Commission's outstanding bonds issued on behalf of the Corporation, to consent to the Amendment;

NOW, THEREFORE, THE EXECUTIVE COMMITTEE OF THE NORTH CAROLINA MEDICAL CARE COMMISSION DOES HEREBY RESOLVE, as follows:

Section 1. The Executive Committee of the Commission hereby consents to the Amendment in substantially the form presented, together with any changes approved by the Assistant Secretary of the Commission.

Section 2. The Assistant Secretary of the Commission is hereby authorized and directed to take such action and to execute and deliver any such documents (including any evidence of consent to the Amendment), certificates or other instruments as they, with the advice of counsel, may deem necessary or appropriate to effect the transactions contemplated by this resolution.

Section 3. This resolution shall take effect immediately upon its passage.

3. Refunding for Duke University Health Systems, Inc.

Resolution: The Commission grants preliminary approval to a transaction for Duke University Health Systems to provide funds, to be used, together with other available funds, to refund the North Carolina Medical Care Commission Series 2005A, Series 2005B, Series 2016B, Series 2016C, Series 2006A, Series 2006B, and Series 2006C, outstanding as of the date of the refunding in the amount of $344,645,000. The proposed refunding will be combined with a previously approved construction project on February 7th, 2025 by the Commission. The previously approved construction project was for the following:

- 111,000 sq. ft. building located in Wake County
  - Free-standing emergency department
  - 6 room ambulatory surgical center
  - 4 gastrointestinal endoscopy rooms
  - 30,000 sq. ft. of clinical infusion space

The proposed transaction (refunding plus previously approved construction project) is in accordance with an application received as follows:

ESTIMATED SOURCES OF FUNDS		
Principal Amount of Bonds to be Issued	$	487,670,000
Premium on Bond Issuance	$	36,857,523
Total Sources	**$**	**524,527,523**

ESTIMATED USE OF FUNDS		
Bonds Refunded (2005AB / 2016BC / 2006ABC)	$	344,645,000
Construction Cost	$	123,942,250
Architect Fees	$	12,995,777

Architect Reimbursables	$	616,543
Contingency	$	1,239,990
Moveable Equipment	$	34,305,761
Surveys	$	3,045,384
Underwriter Placement Fee	$	2,503,868
Accountant Fee	$	100,000
Corporate Counsel	$	100,000
Bond Counsel	$	200,000
Trustee Fee	$	2,000
Trustee Counsel	$	7,500
Underwriter Counsel	$	140,000
Local Government Commission Fee	$	8,750
Financial Advisor Fee	$	237,500
Rating Agencies Fee	$	412,200
Printing Costs	$	25,000
Total Uses	**$**	**524,527,523**

Tentative approval is given with the understanding that the governing board of Duke University Health Systems, Inc. accepts the following conditions:

1. The project will continue to be developed pursuant to the applicable Medical Care Commission guidelines.

2. Final financial feasibility must be determined prior to the issuance of bonds.

3. The project must, in all respects, meet requirements of G.S. § 131A (Health Care Facilities Finance Act).

4. The Executive Committee of the Commission is delegated the authority to approve the issuance of bonds for this project and may approve the issuance of such greater principal amount of the loan as shall be necessary to finance the project; provided, however, that the amount set forth above shall not be increased by more than ten percent (10%).

5. The bonds or notes shall be sold in such a manner and upon such terms and conditions as will, in the sole judgment of the Executive Committee of the Commission, result in the lowest cost to the facility and its residents.

6. If public approval of the bonds is required for the purpose of Section 147(f) of the Internal Revenue Code of 1986, as amended ("Section 147(f)"), this tentative approval shall constitute the recommendation of the Commission that the Governor of the State of North Carolina (the "Governor") approve the issuance of such bonds,

subject to the satisfaction of the requirements of Section 147(f) concerning the holding of a public hearing prior to the submission of such recommendation to the Governor.

7. The borrower will provide the Commission annually a copy of Schedule H of the IRS form 990 to demonstrate community benefits provided by the borrower.

8. The borrower will furnish, prior to the sale of or issuance of the bonds or notes or execution of the leases, evidence that it is in compliance with the covenants of all of its outstanding Medical Care Commission debt.

9. All health care facilities and services directly or indirectly owned or controlled by the health care organization, including physician practices, shall be available to Medicare and Medicaid patients with no limitations imposed as a result of the source of reimbursement.

Based on information furnished by applicant, the project is:

Financially Feasible: YES
Construction Costs are Reasonable: N/A

(See **Exhibit A** for selected application information)

Executive Committee Action: *A motion was made to approve the resolution by Mrs. Eileen Kugler, seconded by Mr. Bryant Foriest, and unanimously approved.*

4. Adjournment

There being no further business, the meeting was adjourned at 5:05 p.m.

Respectfully submitted,

Geary W. Knapp, JD, CPA
Assistant Secretary

EXHIBIT A

Compliance Summary:

- **No Violation of MCC Compliance policy**

1) Does Organization have a formal post tax issuance compliance policy?

   Yes

2) Who in the Organization will be designated to ensure appropriate compliance with the issuance?

   Lisa M. Goodlett

3) What is the Organization's compliance monitoring plan?

   DUHS continuously monitors its Space Use compliance as follows: Comprehensive Quarterly Debt Service Covenant Checklist Completion and Reporting; Completion of Annual Tax Compliance checklists; Annual Sch K Form 990 Completion; Continual review of asset disposals to determine financing status and avoid potential remediation; Comprehensive annual Space Use Compliance Reviews and Reporting, Annual review of Debt/Swap Policy with any proposed changes reported to the Finance Committee and full Board.

4) How will the Organization report compliance deficiencies to leadership and the Board?

   Any compliance deficiencies would be immediately reported to DUHS Senior Leadership, with concomitant reporting to the Finance Committee and Board as deemed necessary, as well as to internal and external Counsel, and to NCMCC's Bond Counsel, Robinson, Bradshaw. Any requisite remediation would be undertaken immediately and timely reported to the NCMCC and IRS as deemed necessary.

Selected Application Information:

1) Information from FYE 2024 (6/30 Year End) Audit of DUHS:

Net Income	$ 562,404,000
Operating Revenue	$ 6,821,932,000
Operating Expenses	($ 6,619,243,000)

Net Cash provided by Operating Activities	$ 158,902,000
Unrestricted Cash	$ 30,556,000
Change in Cash	($ 84,532,000)

Note: Decrease in cash largely due to financing activities (payments on commercial paper)

2) Ratings:

AA- Outlook Stable (Fitch)

3) Community Benefits (FYE 2024):

- Total Community Benefits and Charity Care - $1,178,463,554
- Estimated Cost of Treating Bad Debt Patients - $48,940,561

4) Long-Term Debt Service Coverage Ratios:

Actual 2024	6.5
Forecasted FYE 2025	5.3
Forecasted FYE 2026	2.7
Forecasted FYE 2027	5.0
Forecasted FYE 2028	5.2
Forecasted FYE 2029	6.0

5) Transaction Participants:

Bond Counsel:	Robinson Bradshaw & Hinson
Corporate Counsel:	Womble Bond Dickinson
Underwriter:	JP Morgan
Underwriter Counsel:	Hawkins Delafield & Wood
Trustee:	Bank of New York Mellon
Trustee Counsel:	McGuireWoods

6) Board Diversity:

Male:	12
Female:	9
Total:	**21**

Caucasian:	14
African American:	5
Asian:	1
Latino:	1
Total:	**21**

EXHIBIT B

SECOND AMENDMENT TO MASTER TRUST INDENTURE

by and among

ALDERSGATE UNITED METHODIST RETIREMENT COMMUNITY, INC.

and

THE BANK OF NEW YORK MELLON TRUST COMPANY, N.A.,
as Master Trustee

Dated as of _____, 2025

Amending the Master Trust Indenture
Dated as of October 1, 2013

THIS SECOND AMENDMENT TO MASTER TRUST INDENTURE is made and entered into as of _____, 2025 (the "Second Amendment"), by and between **ALDERSGATE UNITED METHODIST RETIREMENT COMMUNITY, INC.**, a North Carolina nonprofit corporation (the "Corporation"), and **THE BANK OF NEW YORK MELLON TRUST COMPANY, N.A.,** a national banking association (the "Master Trustee") as master trustee under the Master Trust Indenture, dated as of October 1, 2013 (the "Master Indenture"), by and between the Corporation and the Master Trustee.

W I T N E S S E T H:

WHEREAS, the Corporation and the Master Trustee made certain amendments to the Master Indenture pursuant to Supplemental Indenture for Obligation No. 4, dated as of November 1, 2015; and

WHEREAS, the Corporation and the Master Trustee desire to make certain amendments to the Master Indenture as set forth herein; and

WHEREAS, Section 6.02 of the Master Indenture provides that the Holders of not less than a majority in aggregate principal amount of Obligations then Outstanding shall have the right, from time to time, anything contained therein to the contrary notwithstanding, to consent to and approve the execution by each Member of the Obligated Group, when authorized by resolution or other action of equal formality by its Governing Body, and the Master Trustee of such Supplements as shall be deemed necessary and desirable for the purpose of modifying, altering, amending, adding to or rescinding, in any particular, any of the terms or provisions contained in the Master Indenture, subject to certain restrictions contained in Section 6.02; including without limitation, consent of the North Carolina Medical Care Commission and the Local Government Commission of North Carolina; and

WHEREAS, the registered owners of the Outstanding North Carolina Medical Care Commission Retirement Facilities First Mortgage Revenue Bonds (Aldersgate) Series 2015 (the "2015 Bonds") will be deemed such Holders for the purpose of any consents for amendments, all as set forth in Section 8.01 of the Master Indenture; and

WHEREAS, the registered owners of the Outstanding North Carolina Medical Care Commission Retirement Facilities First Mortgage Revenue Refunding Bonds (Aldersgate) Series 2017A (the "2017A Bonds") will be deemed such Holders for the purpose of any consents for amendments, all as set forth in Section 8.01 of the Master Indenture; and

WHEREAS, the registered owners of the Outstanding North Carolina Medical Care Commission Taxable Retirement Facilities First Mortgage Revenue Refunding Bonds (Aldersgate) Series 2021A (the "2021A Bonds") will be deemed such Holders for the purpose of any consents for amendments, all as set forth in Section 8.01 of the Master Indenture; and

WHEREAS, the registered owners of the Outstanding North Carolina Medical Care Commission Tax-Exempt Retirement Facilities First Mortgage Revenue Refunding Bonds (Aldersgate) Series 2021B (the "2021B Bonds") will be deemed such Holders for the purpose of any consents for amendments, all as set forth in Section 8.01 of the Master Indenture; and

WHEREAS, the 2015 Bonds, the 2017A Bonds, the 2021A Bonds and the 2021B are currently outstanding in the following amounts:

Series	Amount Outstanding
2015 Bonds	$
2017A Bonds	
2021A Bonds	
2021B Bonds	
	[Total]

WHEREAS, the registered owners of $_____ of Outstanding 2015 Bonds have consented to this Second Amendment; and

WHEREAS, the registered owners of $_____ of Outstanding 2015 Bonds have consented to this Second Amendment; and

WHEREAS, Truist Bank, as registered owner of the 2021A Bonds and certain Obligations relating to derivative agreements with the Corporation, has consented to this Second Amendment; and

WHEREAS, Truist Commercial Equity, Inc., as registered owner of the 2021B Bonds, has consented to this Second Amendment; and

WHEREAS, the North Carolina Medical Care Commission has consented to this Second Amendment; and

WHEREAS, the Local Government Commission of North Carolina has consented to this Second Amendment; and

WHEREAS, the Master Trustee has received or will receive an Opinion of Counsel as set forth in Section 6.03(a) of the Master Indenture; and

WHEREAS, over a majority of Holders having consented to this Second Amendment, together with the North Carolina Medical Care Commission and the Local Government Commission of North Carolina; and

WHEREAS, all acts and things necessary for the Second Amendment to constitute a valid indenture and agreement according to its terms have been done and performed, and the Corporation has duly authorized the execution and delivery hereof;

NOW, THEREFORE, in consideration of the premises, the Corporation covenants and agrees with the Master Trustee, as follows:

Section 1. Amendments to Section 1.01.

(i) Part (a) of the definition of "*Income Available for Debt Service*" in Section 1.01 is hereby amended to read as follows:

(a) any gain or loss from either the extinguish of Indebtedness (except with respect to Short-Term Indebtedness from The Givens Estates, Inc. or any affiliate thereof)[1]

[1] Highlighted section is the additional wording added.

or the sale, exchange or other disposition of capital assets not made in the ordinary course of business;

(ii) The definition of "*Maximum Annual Debt Service*" in Section 1.01 is hereby amended to read as follows:

"*Maximum Annual Debt Service*" means the highest Long-Term Debt Service Requirement, excluding the Long-Term Debt Service Requirements with respect to (i) Qualifying Intermediate-Term Indebtedness and (ii) Subordinated Indebtedness.[1]

(iii) The definition of "*Subordinated Indebtedness*" in Section 1.01 and shall read as follows:

"*Subordinated Indebtedness*" means Indebtedness which is not secured by this Master Indenture or any other property, has all the elements the set forth in Annex 3.06(h) and is borrowed from The Givens Estates, Inc. or any affiliate thereof.[1]

Section 2. Amendment to Section 3.06.

There is hereby added a new Section 3.06(h) which shall read as follows:

(h) Subordinated Indebtedness may be incurred without limit.[1]

Section 3. Amendment to Section 5.04.

The first paragraph of Section 5.04 is hereby amended by adding the following sentence to the end of such paragraph:

A successor Master Trustee shall not be required if the Master Trustee shall sell or assign substantially all of its corporate trust business and the vendee or assignee shall continue in the corporate trust business, of if a transfer of the corporate trust department of the Master Trustee is required by operation of law, provided that such vendee, assignee or transferee is (i) a trust company or bank having the powers of a trust company as to trusts, qualified to do and doing trust business in one or more states of the United States of America, (ii) of good standing, (iii) having a combined capital and surplus aggregating not less than One Hundred Million Dollars ($100,000,000).[1]

Section 4. Addition of Section 9.12.

There is hereby added a Section 9.12 which shall read as follows:

Section 9.12 Substitution of Obligations. Notwithstanding anything in the Master Indenture to the contrary, each then Outstanding Obligation may, upon the request of the Obligated Group Representative (and without the consent of any Holder) be substituted with a replacement obligation issued and secured pursuant to that certain Second Amended and Restated Master Trust Indenture, dated as of October 1, 2021, between The Givens Estates, Inc., Givens Highland Farms LLC, Givens Gerber Park II LLC and Truist Bank, as master trustee thereunder.[1]

Section 5. Addition of Annex 3.06(h). There shall be added to the Master Indenture a new Annex 3.06(h) substantially in form attached to this Second Amendment.

Section 6. ***Defined Terms***. Capitalized words and terms used in this Second Amendment and not otherwise defined herein shall have the same meanings in this Second Amendment as such words and terms are given in the Master Indenture.

Section 7. ***Ratification of Master Indenture***. As amended hereby, the Master Indenture is in all respects ratified and confirmed and the Master Indenture as so amended hereby shall be read, taken and construed as one and the same instrument.

Section 8. ***Severability***. If any provision of this Second Amendment shall be held or deemed to be or shall, in fact, be inoperative or unenforceable as applied in any particular case and any jurisdiction or jurisdictions or in all jurisdictions, or in all cases, because it conflicts with any other provision or provisions hereof or any constitution, statute, rule or public policy, or for any other reason, such circumstances shall not have the effect of rendering the provision in question inoperative or unenforceable in any other case or circumstance, or of rendering any other provision or provisions herein contained invalid, inoperative or unenforceable to any extent whatever.

The invalidity of any one or more phrases, sentences, clauses, sections or subsections contained in this Second Amendment shall not affect the remaining portions of this Second Amendment or any part thereto.

Section 9. ***Counterparts***. This Second Amendment may be executed in several counterparts, each of which shall be an original and all of which shall constitute one instrument.

Section 10. ***Effectiveness***. This Second Amendment shall take effect upon its due execution and delivery by the Corporation and the Master Trustee and the consent to the amendments to the Master Indenture as set forth in described in the WHEREAS clauses to this Second Amendment.

Section 11. ***Governing Law***. This Second Amendment shall be governed by and construed in accordance with laws of the State of North Carolina.

(signatures contained on the following page)

IN WITNESS WHEREOF, the Corporation and the Master Trustee have caused these presents be signed in their respective names and on their behalf by their duly authorized officers, all of as of the day and year first above written.

ALDERSGATE UNITED METHODIST RETIREMENT COMMUNITY, INC.

By:_____
President and Chief Executive Officer

THE BANK OF NEW YORK MELLON TRUST COMPANY, N.A., as Master Trustee

By:_____
Vice President

[Signature Page to the Second Amendment to Master Trust Indenture (Aldersgate)]

ANNEX 3.06(h)[1]

All documents, promissory notes and other materials documenting any Subordinated Indebtedness shall state the following:

(A) This indebtedness is unsecured and is subordinate in all respects to any principal of or premium and interest on Obligations issued pursuant to the Master Indenture.

(B) This indebtedness is payable only if, upon payment thereof, the Corporation:

(i) is current on all payments due on any outstanding Obligations;

(ii) has a Long-Term Debt Service Coverage Ratio of no less than 1.30 after giving effect to such payment; and

(iii) has Days' Cash on Hand of no less than 200 days after giving effect to such payment.

All capitalized terms used in this Annex shall have the definitions given such terms in the Master Indenture.

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES

The North Carolina Medical Care Commission
809 Ruggles Drive
Raleigh, North Carolina

MINUTES

CALLED MEETING OF THE EXECUTIVE COMMITTEE CONFERENCE TELEPHONE MEETING ORIGINATING FROM THE COMMISSION'S OFFICE APRIL 30, 2025 4:30 P.M.

Members of the Executive Committee Present:

John J. Meier, IV, M.D., Chairman
Joseph D. Crocker, Vice-Chairman
Paul R.G. Cunningham, M.D.
Bryant C. Foriest
Eileen C. Kugler, RN, MSN, MPH, FNP
David C. Mayer, M.D.
Neel G. Thomas, M.D.

Members of the Executive Committee Absent:

None

Members of Staff Present:

S. Mark Payne, Director, DHSR/Secretary, MCC
Emery E. Milliken, Deputy Director, DHSR
Geary W. Knapp, JD, CPA, Assistant Secretary, MCC
Kathy C. Larrison, Auditor, MCC
Crystal Watson-Abbott, Auditor, MCC
Alice S. Creech, Executive Assistant, MCC

Others Present:

Pam Fox, Twin Lakes Community
Tad Melton, Ziegler
Adam Garcia, Ziegler
Jeff Poley, Hawkins Delafield & Wood, LLP

1. Purpose of Meeting

To authorize the sale of bonds, the proceeds of which are to be loaned to Lutheran Retirement Ministries of Alamance County, North Carolina d/b/a Twin Lakes Community.

2. Resolution of the North Carolina Medical Care Commission Authorizing the Issuance of $35,310,000 North Carolina Medical Care Commission Retirement Facilities First Mortgage Revenue Bonds (Twin Lakes Community) Series 2025.

Executive Committee Action: *A motion was made to approve the resolution by Mr. Joe Crocker, seconded by Mr. Bryant Foriest, and unanimously approved*.

WHEREAS, the North Carolina Medical Care Commission (the "Commission") is a commission of the Department of Health and Human Services of the State of North Carolina and is authorized under Chapter 131A of the General Statutes of North Carolina, as amended (the "Act"), to borrow money and to issue in evidence thereof bonds and notes for the purpose of providing funds to pay all or any part of the cost of financing or refinancing health care facilities (including retirement facilities); and

WHEREAS, Lutheran Retirement Ministries of Alamance County, North Carolina d/b/a Twin Lakes Community (the "Corporation") is a nonprofit corporation duly incorporated and validly existing under and by virtue of the laws of the State of North Carolina and is a "nonprofit agency" within the meaning of the Act; and

WHEREAS, the Corporation has made application to the Commission for a loan for the purpose of providing funds, together with other available funds, to (1) pay all or a portion of the cost of acquiring, constructing and equipping an expansion of and renovation to the Corporation's existing continuing care retirement community located at 3815 Wade Coble Drive, Burlington, North Carolina 27215, known as Twin Lakes Community, including but not limited to (a) constructing and equipping approximately 36 new independent living apartments and various other capital improvements throughout the community, and (b) paying working capital directly related thereto (collectively, the "Project"); (2) pay a portion of the interest accruing on the Bonds; and (3) pay certain expenses incurred in connection with the authorization and issuance of the Bonds by the Commission; and

WHEREAS, the Commission has determined that the public will best be served by the proposed financing and, by a resolution adopted on August 19, 2024, has approved the issuance of the Bonds, subject to compliance by the Corporation with the conditions set forth in such resolution, and the Corporation has complied with such conditions to the satisfaction of the Commission; and

WHEREAS, there have been presented to officers and staff of the Commission draft copies of the following documents relating to the issuance of the Bonds:

(a) a Trust Agreement, dated as of May 1, 2025 (the "Trust Agreement"), between the Commission and The Bank of New York Mellon Trust Company, N.A., as

bond trustee (the "Bond Trustee"), the provisions of which relate to the issuance of and security for the Bonds and includes the form of the Bonds;

(b) a Loan Agreement, dated as of May 1, 2025 (the "Loan Agreement"), between the Commission and the Corporation, pursuant to which the Commission will lend the proceeds of the Bonds to the Corporation;

(c) a Contract of Purchase, dated April 30, 2025 (the "Purchase Contract"), between B.C. Ziegler & Company (the "Underwriter") and the Local Government Commission of North Carolina (the "LGC"), and approved by the Commission and the Corporation, pursuant to which the Underwriter has agreed to purchase the Bonds on the terms and conditions set forth therein and in the Trust Agreement;

(d) a Supplemental Indenture for 2025 Obligations, dated as of May 1, 2025 (the "Supplemental Indenture"), between the Corporation and The Bank of New York Mellon Trust Company, N.A., as master trustee (the "Master Trustee") under the Amended and Restated Master Trust Indenture, dated as of October 1, 2019 (as further amended or supplemented from to time to time in accordance with its terms, the "Master Indenture"), between the Corporation and the Master Trustee;

(e) Obligation Nos. 16A, 16B-1 and 16B-2, to be dated the date of delivery of the Bonds (the "2025 Obligations"), to be issued by the Corporation to the Commission;

(f) a Second Amendment to Deed of Trust, dated as of May 1, 2025, amending the Amended and Restated Deed of Trust, dated as of October 1, 2019 (as amended, the "Corporation Deed of Trust"), from the Corporation to the trustee named therein for the benefit of the Master Trustee;

(g) an Assignment of Contracts, dated as of May 1, 2025 (the "Assignment of Contracts"), from the Corporation to the Master Trustee; and

(h) a Preliminary Official Statement, dated April 8, 2025, relating to the Bonds (the "Preliminary Official Statement").

WHEREAS, the Commission has determined that the Corporation is financially responsible and capable of fulfilling its obligations under the Loan Agreement, the Master Indenture, the Supplemental Indenture and the 2025 Obligations; and

WHEREAS, the Commission has determined that adequate provision has been made for the payment of the principal of, redemption premium, if any, and interest on the Bonds;

NOW, THEREFORE, THE NORTH CAROLINA MEDICAL CARE COMMISSION DOES HEREBY RESOLVE, as follows:

Section 1. Capitalized words and terms used in this Series Resolution and not defined herein shall have the same meanings in this Series Resolution as such words and terms are given in the Master Indenture, the Trust Agreement and the Loan Agreement.

Section 2. Pursuant to the authority granted to it by the Act, the Commission hereby authorizes the issuance of its Retirement Facilities First Mortgage Revenue Bonds (Twin Lakes Community) Series 2025A (the "2025A Bonds") and Tax-Exempt Mandatory Paydown Securities (TEMPS-85^{SM}) (Twin Lakes Community) Series 2025B-1 (the "2025B-1 Bonds") and Tax-Exempt Mandatory Paydown Securities (TEMPS-50^{SM}) (Twin Lakes Community) Series 2025B-2 (the "2025B-2 Bonds," and collectively with the 2025A Bonds and the 2025B-1 Bonds, the "Bonds") in the aggregate principal amount of $35,310,000. The Bonds shall mature in such amounts and at such times and shall bear interest at such rates as are set forth in the pricing numbers included with this Series Resolution.

The Bonds shall be issued as fully registered bonds in the denominations of $5,000 or any whole multiple thereof. The Bonds shall be issued in book-entry form as provided in the Trust Agreement. Interest on the Bonds shall be paid on each January 1 and July 1, beginning July 1, 2025. Payments of principal of and interest on the Bonds shall be made to the registered owners of the Bonds in such manner as is set forth in the Trust Agreement.

Section 3. The Bonds shall be subject to optional, extraordinary and mandatory sinking fund redemption, all at the times, upon the terms and conditions, and at the prices set forth in the Trust Agreement. Additionally, the 2025B-1 Bonds and the 2025B-2 Bonds are subject to redemption on a monthly basis from initial entrance fees received from the Project in accordance with the provisions set forth in the Trust Agreement and the Supplemental Indenture.

Section 4. The proceeds of the Bonds shall be applied as provided in Section 2.08 of the Trust Agreement. The Commission hereby finds that the use of the proceeds of the Bonds for a loan to fund a portion of the cost of the Project, fund interest on the Bonds during construction of the Project and pay certain costs of issuing the Bonds will accomplish the public purposes set forth in the Act.

Section 5. The forms, terms and provisions of the Trust Agreement and the Loan Agreement are hereby approved in all respects, and the Chairman or Vice Chairman (or any member of the Commission designated by the Chairman) and the Secretary or any Assistant Secretary of the Commission are hereby authorized and directed to execute and deliver the Trust Agreement and the Loan Agreement in substantially the forms presented, together with such changes, modifications and deletions as they, with the advice of counsel, may deem necessary and appropriate, and such execution and delivery shall be conclusive evidence of the approval and authorization thereof by the Commission.

Section 6. The form, terms and provisions of the Purchase Contract are hereby approved in all respects, and the Chairman, Vice Chairman, Secretary or any Assistant Secretary of the Commission (or any member of the Commission designated by the Chairman) are hereby authorized and directed to execute and deliver the Purchase Contract in substantially the form presented, together with such changes, modifications, insertions and deletions as they, with the advice of counsel, may deem necessary and appropriate, and such execution and delivery shall be conclusive evidence of the approval and authorization thereof by the Commission.

Section 7. The form of the Bonds set forth in the Trust Agreement is hereby approved in all respects, and the Chairman or Vice Chairman (or any member of the Commission designated

by the Chairman) and the Secretary or any Assistant Secretary of the Commission are hereby authorized and directed to execute, by manual or facsimile signature as provided in such form of the Bonds, and to deliver to the Bond Trustee for authentication on behalf of the Commission, the Bonds in definitive form, which shall be in substantially the form presented, together with such changes, modifications and deletions as they, with the advice of counsel, may deem necessary, appropriate and consistent with the Trust Agreement, and such execution and delivery shall be conclusive evidence of the approval and authorization thereof by the Commission.

Section 8. The forms, terms and provisions of the Supplemental Indenture, the 2025 Obligations, the Corporation Deed of Trust and the Assignment of Contracts are hereby approved in substantially the forms presented, together with such changes, modifications, insertions and deletions as the Chairman or Vice Chairman (or any member of the Commission designated by the Chairman) and the Secretary or any Assistant Secretary of the Commission, with the advice of counsel may deem necessary and appropriate; and the execution and delivery of the Trust Agreement as provided in Section 5 of this Series Resolution shall be conclusive evidence of the approval of the documents listed in this Section by the Commission.

Section 9. The Commission hereby approves the action of the Local Government Commission in awarding the Bonds to the Underwriter at the purchase price of $34,993,125.80 (representing the principal amount of the Bonds plus original issue premium of $18,570.80 and less underwriter's discount of $335,445.00).

Section 10. Upon their execution in the form and manner set forth in the Trust Agreement, the Bonds shall be deposited with the Bond Trustee for authentication, and the Bond Trustee is hereby authorized and directed to authenticate the Bonds and, upon the satisfaction of the conditions set forth in Section 2.08 of the Trust Agreement, the Bond Trustee shall deliver the Bonds to the Underwriter against payment therefor.

Section 11. The Commission hereby approves and ratifies the use and distribution of the Preliminary Official Statement and approves the use and distribution of a final Official Statement (the "Official Statement"), both in connection with the offer and sale of the Bonds. The Chairman, Vice Chairman, Secretary or any Assistant Secretary (or any member of the Commission designated by the Chairman) are hereby authorized to execute, if applicable, and deliver on behalf of the Commission, the Official Statement in substantially the form of the Preliminary Official Statement, together with such changes, modifications and deletions as they, with the advice of counsel, may deem appropriate. The execution of the Purchase Contract shall be conclusive evidence of the approval of the Official Statement by the Commission. The Commission hereby approves and authorizes the distribution and use of copies of the Official Statement, the Trust Agreement, the Loan Agreement, the Master Indenture, the Supplemental Indenture, the 2025 Obligations, the Corporation Deed of Trust and the Assignment of Contracts by the Underwriter in connection with such offer and sale.

Section 12. The Bank of New York Mellon Trust Company, N.A.is hereby appointed as the initial Bond Trustee for the Bonds.

Section 13. The Depository Trust Company, New York, New York is hereby appointed as the initial Securities Depository for the Bonds, with Cede & Co., a nominee thereof, being the initial Securities Depository Nominee and initial registered owner of the Bonds.

Section 14. S. Mark Payne, Secretary of the Commission, Geary W. Knapp, Assistant Secretary of the Commission, Anthony J. Harms, Chief of the Construction Section of the Division of Health Service Regulation, and Kathy C. Larrison and Crystal Watson-Abbott, Auditors for the Commission, are each hereby appointed a Commission Representative as that term is defined in the Loan Agreement, with full power to carry out the duties set forth therein.

Section 15. The Chairman, Vice Chairman, Secretary, and any Assistant Secretary of the Commission (or any member of the Commission designated by the Chairman) are each hereby authorized and directed (without limitation except as may be expressly set forth herein) to take such action and to execute and deliver any such documents, certificates, undertakings, agreements or other instruments as they, with the advice of counsel, may deem necessary or appropriate to effect the transactions contemplated by the Trust Agreement, the Loan Agreement, the Purchase Contract and the Official Statement.

Section 16. This Series Resolution shall take effect immediately upon its passage.

3. <u>Adjournment</u>

There being no further business, the meeting was adjourned at 4:50 p.m.

Respectfully submitted,

Geary W. Knapp
Assistant Secretary

Professional Fees Comparison for
Twin Lakes Community

Professional	Fees Estimated In Preliminary Approval Resolution	Actual Fees
Underwriter's Discount	$500,000	$335,445
Underwriter's Counsel	85,000	88,000[1]
Accountants	20,000	25,000
Bond Counsel	95,000	120,000
Corporation Counsel	50,000	95,000
Feasibility Consultant	125,000	-
Trustee Fee w/Counsel	15,000	15,450
Total	$890,000	$678,895

[1] Includes Blue Sky analysis and memo.

BOND PRICING

Twin Lakes (NC)
Series 2025 - All Bond Financing - BBB Rated (Stockton Phase II)
***** ***** ***** ***** *****
VERBAL AWARD

Bond Component	Maturity Date	Amount	Rate	Yield	Price	Yield to Maturity	Call Date	Call Price	Premium (-Discount)
2025A: 2055 Term Bond:									
	01/01/2055	27,310,000	5.250%	5.240%	100.068 C	5.245%	01/01/2035	100.000	18,570.80
2025B2: Short-Term Entry Fee Bond (TEMPs-50):									
	01/01/2029	4,750,000	3.900%	3.900%	100.000				
2025B1: Short-Term Entry Fee Bond (TEMPs-85):									
	01/01/2030	3,250,000	4.050%	4.050%	100.000				
		35,310,000							18,570.80

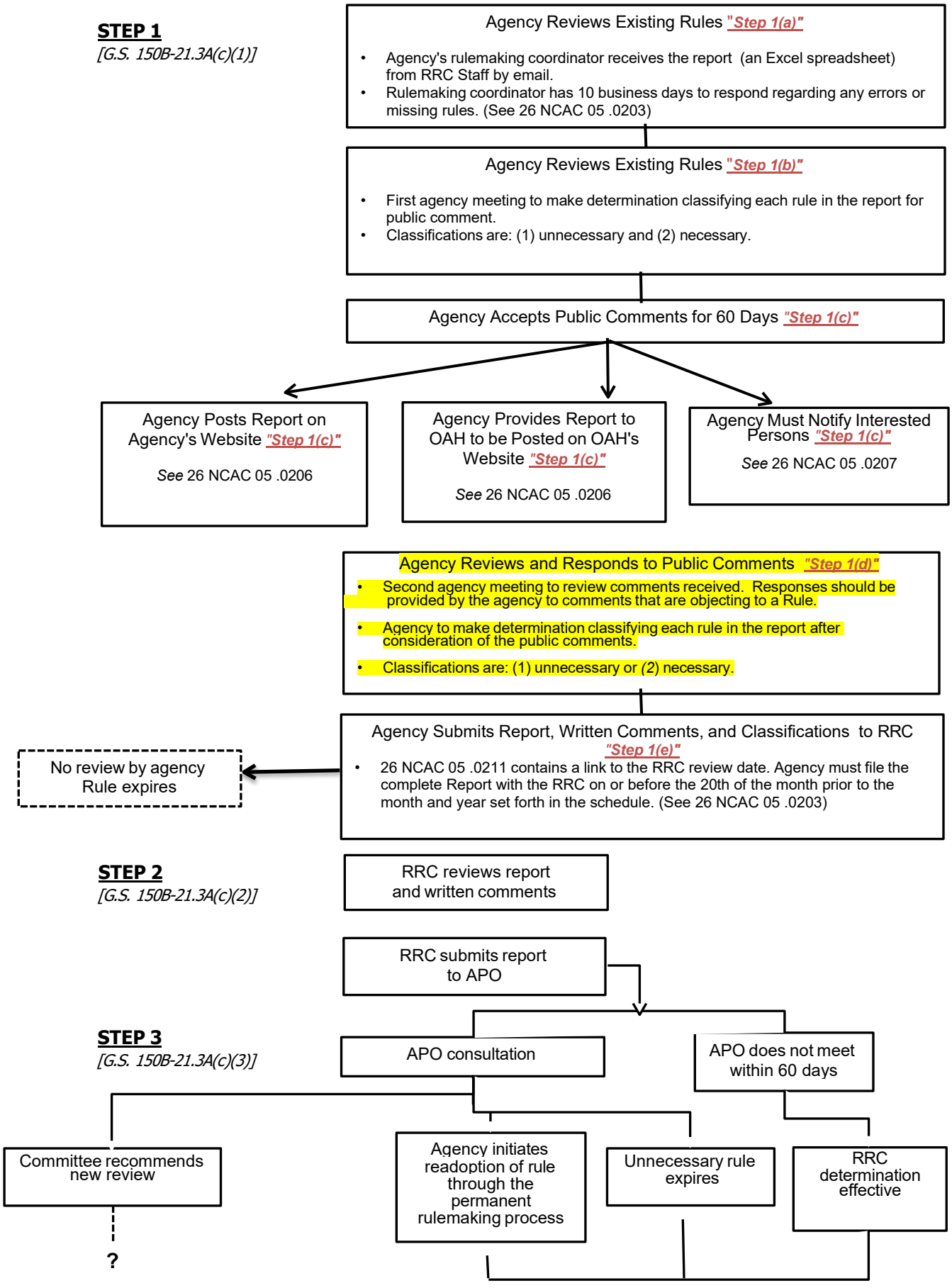
Dated Date	05/14/2025	
Delivery Date	05/14/2025	
First Coupon	07/01/2025	
Par Amount	35,310,000.00	
Premium	18,570.80	
Production	35,328,570.80	100.052594%
Underwriter's Discount	(335,445.00)	(0.950000%)
Purchase Price	34,993,125.80	99.102594%
Accrued Interest		
Net Proceeds	34,993,125.80	

BOND MATURITY TABLE

Twin Lakes (NC)
2025A: Long-Term Bond

Maturity Date	2025A: 2055 Term Bond
01/01/2046	
01/01/2047	
01/01/2048	
01/01/2049	
01/01/2050	3,125,000
01/01/2051	3,290,000
01/01/2052	3,485,000
01/01/2053	3,670,000
01/01/2054	6,690,000
01/01/2055	7,050,000
	27,310,000

Periodic Review and Final Determinations



10A NCAC 13K .0102 DEFINITIONS

In addition to the definitions set forth in G.S. 131E-201, the following definitions shall apply throughout this Subchapter:

(1) "Agency" means a licensed hospice as defined in G.S. 131E-201(3).

(2) "Care Plan" means the proposed method developed in writing by the interdisciplinary care team through which the hospice seeks to provide services that meet the patient's and family's medical, psychosocial, and spiritual needs.

(3) "Clergy Member" means an individual who has received a degree from a theological school and has fulfilled denominational seminary requirements; or an individual who, by ordination or authorization from the individual's denomination, has been approved to function in a pastoral capacity. Each hospice shall designate a clergy member responsible for coordinating spiritual care to hospice patients and families.

(4) "Coordinator of Patient Family Volunteers" means an individual on the hospice team who coordinates and supervises the activities of all patient family volunteers.

(5) "Dietary Counseling" means counseling given by a licensed dietitian/nutritionist or licensed nutritionist as defined in G.S. 90-352.

(6) "Director" means the person having administrative responsibility for the operation of the hospice.

(7) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.

(8) "Governing Body" means the group of persons responsible for overseeing operations of the hospice, including the development and monitoring of policies and procedures related to all aspects of the operations of the hospice program. The governing body ensures that all services provided are consistent with accepted standards of hospice practice.

(9) "Hospice" means a coordinated program of services as defined in G.S. 131E-201.

(10) "Hospice Caregiver" means an individual on the hospice team who has completed hospice caregiver training as defined in Rule .0402 of this Subchapter and is assigned to a hospice residential facility or hospice inpatient unit.

(11) "Hospice Inpatient Facility or Hospice Inpatient Unit" means as defined in G.S. 131E-201(3a).

(12) "Hospice Residential Facility" means as defined in G.S. 131E-201(5a).

(13) "Hospice Team" means as defined in G.S. 131E-201(6).

(14) "Informed Consent" means the agreement to receive hospice care made by the patient and family that specifies in writing the type of care and services to be provided. The informed consent form shall be signed by the patient prior to service. If the patient's medical condition is such that a signature cannot be obtained, a signature shall be obtained from the individual having legal guardianship, applicable durable or health care power of attorney, or the family member or individual assuming the responsibility of primary caregiver.

(15) "Interdisciplinary Team" means as defined in G.S. 131E-201(6).

(16) "Licensed Practical Nurse" means as defined in G.S. 90-171.30 or G.S. 171.32.

(17) "Medical Director" means a physician licensed to practice medicine in North Carolina who directs the medical aspects of the hospice's patient care program.

(18) "Nurse Practitioner" means as defined in G.S. 90-18.2(a).

(19) "Nurse Aide" means an individual who is authorized to provide nursing care under the supervision of a licensed nurse, has completed a training and competency evaluation program or competency evaluation program and is listed on the Nurse Aide Registry, at the Division of Health Service Regulation. If the nurse aide performs Nurse Aide II tasks, the nurse aide shall also meet the requirements established by the N.C. Board of Nursing as defined in 21 NCAC 36 .0405, incorporated by reference including subsequent amendments.

(20) "Patient and Family Care Coordinator" means a registered nurse designated by the hospice to coordinate the provision of hospice services for each patient and family.

(21) "Patient Family Volunteer" means an individual who has received orientation and training as defined in Rule .0402 of this Subchapter, and provides volunteer services to a patient and the patient's family in the patient's home or in a hospice inpatient facility or hospice inpatient unit, or a hospice residential facility.

(22) "Pharmacist" means as defined in G.S. 90-85.3.

(23) "Physician" means as defined in G.S. 90-9.1 or G.S. 90-9.2.

(24) "Premises" means the location or licensed site where the agency provides hospice services or maintains patient service records or advertises itself as a hospice agency.

(25) "Primary Caregiver" means the family member or other person who assumes the overall responsibility for the care of the patient in the patient's home.

(26) "Registered Nurse" means as defined in G.S. 90-171.30 or G.S. 90-171.32.

(27) "Respite Care" means care provided to a patient for temporary relief to family members or others caring for the patient at home.

(28) "Spiritual Caregiver" means an individual authorized by the patient and family to provide for their spiritual needs.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; February 1, 1995; June 1, 1991; November 1, 1989;
Readopted Eff. January 1, 2021.

SECTION .0200 - LICENSE

10A NCAC 13K .0201 LICENSE REQUIRED

Each hospice agency premises shall obtain a license unless exempted by G.S. 131E-203.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .0202 APPLICATION FOR AND ISSUANCE OF A LICENSE

(a) An application for a license to operate a hospice agency or facility shall be submitted to the Department prior to the scheduling of an initial licensure survey. The hospice agency shall establish, maintain and make available for inspection such documents, records and policies as required in this Section and statistical data sufficient to complete the licensure application and upon request of the Department, to submit an annual data report, including all information required by the Department as noted in Rule .0303 of this Subchapter.

(b) The Department shall issue a license to each hospice agency premises when determined to be in compliance with licensure rules. Initial licensure inspections shall be conducted at the Department offices. On-site inspections shall include one or all sites as described in Rule .0209 of this Subchapter. Initial licensure shall be for a period of not more than one year. Subsequent licensure shall extend for a minimum of one year and a maximum of three years, at the discretion of the Department. Each license shall expire at midnight on the expiration date on the license and is renewable upon application.

(c) The license shall be posted in a prominent location accessible to public view within the premises. The agency shall also post a sign at the public access door with the hospice agency name.

(d) The license shall be issued for the premise and persons named in the application and shall not be transferable. The name and street address under which the agency operates shall appear on the license. If the agency operates an inpatient facility or unit, or a residential facility to provide inpatient or residential hospice care, the number of beds for each shall be reflected on the license.

(e) Prior to change of ownership or the establishment of a new hospice agency, the agency shall be in compliance with all the applicable statutes and rules established under Article 10 of G.S. 131E.

(f) The licensee shall notify the Department in writing of any proposed change in ownership or name at least 30 days prior to the effective date of the change.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. April 1, 1996; June 1, 1991; November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .0206 ADVERSE ACTION

A hospice may appeal any adverse decision made by the Department concerning its license by making such appeal in accordance with the Administrative Procedure Act, G.S. 150B and Departmental Rules 10ANCAC 01 et seq. As provided for in G.S. 131E-206, the Department shall seek injunctive relief to prevent an entity from establishing or operating a hospice agency without a license.

(1) The Department may amend a license by reducing it from a full license to a provisional license whenever the Department finds that:
   (a) the licensee has substantially failed to comply with the provisions of Article 10 of G.S. 131E and the rules promulgated under that Part; and
   (b) there is a reasonable probability that the licensee can remedy the licensure deficiencies within a reasonable length of time; and
   (c) there is a reasonable probability that the licensee will be able thereafter to remain in compliance with the hospice licensure rules for the foreseeable future.

The Department shall give the licensee written notice of the amendment of its license. This notice shall be given by registered or certified mail or by personal service and shall set forth the reasons for the action.

(2) The provisional license shall be effective immediately upon its receipt by the licensee and must be posted in a prominent location, accessible to public view, within the licensed premises in lieu of the full license. The provisional license shall remain in effect until:
   (a) the Department restores the licensee to full licensure status; or
   (b) the Department revokes the licensee's license; or
   (c) the end of the licensee's licensure year.

If a licensee has a provisional license at the time that the licensee submits a renewal application, the license, if renewed, shall also be provisional license unless the Department determines that the licensee can be returned to full license status. A decision to issue a provisional license shall be stayed during the pendency of an administrative appeal and the licensee may continue to display its full license during the appeal.

(3) The Department may revoke a license whenever:
   (a) The Department finds that:
      (i) the licensee has substantially failed to comply with the provisions of Article 10 of G.S. 131E and the rules promulgated under those parts; and
      (ii) it is not reasonably probable that the licensee can remedy the licensure deficiencies within a reasonable length of time; or
   (b) The Department finds that:
      (i) the licensee has substantially failed to comply with the provisions of Article 10 of G.S. 131E; and
      (ii) although the licensee may be able to remedy the deficiencies within a reasonable time, it is not reasonably probable that the licensee will be able to remain in compliance with the hospice licensure rules for the foreseeable future; or
   (c) The Department finds that there has been any failure to comply with the provisions of Article 10 of G.S. 131E and the rules promulgated under those parts that endangers the health, safety or welfare of the patients receiving services from the agency.

The issuance of a provisional license is not a procedural prerequisite to the revocation of a license pursuant to Sub-Item (3)(a), (b) or (c) of this Rule.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .0209 MULTIPLE PREMISES

If a person operates multiple hospice agency premises:

(1) the Department may conduct inspections at any or all of the premises and may issue a license to each of the premises based upon inspection of any or all of the premises;

(2) with 72 hours advance notice, the Department may request records from any of the premises necessary to ensure compliance with the rules of this Subchapter be brought to the site being inspected, including the portions of personnel records subject to review. For agencies for whom a business or government policy precludes the disclosure of employee evaluations, a statement signed by the employee's supervisor attesting to its completion shall be accepted;

(3) the premises may share staff or administrative staff, and may centralize the maintenance of records.

History Note: *Authority G.S. 131E-202;*
Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .0208 INSPECTIONS

(a) Any hospice agency or facility shall be subject to inspections by authorized representatives of the Department at any time as a condition of holding such license.

(b) Any person or organization subject to licensure which presents itself to the public as a hospice which does not hold a license, and is or may be in violation of Rule .0202 of this Section and G.S. 131E-203(a) shall be subject to proper inspections at any time by authorized representatives of the Department.

(c) Representatives of the Department shall make their identities known to the person in charge prior to the inspection.

(d) Licensure inspection of medical records shall be carried out in accordance with G.S. 131E-207.

(e) An inspection shall be conducted whenever the purpose of the inspection is to determine whether the agency complies with the provisions of this Subchapter or whenever there is reason to believe that some condition exists which is not in compliance with the rules in this Subchapter. The agency shall allow immediate access to its premises and the records necessary to conduct an inspection and determine compliance with the rules of this Subchapter. Failure to do so shall result in termination of the survey and may result in injunctive relief as outlined in G.S. 131E-206.

(f) An agency shall file a plan of correction for cited deficiencies within 10 working days of receipt of a report of deficiencies. The Department shall review and respond to a written plan of correction within 10 working days of receipt.

(g) Representatives of the Department may visit patients in their homes to assess the agency's compliance with the patients' plans of care and with the licensure rules. Patients shall be contacted by the hospice agency staff in the presence of the Department staff for permission to visit.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .0210 COMPLIANCE WITH LAWS

(a) The hospice agency shall be in compliance with all applicable federal, state and local laws, rules and regulations.

(b) Staff of the hospice agency shall be currently licensed, listed or registered in accordance with applicable laws of the State of North Carolina.

History Note: *Authority G.S. 131E-202;*
Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

SECTION .0300 - ADMINISTRATION

10A NCAC 13K .0301 AGENCY MANAGEMENT AND SUPERVISION

(a) The governing body or its designee shall establish and implement at a minimum, a description of written policies governing all aspects of the hospice program. Such policies shall be available for inspection by the Department and shall include at a minimum:

(1) provision for offering of the full scope of hospice services in the agency's defined service area;
(2) admission and discharge policies;
(3) patient's rights policies, including the right to have an advance directive;
(4) personnel policies and records;
(5) orientation, patient family volunteer training, and inservice education policies;
(6) communicable disease exposure and infection control policies;
(7) care planning and updates policies;
(8) medical record content and handling of orders for drug treatment administration;
(9) annual evaluation of the agency;
(10) storage, preventive maintenance, and infection control of supplies and equipment;
(11) handling of complaints about services; and
(12) emergency preparedness and disaster planning.

(b) The governing body shall designate an individual to serve as agency director.

(c) There shall be written policies that specify the authority and responsibilities of the director. In the event this position becomes vacant, the Department shall be notified in writing within five working days of the vacancy along with the name of the replacement if available. Agency policies shall define the order of authority in the absence of the administrator.

(d) The agency shall have the ultimate responsibility for the services provided under its license; however, it may make arrangements with contractors and others to provide services in accordance with Rule .0505 of this Subchapter.

(e) A hospice agency shall have written policies which identify the specific geographic areas in which the agency provides its services.

(f) If an agency plans to permanently expand its geographic service area beyond that currently on file with the Department without opening an additional site, the Department shall be notified in writing 30 days in advance. The agency must offer its full scope of hospice services in its entire geographic service area.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .0303 ADMINISTRATIVE FINANCIAL AND STATISTICAL RECORDS

(a) The hospice shall establish, maintain and make available for inspection the hospice annual budget.

(b) The hospice shall record, maintain and make available to the Department statistical records as requested. Records shall include: hours worked by staff, including patient family volunteers; patient census information regarding the numbers of referrals, admissions and discharges; and patient diagnoses and service location (home or inpatient).

(c) Records shall be retained for a period of not less than five years.

(d) When a hospice agency or facility operates as a part of a health care facility licensed under Article 5 or 6 of G.S. 131E, or as part of a larger diversified agency, records of hospice activities and expenditures that are separate and identifiable shall be maintained for the hospice agency.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

SECTION .0400 - PERSONNEL

10A NCAC 13K .0401 PERSONNEL

(a) Written policies shall be established and implemented by the agency regarding infection control and exposure to communicable diseases consistent with the rules set forth in 10A NCAC 41A, which is incorporated by reference, including subsequent amendments. These policies and procedures shall include provisions for compliance with 29 CFR 1910 Occupational Safety and Health Standards, which is incorporated by reference including subsequent amendments and editions. These editions shall include 29 CFR 1910.1030 Bloodborne Pathogens. Copies of Title 29 Part 1910 can be obtained online at no charge at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS.

(b) Hands-on care team members shall have a baseline test for tuberculosis. Individuals who test positive shall demonstrate non-infectious status prior to assignment in a patient's home. Individuals who have previously tested positive for the tuberculosis test shall obtain a baseline and subsequent annual verification that they are free of tuberculosis symptoms. The verification shall be obtained from the local health department, a private physician, or health nurse employed by the agency. The Communicable Disease Branch of the North Carolina Department of Health and Human Services, Division of Public Health, 1905 Mail Service Center, Raleigh, NC 27699-1905 will provide free of charge guidelines for conducting and verification utilizing Form DHHS 3405 (Record of Tuberculosis Screening). Employees identified by agency risk assessment to be at risk for exposure shall be subsequently tested in accordance with Centers for Disease Control (CDC) guidelines, which is incorporated by reference with subsequent amendments and editions. A copy of the CDC guidelines can be obtained online at no charge at https://search.cdc.gov/search/?query=TB+testing+intervals&sitelimit=&utf8=%E2%9C%93&affiliate=cdc-main.

(c) Written policies shall be established and implemented by the agency that include personnel record content, orientation, patient family volunteer training, and in-service education. Records on the subject of in-service education and attendance shall be maintained by the agency and retained for one year.

(d) Job descriptions for every position, including volunteers involved in direct patient/family services, shall be established by the agency and shall include the position's qualifications and specific responsibilities. Hospice team member(s) shall be assigned only to duties that they are trained and competent to perform, or licensed to perform.

(e) Personnel records shall be established and maintained for hospice team members, including paid and direct patient/family services volunteers. These records shall be maintained for one year after employment or volunteer service ends. When requested by the State surveyors, the records shall be available on the agency premises for inspection by the Department. The records shall include:

(1) an application or resume that lists education, training, and previous employment, including job title;
(2) a job description with record of acknowledgment by the team member(s);
(3) reference checks or verification of previous employment;
(4) records of tuberculosis annual screening for hands-on care team members;
(5) documentation of Hepatitis B immunization or declination for hands-on care team members;
(6) bloodborne pathogen training for hands-on care team members, including annual updates, in compliance with 29 CFR 1910 and in accordance with the agency's exposure control plan;
(7) performance evaluations according to agency policy, or at least annually;
(8) verification of team member(s) credentials;
(9) records of the verification of competencies by agency supervisory personnel of skills required of hospice services personnel to carry out patient care tasks. The method of verification shall be defined in agency policy.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; November 1, 1989;
Readopted Eff. January 1, 2021.

SECTION .0500 - SCOPE OF SERVICES

10A NCAC 13K .0501 SERVICE REQUIREMENTS

The governing body shall ensure through policies and implemented procedures that the following services encompassing the essential elements of hospice care be provided, either directly by hospice personnel, or by contractual arrangement:

(1) Hospice nursing services, available 24 hours a day, by or under the supervision of a registered nurse; provided in accordance with the North Carolina Nurse Practice Act (G.S. 90, Article 9A) and the hospice care plan; and sufficient to ensure that nursing needs of each patient are met.
   (a) Registered nurse duties include the following as a minimum:
      (i) regularly assess the nursing needs of the hospice patient;
      (ii) develop and implement the patient's hospice nursing care plan;
      (iii) provide hospice nursing services, treatment, and diagnostic and preventive procedures;
      (iv) initiate nursing procedures appropriate for the patient's hospice care and safety;
      (v) observe signs and symptoms and report to the physician any unexpected changes in the patient's physical or emotional condition;
      (vi) teach, supervise, and counsel the hospice patient and family members about providing care for the patient at home; and
      (vii) supervise and train other nursing service personnel.
   (b) Licensed practical nurse duties are delegated by and performed under the supervision of a registered nurse. Consistent with the hospice care plan, duties may include:
      (i) participating in assessment of the patient's condition;
      (ii) implementing nursing activities, including the administration of prescribed medical treatments and medications;
      (iii) assisting in teaching the hospice patient and family members about providing care to the patient at home; and
      (iv) delegating tasks to nurse aides and supervising their performance of tasks within the limitations established in 21 NCAC 36 .0225(d)(2) adopted by reference.
   (c) The agency must retain current nursing on-call schedules and previous schedules for one year and make them available, on request, to the Department.

(2) Social work services which shall include, but not be limited to conducting an assessment of the psychosocial needs of the patient and family with the establishment of goals in the care plan to meet those needs; on-going counseling related to issues of death and dying to the patient and family as needed; and assisting the patient and family in the utilization of appropriate community resources.

(3) Spiritual counseling shall be offered to each hospice patient/family. The hospice shall assure that:
   (a) no spiritual value or belief system is imposed on patients and families;
   (b) a spiritual assessment is completed on each patient during the admission process; and
   (c) a liaison and consultation is maintained with the patient family clergy or spiritual caregiver and other community based clergy or spiritual caregivers.

(4) Patient family volunteer services for a broad range of activities under the direction of the coordinator of patient family volunteers.

(5) Inpatient care services, for symptom management or respite care in a licensed hospital, nursing facility or licensed hospice inpatient facility, unless the hospice operates its own inpatient facility. The hospice shall assure that:
   (a) a written agreement, is signed by both providers, which assures that the inpatient facility will provide care and services to hospice patients when necessary;
   (b) the inpatient provider has policies consistent with the needs of hospice patients and their families and will, if necessary, modify policies such as visiting hour restrictions and routine tests, to meet those needs;
   (c) the hospice monthly updated plan of care is furnished to the inpatient provider to ensure that the regimen established is followed as closely as feasible during the inpatient stay;
   (d) all inpatient treatment and services are documented in the inpatient medical record and copy of the discharge summary retained as part of the hospice record; and

(e) effective transition from one type care to another be maintained with continuity of care being the primary goal.

(6) If the hospice provides or arranges for nurse aide services, those services shall be provided in accordance with physician's orders and interdisciplinary team care plan.

(a) Nurse aides shall only be assigned duties for which competence has been demonstrated and recorded in appropriate personnel records.

(b) Nurse aide duties may include, but are not limited to:

(i) providing or assisting with personal care, i.e. bathing, mouth care, hair and skin care;

(ii) checking vital signs and observing the patient's condition;

(iii) assisting with ambulation and limited, routine exercises.

(c) All nurse aide services shall be performed in accordance with a written assignment prepared by and under the supervision of the registered nurse. Supervision shall include a visit to the home by the nurse at least every two weeks, with or without the aide's presence, to assess the care and services provided. Documentation of supervisory visits shall be maintained in the medical record and include an assessment of the aide's performance in carrying out assigned duties and of the aide's relationship with the patient and family.

(7) Additional services shall be offered either directly by the hospice or by arrangement when ordered by the physician. These include physical therapy, occupational therapy, nutritional assessment and dietary counseling and other services as needed and ordered by the physician in accordance with the hospice plan of care.

(8) Bereavement counseling shall be offered to family members and others identified in the bereavement plan of care for a period of 12 months after the patient patient's death. The hospice shall assure that:

(a) an assessment of survivor risk factors is completed during the patient's admission to hospice and during the patient's illness;

(b) the bereavement care plan is established within six weeks after the patient's death;

(c) the bereavement care plan shall contain information about who shall receive bereavement services and what services will be offered;

(d) the bereavement care plan is reviewed quarterly at a minimum or more often as needed; and

(e) discharge from bereavement services before the 12 months expire is justified and documented.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; June 1, 1991; November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .0402 INSERVICE EDUCATION AND TRAINING

(a) Written policies shall be established and implemented which include orientation, patient family volunteer training and inservice education for all hospice staff. Hospice residential facilities shall establish and implement a policy addressing hospice caregiver training. Attendance records on training shall be kept. Patient family care volunteers shall be required to meet the requirements of Rule .0401 of this Section. Training hours for patient family care volunteers shall include a minimum of 12 hours. Staff shall be required to participate in a minimum of eight hours included with other job specific training.

(b) Training for hospice staff, including patient family volunteers, providing direct patient and family services shall include, but not be limited to the following:

(1) an introduction to hospice;
(2) the patient family volunteer role in hospice care;
(3) concepts of death and dying;
(4) communication skills;
(5) care and comfort measures;
(6) diseases and medical conditions;
(7) psychosocial and spiritual issues related to death and dying;
(8) the concept of the hospice family;
(9) stress management;
(10) bereavement;
(11) infection control;
(12) safety;
(13) confidentiality; and
(14) patient rights.

(c) In addition to the training described in Paragraph (b) of this Rule, the following additional training shall be provided to hospice caregivers assigned to a hospice residential facility:

(1) training specific to the types of medications being administered when assisting the patient with self administration of medicines and provision of personal care from a curriculum approved by the Division of Health Service Regulation;
(2) orientation and instruction specific to the care needs of individual patients in the hospice residential facility; and
(3) notification criteria for licensed nursing staff as defined in the agency policies and procedures.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; February 1, 1995; November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .0504 HOME MEDICAL EQUIPMENT AND SUPPLIES

(a) The hospice shall make arrangements for obtaining any necessary supplies, equipment or prosthetic devices needed by the patient in the home, e.g., dressings, catheters, and oxygen. If the agency provides its own equipment and supplies, such services shall be in compliance with G.S. 90-85.22 unless exempted by the law.

(b) The agency shall have policies that address at a minimum:

(1) Set-up, delivery, electrical safety and environmental requirements for equipment.

(2) Proper cleaning and storage, preventive maintenance and repair according to manufacturer's guidelines.

(3) Transportation, tracking and recall of equipment to meet all applicable regulatory requirements.

(4) Emergency preparedness and backup of systems for equipment or power failure.

(5) Patient instruction materials for each item of home medical equipment or supplies provided. Appropriate staff shall document the instruction.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .0505 SERVICES ARRANGED WITH OTHER AGENCIES AND INDIVIDUALS

(a) When a hospice makes arrangements for the provision of services by other agencies and individuals; there shall be a written agreement, signed by both parties prior to the initiation of services, which includes the following:

(1) the specific service to be provided;
(2) the period of time the contract is to be in effect;
(3) the availability of service;
(4) the financial arrangements;
(5) the provision for supervision of contracted personnel where applicable;
(6) the verification that any individual providing services is appropriately licensed or registered as required by statute;
(7) the assurance that individuals providing services under contractual arrangement meet the same requirements as found in this Subchapter for hospice staff;
(8) the provision for the documentation of services provided in the patient's medical record; and
(9) provision for the sharing of assessment and care plan data.

(b) All contracted services shall be provided in accordance with the orders of the attending physician and the care plan.

(c) The hospice shall assure that all contracted services are provided in accordance with the agreement. The agreement shall be reviewed annually and updated as needed.

(d) The hospice shall provide information and training as necessary on the hospice philosophy and concept of care to all agencies and individuals providing contracted services.

(e) Contract providers of direct patient care shall document services on the day of care, and shall submit, every two weeks at a minimum, records of all services provided within that timeframe.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

SECTION .0600 - PATIENT/FAMILY CARE

10A NCAC 13K .0601 ACCEPTANCE OF PATIENTS FOR HOSPICE SERVICES

A hospice shall implement and follow written policies governing the acceptance of patients which include at the minimum:

(1) Involvement of the interdisciplinary care team in making decisions regarding acceptance of patients and families and the designation of a primary caregiver.

(2) Initial assessment of the patient prior to acceptance to ensure that its resources are sufficient to meet the needs of the patient and family.

(3) Provision for a determination by the patient's physician that hospice care is appropriate and agreement to continue as the attending physician while the patient receives hospice services. All care and services provided shall be in accordance with the attending physician's written orders and the plan of care. Physician's orders shall be reviewed and signed by the physician at least every 90 days.

(4) Informed consent signed by the patient thereby agreeing to hospice services being provided.

(5) Advance notification of at least 48 hours to the patient or family when service provision is to be terminated, except in cases where the patient is in agreement with changes or there is a danger to a patient or staff member.

(6) Each patient or family accepted for hospice care shall receive written information pertaining to services available, including the means for contacting "on-call" personnel when needed and other information as necessary.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; June 1, 1991; November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .0605 HOME CARE

If a hospice agency wishes to provide home care services as defined in G.S 131E-136 and meets the requirements of 10A NCAC 13J and the standards for the specific home care services applied for, the hospice agency may apply for a home care license. The licensure inspection shall be conducted either at the Department offices or on-site.

History Note: *Authority G.S. 131E-202;*
Eff. April 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .0604 PATIENT'S RIGHTS AND RESPONSIBILITIES

(a) A hospice agency shall provide each patient with a written notice of the patient's rights and responsibilities in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of services. The agency shall maintain documentation showing that each patient has received a copy of his or her rights and responsibilities as defined in G.S. 131E-144.3.

(b) A hospice agency shall provide patients with a business hours telephone number for information, questions, or complaints about services provided by the agency. The agency shall also provide the Division of Health Service Regulation's complaints intake telephone numbers: within N.C. (800) 624-3004; outside of N.C. (919) 855-4500. The Division of Health Service Regulation shall investigate all allegations of non-compliance with the rules of this Subchapter.

(c) A hospice agency shall initiate an investigation within 72 hours of complaints made by a patient or his or her family. Documentation of both the existence of the complaint and the resolution of the complaint shall be maintained by the agency, for a minimum of one-year, in accordance with hospice agency policy and procedures.

History Note: *Authority G.S. 131E-202;*
Eff. February 1, 1996;
Readopted Eff. January 1, 2021.

SECTION .0700 - PATIENT/FAMILY CARE PLAN

10A NCAC 13K .0701 CARE PLAN

(a) The agency shall develop and implement policies and procedures that ensure a written care plan is developed and maintained for each patient and family. The plan shall be established by the interdisciplinary team in accordance with the orders of the attending physician and be based on the assessment of the patient's and family's medical, psychosocial, and spiritual needs. The patient and family care coordinator shall have the primary responsibility for assuring the implementation of the patient's care plan. The care plan shall include the following:

(1) the patient's diagnosis and prognosis;
(2) the identification of problems or needs and the establishment of goals that are appropriate for the patient;
(3) the types and frequency of services required to meet the goals; and
(4) the identification of personnel and disciplines responsible for each service.

(b) The care plan shall be reviewed by the interdisciplinary team members and updated monthly. The interdisciplinary team and other personnel shall meet at a minimum every 15 days for the purpose of care plan review and staff support. Minutes shall be kept of these meetings that include the date, names of those in attendance, and the names of the patients discussed. Additionally, entries shall be recorded in the medical records of those patients whose care plans are reviewed.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; November 1, 1989;
Readopted Eff. January 1, 2021.

SECTION .0800 - PHARMACEUTICAL AND MEDICAL TREATMENT ORDERS AND ADMINISTRATION

10A NCAC 13K .0801 PHARMACEUTICAL AND MEDICAL TREATMENT ORDERS

(a) The hospice shall develop and implement written policies and procedures for the administration of drugs and treatments including controlled substances.

(b) The original order for drugs and treatments shall be signed by the attending physician and incorporated in the patient's medical record. Signed faxed orders are acceptable. The receiver of faxed orders shall assure a hard copy is incorporated in the patient record. Thermal paper faxes are not acceptable.

(c) Verbal orders shall be given to a licensed nurse, physician or other person authorized by state law to implement orders, recorded and signed by the person receiving it and countersigned by the prescribing physician, or person authorized by the North Carolina Medical Board to sign for another physician. Care may commence with a verbal order documented in the patient record.

(d) Changes in drugs and treatments shall be signed by the physician and incorporated in the medical record within 30 days.

(e) Each patient's drug regimen shall be monitored to assure optimal symptom control in accordance with physician's orders. Individuals qualified to perform such reviews are registered nurses, pharmacists, licensed physicians, nurse practitioners, and physician's assistants approved to practice in North Carolina.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. April 1, 1996; November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .0802 ADMINISTRATION OF PHARMACEUTICALS

(a) In a private home, the administration of prescribed medications is the primary responsibility of the patient, family member or caregiver. Where special skills or knowledge are required, medication shall be administered by a licensed registered nurse, licensed practical nurse with training specified by the North Carolina Board of Nursing, or physician.

(b) In a licensed hospice residence, medications shall be administered by a licensed nurse. Exceptions to this requirement are as follows:

(1) persons who hold statutory authority to administer medications;
(2) hospice patients, their families or caregivers who provide personal care to individuals whose health care needs are incidental to the personal care required;
(3) administration of oral nutritional supplements;
(4) applications of non-systemic, topical skin preparations which have local effects only provided that ongoing, periodic assessment of any skin lesion present is carried out by a person licensed to make such assessments; and
(5) administration of commonly used cleansing enema solutions or suppositories with local effects only.

(c) In a hospice inpatient unit or freestanding hospice inpatient facility, medications shall be administered by a licensed nurse, in accordance with the agency's, policies or in accordance with the contractual agreement between the hospice and the facility.

(d) The administration of all medications must be documented in the patient's record by the licensed nurse, including those medications administered by the licensed nurse and those administered by the patient family or, caregiver, as ordered by the physician.

(e) The provision of medications shall be specified in the agency's policies or in accordance with the contractual agreement between the hospice and the facility.

(f) A hospice agency or facility shall develop and implement written policies and procedures to govern the procurement, storage, administration and disposal of all drugs and biologicals in accordance with federal and state laws.

(g) Medications used in the home are the property of the patient and family and shall be appropriately stored. Hospice staff shall encourage disposal of unused or discontinued medications. Witnessed or reported disposal of medications shall be documented by hospice staff in the patient's record.

(h) If the agency maintains an emergency drug kit, handling shall be in accordance with the North Carolina Board of Pharmacy 21 NCAC 46 .1400.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; June 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

SECTION .0900 - MEDICAL RECORDS

10A NCAC 13K .0901 CONTENT OF MEDICAL RECORD

(a) The hospice shall develop and implement policies and procedures to ensure that a medical record is maintained for each patient and is made available for licensure inspection. If the patient or responsible party wishes to deny the Department access to the medical record, that person shall sign a statement denying access. This statement shall be kept at the front of the record. If the patient is not able to approve or disapprove the release of such information for inspection, the patient's legal guardian shall make the decision and so indicate in writing.

(b) The record shall contain past and current medical and social data and include the following information:

(1) identification data (name, address, telephone, date of birth, sex, marital status);
(2) name of next of kin or legal guardian;
(3) names of other family members;
(4) religious preference and church affiliation and spiritual caregiver if appropriate;
(5) diagnosis, as determined by attending physician;
(6) authorization from attending physician for hospice care;
(7) source of referral;
(8) initial assessments, including physical, social, spiritual, environmental, and bereavement;
(9) consent for care form;
(10) physician's orders for drugs, treatments and other special care, diet, activity and other specific therapy services;
(11) care plan;
(12) clinical notes containing a record of all professional services provided directly or by contract with entries signed by the individual providing the services;
(13) nurse aide and hospice caregiver notes describing activities performed and pertinent observations;
(14) a copy of the signed patient's rights form or documentation of its delivery;
(15) patient family volunteer notes, as applicable, indicating type of contact, activities performed and time spent;
(16) discharge summary to include services provided, or reason for discharge if services are terminated prior to the death of the patient; and
(17) bereavement counseling notes.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. April 1, 1996; February 1, 1995; November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .0902 RECORD CONTENT, HANDLING AND RETENTION

(a) The hospice agency shall develop and implement written policies governing the content, handling and retention of patient records.

(b) The agency shall maintain a patient record for each patient. Each page of the patient record shall have the patient's name. All entries in the record shall reflect the actual date of entry. Reference to any activity which occurred on a date prior to the date of entry shall be identified as a late or out of sequence entry. A system for maintaining originals and copies shall be described in the agency policies and procedures.

(c) The agency shall assure that originals of patient records are kept confidential and secure on the licensed premises unless in accordance with Rule .0209 of this Subchapter, or subpoenaed by a court of legal jurisdiction, or to conduct an evaluation as required in Rule .1001 of this Subchapter.

(d) If a record is removed to conduct an evaluation, the record shall be returned to the agency premises within five working days. The agency shall maintain a sign out log that includes to whom the record was released, patient's name and date removed.

(e) A copy of the patient record for each patient must be readily available to the hospice staff providing services or managing the delivery of such services.

(f) Patient records shall be retained for a period of not less than three years from the date of discharge of the patient, unless the patient is a minor in which case the record must be retained until five years after the patient's eighteenth birthday. If a minor patient dies, as opposed to being discharged for other reasons, the minor's records must be retained at least five years after the minor's death. When an agency ceases operation, the Department shall be notified in writing where the records will be stored for the required retention period.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

SECTION .1000 - EVALUATION

10A NCAC 13K .1001 EVALUATION REQUIRED

(a) The hospice shall develop and implement policies and a written plan for the implementation of a comprehensive assessment at least annually of its overall program and performance. The quality and appropriateness of care provided shall be assessed with the findings used to verify policy implementation, to identify problems and to establish problem resolution and policy revision as necessary.

(b) The hospice shall determine what individuals will carry out the evaluation. Representatives of the governing body, hospice staff, the interdisciplinary care team, and other appropriate professionals may be used.

(c) The evaluation shall include, as a minimum, a review of all policies and procedures and a medical record review.

(d) Documentation of the evaluation shall include the names and qualifications of the persons carrying out the evaluation, the criteria and methods used to accomplish it, and the action taken by the agency as a result of the findings.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

SECTION .1100 - HOSPICE RESIDENTIAL CARE

10A NCAC 13K .1101 ADMINISTRATION

(a) Hospice residences must conform to the rules outlined in 10A NCAC 13K .0100 through .1000.

(b) The hospice shall maintain administrative control of and responsibility for the provision of all services.

(c) The governing body shall have written policies and procedures governing the admission and delivery of all residential and inpatient hospice care services, including the management of medical and other emergencies.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .1102 HOSPICE RESIDENCE STAFFING

(a) There shall be trained hospice caregivers on duty 24 hours a day. A registered nurse shall be continuously available, for consultation and direct participation in nursing care. The registered nurse shall be on site when required to perform duties specified in the Nurse Practice Act. Supervision shall be provided by the Patient and Family Care Coordinator who may delegate this responsibility to the registered nurse on call.

(b) There shall be at least two staff on duty at all times.

(c) All staff, including patient family volunteers, counselors and clergy, shall complete training specific to dealing with the terminally ill and their families.

(d) Nurse aides employed to provide direct care shall be supervised by licensed nurses.

(e) Interdisciplinary team services shall be provided in accordance with the hospice plan of care.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Amended Eff. February 1, 1996; February 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .1103 PHARMACEUTICAL SERVICES

(a) The hospice shall establish and implement written policies and procedures to govern the procurement, storage, administration and disposal of all drugs and biologicals in accordance with federal and state laws.

(b) Pharmaceutical services shall be provided directly or through written agreement under the supervision of a licensed pharmacist and in accordance with Rule .0505 of this Subchapter. The pharmacist's duties shall include, but are not limited to the following:

(1) advising the hospice and the hospice interdisciplinary team on all matters pertaining to the procurement, storage, administration, disposal and record-keeping of drugs and biologicals; interactions of drugs; and counseling staff on appropriate and new drugs;

(2) inspecting all drug storage areas at least monthly;

(3) conducting patients' drug regimen reviews frequently enough to monitor symptom control, no less often than monthly, with appropriate recommendations to the physician and hospice staff.

(c) The hospice shall establish and implement written policies and procedures for drug control and accountability. Records of receipt and disposition of all controlled drugs shall be maintained for accurate reconciliation.

(d) Medications shall be labeled as described in the Pharmacy Laws of North Carolina.

(e) Medications must be stored in locked areas, at proper temperature, and accessible only to authorized persons in accordance with federal and state laws. Separately locked compartments must be provided for storage of controlled substances listed in the North Carolina Controlled Substances Act and other drugs subject to abuse.

(f) Controlled substances no longer needed by the patient are to be disposed of in compliance with the North Carolina Controlled Substances Act.

(g) The hospice shall maintain an emergency drug kit appropriate to the needs of the facility, assembled in consultation with the pharmacist and readily available for use. The pharmacist shall check and restock the kit as necessary, at least monthly, or more often if needed.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .1104 DIETARY SERVICES

(a) The hospice shall develop and maintain written policies and procedures for dietary services.

(b) Dietary services shall be provided directly or through written agreement with a food service company. Any written agreement shall meet the provisions of Rule .0505 of this Subchapter.

(c) The hospice shall offer the residents' favorite foods in their diets.

(d) The food service shall be planned and staffed to serve at least three meals throughout the day, timed to meet the needs of the residents. No more than 14 hours shall elapse between an evening meal which shall consist of three or more menu items, including a protein, and breakfast that includes a protein.

(e) The hospice shall appoint a staff member trained or experienced in nutrition care services to:

(1) plan menus to meet the nutritional needs of the residents; and

(2) supervise meal preparation and service.

(f) Therapeutic diets shall be prescribed by the physician and planned by a licensed dietitian/nutritionist or licensed nutritionist.

(g) Between-meal snacks from the basic food groups shall be offered and be available on a 24-hour basis.

(h) The procurement, storage, and refrigeration of food, refuse handling, and pest control shall comply with 15A NCAC 18A which are hereby incorporated by reference, including subsequent amendments, promulgated by the Commission for Public Health.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Readopted Eff. January 1, 2021.

10A NCAC 13K .1105 HOSPICE VISITATION

(a) The hospice shall:

(1) provide areas that ensure privacy for visitation and at the time of death;

(2) arrange for family members to remain with the patient overnight.

(b) Family and friends may visit at any hour. Children and pets shall not be excluded.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .1106 INFECTION CONTROL

(a) The hospice shall develop and implement an infection control program which shall aim to protect the residents, family and personnel from hospice or community associated infections.

(b) There shall be written policies and procedures governing the infection control program, developed by the hospice administrator and medical director and approved by the governing body.

(c) Universal precautions, as specified by the Centers for Disease Control (CDC), shall be defined in writing and strictly followed.

(d) All employees shall wear clean garments or protective clothing at all times and shall practice good personal hygiene and cleanliness.

(e) A procedure shall be developed whereby the implementation of the infection control program is monitored on a monthly basis.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .1107 HOUSEKEEPING AND LINENS

(a) Requirements for linens and personal care articles shall include:

(1) The use of common towels, washcloths, cups or any other personal care articles is prohibited.

(2) Each resident shall have a supply of towels, washcloths and soap.

(3) There shall be a supply of clean bed linens, towels, and washcloths.

(4) There shall be a separate closed area for storage of clean linen.

(5) Clean bed linens shall be changed as often as necessary, but no less than twice each week.

(6) Mattress pads and pillows shall be of washable material.

(7) There shall be separate storage for soiled linen and clothing. Such storage may consist of individual plastic bags or covered hampers or a soiled linen room. All personnel shall wash their hands thoroughly after handling soiled linen.

(8) Laundry equipment shall be maintained in the facility or arrangements made with a commercial laundry to handle soiled linen.

(b) Housekeeping requirements are as follows:

(1) Housekeeping practices and procedures shall be employed to keep the home free from offensive odors, and accumulations of dirt, rubbish and dust.

(2) Cleaning shall be performed in a manner to minimize the spread of pathogenic organisms. Floors shall be cleaned regularly. Polishes on floors shall provide a non-skid finish; throw or scatter rugs shall not be used except for non-skid entrance mats.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .1108 REPORT OF DEATH

The hospice shall have a written plan to be followed in case of patient death. The plan must provide for:

(1) collection of data needed for the death certificate, as required by G.S. 130A-117;
(2) recording time of death;
(3) pronouncement of death;
(4) notification of attending physician responsible for signing death certificate;
(5) notification of next of kin or legal guardian;
(6) authorization and release of body to funeral home; and
(7) notification to the Department of any death resulting from an injury, accident, or other possible unnatural causes.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .1109 RESIDENT CARE AREAS

(a) A facility shall meet the following requirements for resident bedrooms:

(1) private bedroom with not less than 100 square feet of floor area or semi-private bedroom with not less than 80 square feet of floor area per bed shall be provided;

(2) infants and small children shall not share a bedroom with an adult resident unless requested by the resident and families;

(3) each bedroom shall be furnished with a bed, a mattress protected by waterproof material, a mattress pad, a pillow, and one chair per resident;

(4) each bedroom shall be provided with one closet or wardrobe per bed. Each closet or wardrobe shall have clothing storage space of not less than 48 cubic feet per bed with one-half of this space for hanging clothes;

(5) each bedroom shall:

(A) be located at or above grade level;

(B) have provisions to ensure visual privacy for treatment or visiting; and

(C) be equipped with a towel rack for each resident;

(6) each bedroom shall provide lighting for treatment and non-treatment needs, 50 foot-candles for treatment needs, and 35 foot-candles for non-treatment needs; and

(7) no resident bedroom shall be accessed through a bathroom, kitchen, or another bedroom.

(b) A facility shall meet the following requirements for bathrooms:

(1) bathrooms shall be directly accessible to each resident bedroom without going through the general corridors. One bathroom may serve up to four residents. The bathroom doorway shall be a minimum 32-inch clear opening;

(2) each bathroom shall be furnished with the following:

(A) a toilet with grab bars;

(B) a sink trimmed with valves that can be operated without hands. If the sink is equipped with blade handles, the blade handles shall not be less than four inches in length. If the sink faucet depends on the building electrical service for operation, the faucet must have an emergency power source or battery backup capability. If the faucet has battery operated sensors, the facility shall have a maintenance policy to keep extra rechargeable or non-rechargeable batteries on premises for the faucets;

(C) a mirror;

(D) soap, paper towel dispensers, and waste paper receptacle with a removable impervious liner; and

(E) a tub or shower.

(c) Each facility shall provide:

(1) an area for charting;

(2) storage provisions for personal effects of staff;

(3) storage areas for supplies and resident care equipment;

(4) storage area(s) for housekeeping equipment and cleaning supplies;

(5) a medication preparation area with a counter, a sink trimmed with valves that can be operated without hands, locked medication storage, and a double locked narcotic storage area under visual control of staff. If the sink is equipped with blade handles, the blade handles shall not be less than four inches in length. If the sink faucet depends on the building electrical service for operation, the faucet must have an emergency power source or battery backup capability. If the faucet has battery operated sensors, the facility shall have a maintenance policy to keep extra rechargeable or non-rechargeable batteries on premises for the faucets;

(6) a lockable refrigerator for drug storage only or a separate locked box in a facility refrigerator. The refrigerator must be capable of maintaining a temperature range of 36 degrees F (2 degrees C) to 46 degrees F (8 degrees C);

(7) a kitchen with:

(A) a refrigerator;

(B) a cooking appliance ventilated to the outside;

(C) a 42-inch minimum double-compartment sink and domestic dishwashing machine capable of sanitizing dishes with 160 degrees F water; and

(D) storage space for non-perishables;

(8) a separate dining area measuring not less than 20 square feet per resident bed;

(9) a recreational and social activities area with not less than 150 square feet of floor area exclusive of corridor traffic;

(10) a nurses' calling system shall be provided:

(A) in each resident bedroom for each resident bed. The call system activator shall be such that they can be activated with a single action and remain on until deactivated by staff at the point of origin. The call system activator shall be within reach of a resident lying on the bed. In rooms containing two or more call system activators, indicating lights shall be provided at each calling station;

(B) nurses' calling systems that provide two-way voice communication shall be equipped with an indicating light at each calling station that lights and remains lighted as long as the voice circuit is operating;

(C) a nurses' call emergency activator shall be provided at each residents' use toilet fixture, bath, and shower. The call system activator shall be accessible to a resident lying on the floor; and

(D) calls shall register with the floor staff and shall activate a visible signal in the corridor at the resident's door. In multi-corridor units, additional visible signals shall be installed at corridor intersections; and

(11) heating and air conditioning equipment that can maintain a temperature range between 68 degrees and 80 degrees Fahrenheit, even upon loss of utility power.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Amended Eff. February 1, 1995;
Readopted Eff. October 1, 2021.

10A NCAC 13K .1110 FURNISHINGS

Furnishings of the residence shall be home-like and non-institutional and include lounge furniture in addition to furnishings in resident rooms. Accessories such as wallpaper, bedspreads, carpets and lamps shall be selected to create such an atmosphere. Provision shall be made for each resident to bring items from home to place about the room to the extent available space allows.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .1111 HOSPICE RESIDENCE ZONING AND FIRE SAFETY REQUIREMENTS

Hospices maintained as residential facilities shall provide documentation of approval from local zoning commissions, fire departments and building departments.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .1112 DESIGN AND CONSTRUCTION

(a) A new facility or remodeling of an existing facility shall meet the requirements of the North Carolina State Building Codes, which are incorporated by reference, including all subsequent amendments and editions, in effect at the time of licensure, construction, additions, alterations, or repairs. Copies of these codes may be purchased from the International Code Council online at https://shop.iccsafe.org/ at a cost of eight hundred fifty-eight dollars ($858.00) or accessed electronically free of charge at https://codes.iccsafe.org/codes/north-carolina. Existing licensed facilities shall meet the requirements of the North Carolina State Building Codes in effect at the time of licensure, construction, or remodeling.

(b) Each facility shall be planned, constructed, and equipped to support the services to be offered in the facility.

(c) Any existing building converted to a hospice facility shall meet all requirements of a new facility.

(d) The sanitation, water supply, sewage disposal, and dietary facilities shall meet the requirements of 15A NCAC 18A .1300, which is incorporated by reference including subsequent amendments.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018;
Amended Eff. October 1, 2021.

10A NCAC 13K .1113 PLANS AND SPECIFICATIONS

(a) When construction or remodeling of a facility is planned, one copy of construction documents and specifications shall be submitted by the owner or the owner's appointed representative to the Department for review and approval. Schematic design drawings and design development drawings may be submitted for approval prior to the required submission of construction documents.

(b) Approval of construction documents and specifications shall be obtained from the Department prior to licensure. Approval of construction documents and specifications shall expire one year after the date of approval unless a building permit for the construction has been obtained prior to the expiration date of the approval of construction documents and specifications.

(c) If an approval expires, renewed approval shall be issued by the Department, provided revised construction documents and specifications meeting the standards established in Sections .1100 and .1200 of this Subchapter are submitted by the owner or owner's appointed representative and reviewed by the Department.

(d) Any changes made during construction shall require the approval of the Department to ensure compliance with the standards established in Sections .1100 and .1200 of this Subchapter.

(e) Completed construction or remodeling shall conform to the standards established in Sections .1100 and .1200 of this Subchapter. Construction documents and building construction, including the operation of all building systems, shall be approved in writing by the Department prior to licensure or patient and resident occupancy.

(f) The owner or owner's appointed representative shall notify the Department in writing either by U.S. Mail or e-mail when the construction or remodeling is complete.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Amended Eff. February 1, 1996;
Readopted Eff. October 1, 2021.

10A NCAC 13K .1114 PLUMBING

For hospice residential facilities with five or more residents, a 50-gallon quick recovery water heater is required. For hospice residential facilities with fewer than five residents, a 40-gallon quick recovery water heater is required.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Readopted Eff. October 1, 2021.

10A NCAC 13K .1115 WASTE DISPOSAL

(a) Sewage shall be discharged into a public sewer system, or in the absence of a public sewer system, sewage shall be disposed of in a manner approved by the North Carolina Department of Health and Human Services, Division of Public Health, Environmental Health Section.

(b) Garbage and rubbish shall be stored in impervious containers in a manner as to prevent insect breeding and public health nuisances. Impervious containers with tight-fitting lids shall be provided and kept clean and in good repair. Garbage shall be removed from the outside storage at least once a week to a disposal site approved by the local health department having jurisdiction.

(c) The facility or unit shall take measures to keep insects, rodents, and other vermin out of the residential care facility. All openings to the outer air shall be protected against the entrance of flying insects by screens, closed doors, closed windows, or other means.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Readopted Eff. October 1, 2021.

10A NCAC 13K .1116 APPLICATION OF PHYSICAL PLANT REQUIREMENTS

The physical plant requirements for each hospice residential facility or unit shall be applied as follows:

(1) New construction shall comply with all the requirements of this Section.

(2) Except where otherwise specified, existing buildings shall meet the licensure and code requirements in effect at the time of licensure, construction, alteration, or modification.

(3) Rules contained in this Section are minimum requirements and are not intended to prohibit buildings, systems, or operational conditions that exceed minimum requirements.

(4) The Division may grant an equivalency to allow alternate methods, procedures, design criteria, or functional variation from the requirements of this Rule and the rules contained in this Section. The equivalency may be granted by the Division when a governing body submits a written equivalency request to the Division that states the following:

(a) the rule citation and the rule requirement that will not be met because strict conformance with current requirements would be:

(i) impractical;

(ii) unable to be met due to extraordinary circumstances;

(iii) unable to be met due to new programs; or

(iv) unable to be met due to unusual conditions;

(b) the justification for the equivalency; and

(c) how the proposed equivalency meets the intent of the corresponding rule requirement.

(5) In determining whether to grant an equivalency request, the Division shall consider whether the request will reduce the safety and operational effectiveness of the facility. The governing body shall maintain a copy of the approved equivalence issued by the Division.

(6) Where rules, codes, or standards have any conflict, the more stringent requirement shall apply.

History Note: *Authority G.S. 131E-202;*
Eff. February 1, 1996;
Readopted Eff. October 1, 2021.

SECTION .1200 - HOSPICE INPATIENT CARE

10A NCAC 13K .1201 REQUIREMENTS FOR HOSPICE INPATIENT UNITS

(a) Hospice inpatient facilities or units shall conform to the rules outlined in Sections .0100 through .1100 of this Subchapter and the rules of this Section.

(b) Hospice inpatient units located in a licensed hospital shall meet the requirements of 10A NCAC 13B, which is incorporated by reference with subsequent amendments except for rules: 10A NCAC 13B .1912, .1919, .1922, and .1923.

(c) Hospice inpatient units located in a licensed nursing facility shall meet the requirements of 10A NCAC 13D, which is incorporated by reference with subsequent amendments.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Readopted Eff. October 1, 2021.

10A NCAC 13K .1202 ADDITIONAL STAFFING REQUIREMENTS FOR HOSPICE INPATIENT UNITS

(a) All nursing services shall be provided under the supervision of a registered nurse.

(b) A facility providing respite care must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed by the physician and must be kept comfortable, clean, well-groomed and protected from accident, injury and infection. The presence of a Registered Nurse (RN) to provide direct care on all shifts is not required for patients receiving general inpatient care for respite unless specific nursing needs are in an individual patient's plan of care. If a patient in an inpatient facility is receiving general inpatient care for symptom management, then the 24-hour patient care RN staff must be available.

(c) Considerations for determining sufficiency of nursing personnel include:

(1) number of patients;
(2) specific patient care requirements;
(3) family care needs; and
(4) availability of support from other interdisciplinary team members.

(d) Hospice caregivers shall only provide care to patients in licensed hospice residential beds in a combined hospice inpatient and residential facility.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Amended Eff. January 1, 2010; February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .1203 ADDITIONAL SERVICES REQUIRED FOR HOSPICE INPATIENT CARE

(a) The hospice shall assure, directly or through written agreement, the provision of duly licensed radiology, laboratory, pathology and other medically related services in accordance with physicians' orders. Written agreement shall be in keeping with Rule .0505 of this Subchapter. If those services are provided directly, written policies and procedures shall govern their implementation.

(b) Radiology, laboratory and pathology services shall be under the direction of a physician qualified by education, training and experience to assume that function.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018.

10A NCAC 13K .1204 ADDITIONAL PATIENT CARE AREA REQUIREMENTS FOR HOSPICE INPATIENT UNITS

(a) A facility shall meet the following requirements for patient bedrooms:
- (1) private bedrooms shall be provided with not less than 100 square feet of floor area;
- (2) semi-private bedrooms with not less than 80 square feet of floor area per bed; and
- (3) floor space for closets, toilet rooms, vestibules, or wardrobes shall not be included in the floor areas required by this Paragraph.

(b) A facility shall meet the following requirements for dining, recreation, and common use areas:
- (1) floor space for dining, recreation, and common use shall not be less than 30 square feet per bed;
- (2) the dining, recreation, and common use areas required by this Paragraph may be combined; and
- (3) floor space for physical and occupational therapy shall not be included in the areas required by this Paragraph.

(c) A facility shall meet the following requirements for toilet rooms, tubs, showers, and central bathing areas:
- (1) a toilet room shall contain a toilet fixture and a sink trimmed with valves that can be operated without hands. If the sink is equipped with blade handles, the blade handles shall not be less than four inches in length. If the sink faucet depends on the building electrical service for operation, the faucet shall be connected to the essential electrical system. For the purposes of the rules of this Section, the "essential electrical system" means a system comprised of alternate sources of power and all connected distribution systems and ancillary equipment, designed to ensure continuity of electrical power to designated areas and functions of a facility during disruption of normal power sources, and also to minimize disruption within the internal wiring system as defined by the North Carolina State Building Codes: Electrical Code. If the faucet has battery operated sensors, the facility shall have a maintenance policy to keep extra rechargeable or non-rechargeable batteries on premises for the faucets;
- (2) if a sink is provided in each bedroom, the toilet room is not required to have a sink;
- (3) a toilet room shall be accessible from each bedroom without going through the general corridors;
- (4) one toilet room may serve two bedrooms, but not more than four beds; and
- (5) a minimum of one central bathing area. In multi-level facilities, each patient floor shall contain a minimum of one central bathing area. Central bathing area(s) shall be provided with the following:
  - (A) wheelchair and stretcher accessible for staff to bathe a patient who cannot perform this activity independently;
  - (B) a bathtub, a manufactured walk-in bathtub, a similar manufactured bathtub designed for easy transfer of patients and residents into the tub, or a shower designed and equipped for unobstructed ease of stretcher entry and bathing on three sides. Bathtubs shall be accessible on three sides. Manufactured walk-in bathtubs or a similar manufactured bathtub shall be accessible on two sides;
  - (C) a roll-in shower designed and equipped for unobstructed ease of shower chair entry and use. If a bathroom with a roll-in shower designed and equipped for unobstructed ease of shower chair entry adjoins each bedroom in the facility, the central bathing area is not required to have a roll-in shower;
  - (D) toilet fixture and lavatory; and
  - (E) an individual cubicle curtain enclosing each toilet, tub, and shower. A closed cubicle curtain at one of these plumbing fixtures shall not restrict access to the other plumbing fixtures.

(d) For each nursing unit on each floor, the following shall be provided:
- (1) a medication preparation area with:
  - (A) a counter;
  - (B) a double locked narcotic storage area under the visual control of nursing staff;
  - (C) a medication refrigerator;
  - (D) medication storage visible by staff standing on the floor;
  - (E) cabinet storage; and
  - (F) a sink trimmed with valves that can be operated without hands. If the sink is equipped with blade handles, the blade handles shall not be less than four inches in length. If the sink faucet depends on the building electrical service for operation, the faucet shall be connected to the essential electrical system. If the faucet has battery operated sensors, the

facility shall have a maintenance policy to keep extra rechargeable or non-rechargeable batteries on premises for the faucets;

(2) a clean utility room with:
  (A) a counter;
  (B) storage; and
  (C) a sink trimmed with valves that can be operated without hands. If the sink is equipped with blade handles, the blade handles shall not be less than four inches in length. If the sink faucet depends on the building electrical service for operation, the faucet shall be connected to the essential electrical system. If the sink has battery operated sensors, the facility shall have a maintenance policy to keep extra rechargeable or non-rechargeable batteries on premises for the faucets;

(3) a soiled utility room with:
  (A) a counter;
  (B) storage; and
  (C) a sink trimmed with valves that can be operated without hands. If the sink is equipped with blade handles, the blade handles shall not be less than four inches in length. If the sink faucet depends on the building electrical service for operation, the faucet shall be connected to the essential electrical system. If the faucet has battery operated sensors, the facility shall have a maintenance policy to keep extra rechargeable or non-rechargeable batteries on premises for the faucets. The soiled utility room shall be equipped for the cleaning and sanitizing of bedpans as required by 15A NCAC 18A .1312, which is incorporated by reference including subsequent amendments;

(4) a nurses' toilet and locker space for personal belongings;

(5) an audiovisual nurse-patient call system arranged to ensure that a patient's call in the facility notifies and directs staff to the location where the call was activated;

(6) a soiled linen storage room with a hand sanitizing dispenser. If the soiled linen storage room is combined with the soiled utility room, a separate soiled linen storage room is not required;

(7) a clean linen storage room provided in one or more of the following:
  (A) a separate linen storage room;
  (B) cabinets in the clean utility room; or
  (C) a linen closet; and

(8) a janitor's closet.

(e) Dietary services and laundry each shall have a separate janitor's closet.

(f) Stretcher and wheelchair storage shall be provided.

(g) The facility shall provide storage at the rate of not less than five square feet of floor area per licensed bed. This storage space shall:

(1) be used by patients to store personal belongings and suitcases;

(2) be either in the facility or within 500 feet of the facility on the same site; and

(3) be in addition to the other storage space required by this Rule.

(h) Office space shall be provided for business transactions. Office space shall be provided for persons holding the following positions if these positions are provided:

(1) administrator;

(2) director of nursing;

(3) social services director;

(4) activities director; and

(5) physical therapist.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Amended Eff. February 1, 1996;
Readopted Eff. October 1, 2021.

10A NCAC 13K .1205 FURNISHINGS FOR HOSPICE INPATIENT CARE

(a) A facility shall provide handgrips at all toilet and bath facilities used by patients. Handrails shall be provided on both sides of all corridors where corridors are defined by walls and used by patients.

(b) For each nursing unit on each floor, the following shall be provided:

(1) a nourishment station separated from the nurses' station with:

(A) work space;

(B) cabinets;

(C) refrigerated storage;

(D) a sink trimmed with valves that can be operated without hands. If the sink is equipped with blade handles, the blade handles shall not be less than four inches in length. If the sink faucet depends on the building electrical service for operation, the faucet shall be connected to the essential electrical system. If the faucet has battery operated sensors, the facility shall have a maintenance policy to keep extra rechargeable or non-rechargeable batteries on premises for the faucets; and

(E) a small stove, microwave, or hot plate; and

(2) a nurses' station with:

(A) desk space for writing;

(B) storage space for office supplies; and

(C) storage space for patients' records.

(c) A facility shall provide flame resistant cubicle curtains in multi-bedded rooms.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Readopted Eff. October 1, 2021.

10A NCAC 13K .1206 HOSPICE INPATIENT FIRE AND SAFETY REQUIREMENTS

(a) The hospice shall establish written policies and procedures governing disaster preparedness and fire protection.

(b) The hospice shall have detailed written plans and procedures to meet potential emergencies and disasters, including fire and severe weather.

(c) The plans and procedures shall be made available upon request to local or regional emergency management offices.

(d) The facility shall provide training for all employees in emergency procedures upon employment and annually.

(e) The facility shall conduct unannounced drills using the emergency procedures.

(f) The facility shall ensure that:

(1) the patients' environment remains as free of accident hazards as possible; and

(2) each patient receives adequate supervision and assistance to prevent accidents.

(g) The fire protection plan shall include:

(1) instruction for all personnel in use of alarms, firefighting equipment, methods of fire containment, evacuation routes, procedures for calling the fire department, and the assignment of specific tasks to all personnel in response to an alarm; and

(2) fire drills for each shift of personnel at least quarterly.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Readopted Eff. October 1, 2021.

10A NCAC 13K .1207 HOSPICE INPATIENT REQUIREMENTS FOR HEATING/AIR CONDITIONING

A facility shall provide heating and cooling systems complying with the following:

(1) The American National Standards Institute and American Society of Heating, Refrigerating, and Air Conditioning Engineers Standard 170: Ventilation of Health Care Facilities, which is incorporated by reference, including all subsequent amendments and editions, and may be purchased for a cost of ninety-four dollars ($94.00) online at https://www.techstreet.com/ashrae/index.html. This incorporation does not apply to Section 9.1, Table 9-1 Design Temperature for Skilled Nursing Facility. The environmental temperature control systems shall be capable of maintaining temperatures in the facility at 71 degrees F. minimum in the heating season and a maximum of 81 degrees F. during non-heating season, even upon loss of utility power; and

(2) The National Fire Protection Association 90A: Standard for the Installation of Air-Conditioning and Ventilating Systems, which is incorporated by reference, including all subsequent amendments and editions, and may be purchased at a cost of fifty dollars and fifty cents ($50.50) from the National Fire Protection Association online at http://www.nfpa.org/catalog/ or accessed electronically free of charge at http://www.nfpa.org/aboutthecodes/AboutTheCodes.asp?DocNum=90A.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Readopted Eff. October 1, 2021.

10A NCAC 13K .1208 HOSPICE INPATIENT REQUIREMENTS FOR EMERGENCY ELECTRICAL SERVICE

A facility shall provide an emergency electrical service for use in the event of failure of the normal electrical service. This emergency electrical service shall consist of the following:

(1) In any existing facility:
   (a) type 1 or 2 emergency lights as required by the North Carolina State Building Codes: Electrical Code;
   (b) additional emergency lights for all nurses' stations required by Rule .1205(b)(2) of this Section, medication preparation areas required by Rule .1204(d)(1) of this Section, storage areas, and for the telephone switchboard, if applicable;
   (c) one or more portable battery-powered lamps at each nurses' station; and
   (d) a source of emergency power for life-sustaining equipment, if the facility admits or cares for occupants needing such equipment, to ensure continuous operation with on-site fuel storage for a minimum of 72 hours.

(2) An emergency power generating set, including the prime mover and generator, shall be located on the premises and shall be reserved exclusively for supplying the essential electrical system.

(3) Emergency electrical services shall be provided as required by the North Carolina State Building Codes: Electric Code with the following modification: Section 517.10(B)(2) of the North Carolina State Building Codes: Electrical Code shall not apply to new facilities.

(4) The following equipment, devices, and systems that are essential to life safety and the protection of important equipment or vital materials shall be connected to the equipment branch of the essential electrical system as follows:
   (a) nurses' calling system;
   (b) fire pump, if installed;
   (c) sewerage or sump lift pump, if installed;
   (d) one elevator, where elevators are used for vertical transportation of patients;
   (e) equipment such as burners and pumps necessary for operation of one or more boilers and their necessary auxiliaries and controls, required for heating and sterilization, if installed; and
   (f) task illumination of boiler rooms, if applicable.

(5) The following equipment, devices, and systems that are essential to life safety and the protection of important equipment or vital materials shall be connected to the life safety branch of the essential electrical system as follows:
   (a) alarm system, including fire alarm actuated at manual stations, water flow alarm devices of sprinkler systems if electrically operated, fire detecting and smoke detecting systems, paging or speaker systems if intended for issuing instructions during emergency conditions, and alarms required for nonflammable medical gas systems, if installed; and
   (b) equipment necessary for maintaining telephone service.

(6) Where electricity is the only source of power normally used for the heating of space, an essential electrical system shall be provided for heating of patient rooms. Emergency heating of patient rooms shall not be required in areas where the facility is supplied by at least two separate generating sources or a network distribution system with the facility feeders so routed, connected, and protected that a fault any place between the generating sources and the facility will not likely cause an interruption of more than one of the facility service feeders.

(7) An essential electrical system shall be so controlled that after interruption of the normal electric power supply, the generator is brought to full voltage and frequency and connected within 10 seconds through one or more primary automatic transfer switches to all emergency lighting, alarms, and equipment necessary for maintaining telephone service. All other lighting and equipment required to be connected to the essential electrical system shall either be connected through the 10 second primary automatic transfer switching or shall be connected through delayed automatic or manual transfer switching. If manual transfer switching is provided, staff of the facility shall operate the manual transfer switch. Electrical outlets connected to the essential electrical system shall be marked for identification.

(8) Fuel shall be stored for the operation of the emergency power generator for a period not less than 72 hours, on a 24-hour per day operational basis with on-site fuel storage. The generator system shall be tested and maintained per National Fire Protection Association Health Care Facilities

Code, NFPA 99, 2012 edition, which is incorporated by reference, including all subsequent amendments and editions. Copies of this code may be purchased at a cost of seventy-nine dollars and fifty cents ($79.50) from the National Fire Protection Association - online at http://www.nfpa.org/catalog/ or accessed electronically free of charge at http://www.nfpa.org/aboutthecodes/AboutTheCodes.asp?DocNum=99. The facility shall maintain records of the generator system tests and shall make these records available to the Division for inspection upon request.

(9) The electrical emergency service at existing facilities shall comply with the requirements established in this Rule in effect at the time a license is first issued. Any remodeling of an existing facility that results in changes to the emergency electrical service shall comply with the requirements established in this Rule in effect at the time of remodeling.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Readopted Eff. October 1, 2021.

10A NCAC 13K .1209 HOSPICE INPATIENT REQUIREMENTS FOR GENERAL ELECTRICAL

(a) All main water supply shut off valves in the sprinkler system shall be electronically supervised so that if any valve is closed an alarm will sound at a continuously manned central station.

(b) No two adjacent emergency life safety branch lighting fixtures shall be on the same circuit.

(c) Receptacles in bathrooms shall have ground fault protection.

(d) Each patient bed location shall be provided with a minimum of eight single or four duplex receptacles.

(e) Each patient bed location shall be supplied by at least two branch circuits, one from the equipment branch and one from the normal system.

(f) The fire alarm system shall be installed to transmit an alarm automatically to the fire department that is legally committed to serve the area where the facility is located, by the direct and reliable method approved by local ordinances.

(g) In patient areas, fire alarms shall be gongs or chimes rather than horns or bells.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018;
Amended Eff. October 1, 2021.

10A NCAC 13K .1210 OTHER HOSPICE INPATIENT REQUIREMENTS

(a) A nurses' calling system shall be provided:

(1) in each patient bedroom for each patient bed. The call system activator shall be such that it can be activated with a single action and remain on until deactivated by staff at the point of origin. The call system activator shall be within reach of a patient lying on the bed. In rooms containing two or more call system activators, indicating lights shall be provided at each calling station;

(2) nurses' calling systems that provide two-way voice communication shall be equipped with an indicating light at each calling station that lights and remains lighted as long as the voice circuit is operating;

(3) a nurses' call emergency activator shall be provided at each patients' use toilet fixture, bath, and shower. The call system activator shall be accessible to a patient lying on the floor; and

(4) calls shall register with the floor staff and shall activate a visible signal in the corridor at the patient's door. In multi-corridor units, additional visible signals shall be installed at corridor intersections.

(b) At least one telephone shall be available in each area where patients are admitted and additional telephones or extensions as are necessary to ensure availability in case of need.

(c) General outdoor lighting shall be provided to illuminate walkways and drive.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018;
Amended Eff. October 1, 2021.

10A NCAC 13K .1211 ADDITIONAL PLUMBING REQUIREMENTS/HOSPICE INPATIENT UNITS

Hospice inpatient facilities or units shall provide a flow of hot water within safety ranges specified as follows:

(1) Patient Areas – 6 ½ gallons per hour per bed and at a temperature of 100 to 116 degrees F;
(2) Dietary Services – 4 gallons per hour per bed and at a minimum temperature of 140 degrees F; and
(3) Laundry Area – 4 ½ gallons per hour per bed and at a minimum temperature of 140 degrees F.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, 1991;
Readopted Eff. October 1, 2021.

10A NCAC 13K .1212 APPLICATION OF PHYSICAL PLANT REQUIREMENTS

The physical plant requirements for each hospice inpatient facility or unit shall be applied as follows:

(1) New construction shall comply with all the requirements of this Section.

(2) Except where otherwise specified, existing buildings shall meet the licensure and code requirements in effect at the time of licensure, construction, alteration, or modification.

(3) Rules contained in this Section are minimum requirements and are not intended to prohibit buildings, systems, or operational conditions that exceed minimum requirements.

(4) The Division may grant an equivalency to allow alternate methods, procedures, design criteria, or functional variation from the requirements of this Rule and the rules contained in this Section. The equivalency may be granted by the Division when a governing body submits a written equivalency request to the Division that states the following:

(a) the rule citation and the rule requirement that will not be met because strict conformance with current requirements would be:

(i) impractical;

(ii) unable to be met due to extraordinary circumstances;

(iii) unable to be met due to new programs; or

(iv) unable to be met due to unusual conditions;

(b) the justification for the equivalency; and

(c) how the proposed equivalency meets the intent of the corresponding rule requirement.

(5) In determining whether to grant an equivalency request, the Division shall consider whether the request will reduce the safety and operational effectiveness of the facility. The governing body shall maintain a copy of the approved equivalence issued by the Division.

(6) Where rules, codes, or standards have any conflict, the more stringent requirement shall apply.

History Note: *Authority G.S. 131E-202;*
Eff. February 1, 1996;
Readopted Eff. October 1, 2021.

G.S. 150B-21.3A Report for 10A NCAC 13K, HOSPICE LICENSING RULES

Agency - Medical Care Commission

Comment Period - February 14, 2025 - April 15, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
SUBCHAPTER 13K – HOSPICE LICENSING RULES	SECTION .0100 – GENERAL INFORMATION	10A NCAC 13K .0102	DEFINITIONS	Readopted Eff. January 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.3	Yes	Necessary	Select One	Select One	Select One
	SECTION .0200 LICENSE	10A NCAC 13K .0201	LICENSE REQUIRED	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.116	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .0202	APPLICATION FOR AND ISSUANCE OF A LICENSE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .0206	ADVERSE ACTION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .0208	INSPECTIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .0209	MULTIPLE PREMISES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.116	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .0210	COMPLIANCE WITH LAWS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.116	No	Necessary	Select One	Select One	Select One
	SECTION .0300 ADMINISTRATION	10A NCAC 13K .0301	AGENCY MANAGEMENT AND SUPERVISION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.100	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .0303	ADMINISTRATIVE FINANCIAL AND STATISTICAL RECORDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .0400 PERSONNEL	10A NCAC 13K .0401	PERSONNEL	Readopted Eff. January 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.60	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .0402	INSERVICE EDUCATION AND TRAINING	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.112	No	Necessary	Select One	Select One	Select One
	SECTION .0500 SCOPE OF SERVICES	10A NCAC 13K .0501	SERVICE REQUIREMENTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.70	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .0504	HOME MEDICAL EQUIPMENT AND SUPPLIES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.106	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .0505	SERVICES ARRANGED WITH OTHER AGENCIES AND INDIVIDUALS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.108	No	Necessary	Select One	Select One	Select One
	SECTION .0600 PATIENT/FAMILY CARE	10A NCAC 13K .0601	ACCEPTANCE OF PATIENTS FOR HOSPICE SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.56	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .0604	PATIENT'S RIGHTS AND RESPONSIBILITIES	Readopted Eff. January 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.52	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .0605	HOME CARE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .0700 PATIENT/FAMILY CARE PLAN	10A NCAC 13K .0701	CARE PLAN	Readopted Eff. January 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.56	No	Necessary	Select One	Select One	Select One
	SECTION .0800 PHARMACEUTICAL AND MEDICAL TREATMENT ORDERS AND ADMINISTRATION	10A NCAC 13K .0801	PHARMACEUTICAL AND MEDICAL TREATMENT ORDERS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.106	No	Necessary	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13K, HOSPICE LICENSING RULES

Agency - Medical Care Commission

Comment Period - February 14, 2025 - April 15, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		10A NCAC 13K .0802	ADMINISTRATION OF PHARMACEUTICALS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.106	No	Necessary	Select One	Select One	Select One
	SECTION .0900 MEDICAL RECORDS	10A NCAC 13K .0901	CONTENT OF MEDICAL RECORD	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.104	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .0902	RECORD CONTENT, HANDLING AND RETENTION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.104	No	Necessary	Select One	Select One	Select One
	SECTION .1000 EVALUATION	10A NCAC 13K .1001	EVALUATION REQUIRED	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.10	No	Necessary	Select One	Select One	Select One
	SECTION .1100 HOSPICE RESIDENTIAL CARE	10A NCAC 13K .1101	ADMINISTRATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1102	HOSPICE RESIDENCE STAFFING	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1103	PHARMACEUTICAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1104	DIETARY SERVICES	Readopted Eff. January 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1105	HOSPICE VISITATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1106	INFECTION CONTROL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.56	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1107	HOUSEKEEPING AND LINENS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1108	REPORT OF DEATH	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1109	RESIDENT CARE AREAS	Readopted Eff. October 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1110	FURNISHINGS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1111	HOSPICE RESIDENCE ZONING AND FIRE SAFETY REQUIREMENTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1112	DESIGN AND CONSTRUCTION	Amended Eff. October 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1113	PLANS AND SPECIFICATIONS	Readopted Eff. October 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1114	PLUMBING	Readopted Eff. October 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1115	WASTE DISPOSAL	Readopted Eff. October 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1116	APPLICATION OF PHYSICAL PLANT REQUIREMENTS	Readopted Eff. October 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .1200 HOSPICE INPATIENT CARE	10A NCAC 13K .1201	REQUIREMENTS FOR HOSPICE INPATIENT UNITS	Readopted Eff. October 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1202	ADDITIONAL STAFFING REQUIREMENTS FOR HOSPICE INPATIENT UNITS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13K, HOSPICE LICENSING RULES

Agency - Medical Care Commission

Comment Period - February 14, 2025 - April 15, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		10A NCAC 13K .1203	ADDITIONAL SERVICES REQUIRED FOR HOSPICE INPATIENT CARE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.100	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1204	ADDITIONAL PATIENT CARE AREA REQUIREMENTS FOR HOSPICE INPATIENT UNITS	Readopted Eff. October 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1205	FURNISHINGS FOR HOSPICE INPATIENT CARE	Readopted Eff. October 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1206	HOSPICE INPATIENT FIRE AND SAFETY REQUIREMENTS	Readopted Eff. October 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.113	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1207	HOSPICE INPATIENT REQUIREMENTS FOR HEATING/AIR CONDITIONING	Readopted Eff. October 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1208	HOSPICE INPATIENT REQUIREMENTS FOR EMERGENCY ELECTRICAL SERVICE	Amended Eff. October 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1209	HOSPICE INPATIENT REQUIREMENTS FOR GENERAL ELECTRICAL	Amended Eff. October 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1210	OTHER HOSPICE INPATIENT REQUIREMENTS	Amended Eff. October 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1211	ADDITIONAL PLUMBING REQUIREMENTS/HOSPICE INPATIENT UNITS	Readopted Eff. October 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 418.110	No	Necessary	Select One	Select One	Select One
		10A NCAC 13K .1212	APPLICATION OF PHYSICAL PLANT REQUIREMENTS	Readopted Eff. October 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One

10A NCAC 13C .0103 DEFINITIONS

In addition to the terms defined in G.S. 131E-214.13, the following terms shall apply throughout this Subchapter, unless the context clearly requires otherwise:

(1) "Adequate" means, when applied to various areas of services, that the services are satisfactory in meeting a referred to need when measured against professional standards of practice.

(2) "AAAASF" means American Association for Accreditation of Ambulatory Surgery Facilities.

(3) "AAAHC" means Accreditation Association for Ambulatory Health Care.

(4) "Ancillary nursing personnel" means persons employed to assist registered nurses or licensed practical nurses in the care of patients.

(5) "Anesthesiologist" means a physician whose specialized training and experience qualify him or her to administer anesthetic agents and to monitor the patient under the influence of these agents. For the purpose of this Subchapter, the term "anesthesiologist" shall not include podiatrists.

(6) "Anesthetist" means a physician or dentist qualified, as defined in Items (10) and (24) of this Rule, to administer anesthetic agents or a registered nurse qualified, as defined in Items (25) and (27) of this Rule, to administer anesthesia.

(7) "Authority having jurisdiction" means the Division of Health Service Regulation.

(8) "Chief executive officer" or "administrator" means a qualified person appointed by the governing authority to act in its behalf in the overall management of the facility and whose office is located in the facility.

(9) "Current Procedural Terminology (CPT)" means a medical code set developed by the American Medical Association.

(10) "Dentist" means a person who holds a valid license issued by the North Carolina Board of Dental Examiners to practice dentistry.

(11) "Department" means the North Carolina Department of Health and Human Services.

(12) "Director of nursing" means a registered nurse who is responsible to the chief executive officer or administrator and has the authority and direct responsibility for all nursing services and nursing care for the entire facility at all times.

(13) "Financial assistance" means a policy, including charity care, describing how the organization will provide assistance at its facility. Financial assistance includes free or discounted health services provided to persons who meet the organization's criteria for financial assistance and are unable to pay for all or a portion of the services. Financial assistance does not include:

(a) bad debt;

(b) uncollectable charges that the organization recorded as revenue but wrote off due to a patient's failure to pay;

(c) the cost of providing such care to the patients in Sub-Item (13)(b) of this Rule; or

(d) the difference between the cost of care provided under Medicare or other government programs, and the revenue derived therefrom.

(14) "Governing authority" means the individual, agency, group, or corporation appointed, elected, or otherwise designated, in which the ultimate responsibility and authority for the conduct of the ambulatory surgical facility is vested.

(15) "Healthcare Common Procedure Coding System (HCPCS)" means a three tiered medical code set consisting of Level I, II and III services and contains the CPT code set in Level I.

(16) "JCAHO" or "Joint Commission" means Joint Commission on Accreditation of Healthcare Organizations.

(17) "Licensing agency" means the Department of Health and Human Services, Division of Health Service Regulation.

(18) "Licensed practical nurse (L.P.N.)" means any person licensed as such under the provisions of G.S. 90-171.20(8).

(19) "Nursing personnel" means registered nurses, licensed practical nurses, and ancillary nursing personnel.

(20) "Operating room" means a room in which surgical procedures are performed.

(21) "Patient" means a person admitted to and receiving care in a facility.

(22) "Person" means an individual, a trust or estate, a partnership or corporation, including associations, joint stock companies and insurance companies; the State, or a political subdivision or instrumentality of the state.

(23) "Pharmacist" means a person who holds a valid license issued by the North Carolina Board of Pharmacy to practice pharmacy in accordance with G.S. 90-85.3A.

(24) "Physician" means a person who holds a valid license issued by the North Carolina Medical Board to practice medicine. For the purpose of carrying out these Rules, a "physician" may also mean a person holding a valid license issued by the North Carolina Board of Podiatry Examiners to practice podiatry.

(25) "Qualified person," when used in connection with an occupation or position, means a person:
(a) who has demonstrated through experience the ability to perform the required functions; or
(b) who has certification, registration, or other professional recognition.

(26) "Recovery area" means a room used for the post-anesthesia recovery of surgical patients.

(27) "Registered nurse" means a person who holds a valid license issued by the North Carolina Board of Nursing to practice nursing as defined in G.S. 90-171.20(7).

(28) "Surgical suite" means an area that includes one or more operating rooms and one or more recovery rooms.

History Note: *Authority G.S. 131E-149; 131E-214.13;*
Eff. October 14, 1978;
Amended Eff. April 1, 2003; November 1, 1989;
Temporary Amendment Eff. December 31, 2014;
Eff. September 30, 2015.

SECTION .0200 - LICENSING PROCEDURES

10A NCAC 13C .0201 APPLICATION

(a) A person shall submit an application for a license to establish or maintain an ambulatory surgical facility to the Department in writing on the form provided by the Department. Each application shall contain all necessary and reasonable information that the Department may by rule require, including the following and other pertinent information the Department may deem appropriate to carry out its responsibilities for statistical data collection and long range health planning:

(1) name of facility,
(2) address of facility,
(3) telephone number of facility,
(4) names of owners,
(5) names of operator and governing authority,
(6) name of chief executive officer,
(7) composition of medical and paramedical staff,
(8) name of chief of staff,
(9) director of nursing service,
(10) number of operating rooms and recovery beds,
(11) list of surgical procedures to be performed in facility,
(12) qualification of persons responsible for anesthesia services,
(13) information regarding use and storage of flammable anesthesia,
(14) description of laboratory and pathology services,
(15) name of hospital(s) with which transfer agreement has been made,
(16) description of arrangements for emergency transportation of patients from the facility,
(17) description of arrangements for food service, and
(18) information regarding sanitation inspection and fire inspection.

(b) The person shall make application for a license for a new facility or for the renewal of a license for an existing facility. Applications for licensure for a new facility shall be submitted at least 120 days prior to opening.

(c) Any ambulatory surgical facility desiring licensure which is in operation at the time of promulgation of any applicable rules or regulations shall be given a reasonable time, not to exceed one year from the date of such promulgation, within which to comply with such rules and regulations.

History Note: *Authority G.S. 131E-147; 131E-149;*
Eff. October 14, 1978;
Amended Eff. November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0202 REQUIREMENTS FOR ISSUANCE OF LICENSE

(a) Upon application for a license from a facility never before licensed, a representative of the Department shall make an inspection of that facility. Every building, institution, or establishment that has been issued a license shall be inspected for compliance with the rules found in this Subchapter. An ambulatory surgery facility shall be deemed to meet licensure requirements if the ambulatory surgery facility is accredited by The Joint Commission, AAAHC, or AAAASF. Accreditation shall not exempt a facility from statutory or rule requirements for licensure nor shall it prohibit the Department from conducting inspections as provided in this Rule to determine compliance with all requirements.

(b) If the applicant has been issued a Certificate of Need and is found to be in compliance with the rules found in this Subchapter, then the Department shall issue a license to expire on December 31 of each year.

(c) The Department shall be notified at the time of:

(1) any change of the owner or operator;

(2) any change of location;

(3) any change as to a lease; and

(4) any transfer, assignment, or other disposition or change of ownership or control of 20 percent or more of the capital stock or voting rights thereunder of a corporation that is the operator or owner of an ambulatory surgical facility, or any transfer, assignment, or other disposition of the stock or voting rights thereunder of such corporation that results in the ownership or control of more than 20 percent of the stock or voting rights thereunder of such corporation by any person.

A new application shall be submitted to the Department in the event of such a change or changes.

(d) The Department shall not grant a license until the plans and specifications that are stated in Section .1400 of this Subchapter, covering the construction of new buildings, additions, or material alterations to existing buildings are approved by the Department.

(e) The facility design and construction shall be in accordance with the licensure rules for ambulatory surgical facilities found in this Subchapter, the North Carolina State Building Code, and local municipal codes.

(f) Submission of Plans.

(1) When construction or remodeling of a facility is planned, one copy of construction documents and specifications shall be submitted by the owner or owner's appointed representative to the Department for review and approval. Schematic design drawings and design development drawings may be submitted for approval prior to the required submission of construction documents.

(2) Approval of construction documents and specifications shall be obtained from the Department prior to licensure. Approval of construction documents and specifications shall expire one year after the date of approval unless a building permit for the construction has been obtained prior to the expiration date of the approval of construction documents and specifications.

(3) 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.

(g) To qualify for licensure or license renewal, each facility shall provide to the Division, with its application, an attestation statement in a form provided by the Division verifying compliance with the requirements defined in Rule .0301(d) of this Subchapter.

History Note: *Authority G.S. 131E-91; 131E-147; 131E-149;*
Eff. October 14, 1978;
Amended Eff. April 1, 2003;
Temporary Amendment Eff. May 1, 2014;
Amended Eff. November 1, 2014;
Readopted Eff. January 1, 2021.

10A NCAC 13C .0203 SUSPENSION OR REVOCATION: AMBULATORY SURGICAL FACILITY
License suspensions and revocations shall be governed by G.S. 131E-148.

History Note: *Authority G.S. 131E-148; 131E-149; 143B-165;*
Eff. October 14, 1978;
Amended Eff. November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;
Amended Eff. January 1, 2021.

10A NCAC 13C .0205 ITEMIZED CHARGES

(a) The facility shall either present an itemized list of charges to all discharged patients or include on patients' bills that are not itemized notification of the right to request an itemized bill within three years of receipt of the non-itemized bill or so long as the facility, collections agency, or other assignee asserts the patient has an obligation to pay the bill.

(b) If requested, the facility shall present an itemized list of charges to each patient or his or her representative. This list shall detail in language comprehensible to an ordinary layperson the specific nature of the charges or expenses incurred by the patient.

(c) The listing shall include each specific chargeable item or service in the following service areas:

(1) Surgery (facility fee);
(2) Anesthesiology;
(3) Pharmacy;
(4) Laboratory;
(5) Radiology;
(6) Prosthetic and Orthopedic appliances; and
(7) Other professional services.

(d) The facility shall indicate on the initial or renewal license application that patient bills are itemized, or that each patient or his or her representative is formally advised of the patient's right to request an itemized listing within three years of receipt of a non-itemized bill.

History Note: *Authority G.S. 131E-91; 131E-147.1; S.L. 2013-382, s. 13.1;*
Eff. December 1, 1991;
Temporary Amendment Eff. May 1, 2014;
Amended Eff. November 1, 2014;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0204 TYPE OF FACILITY DEEMED TO BE LICENSED

An ambulatory surgical facility shall be deemed a suitable facility for the performance of abortions pursuant to G.S. 14-45.1(a).

History Note: *Authority G.S. 14-45.1; 131E-147; 131E-149;*
Eff. June 30, 1980;
Amended Eff. November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0206 REPORTING REQUIREMENTS

(a) The Department shall establish the lists of the statewide 20 most common outpatient imaging procedures and 20 most common outpatient surgical procedures performed in the ambulatory surgical facility setting to be used for reporting the data required in Paragraphs (c) and (d) of this Rule. The lists shall be determined annually based upon data provided by the certified statewide data processor. The Department shall make the lists available on its website. The methodology to be used by the certified statewide data processor for determining the lists shall be based on the data collected from all licensed facilities in the State in accordance with G.S. 131E-214.2 as follows:

(1) the 20 most common imaging procedures shall be based upon all outpatient data for ambulatory surgical facilities and represent all occurrences of the diagnostic radiology imaging codes section of the CPT codes, then selecting the top 20 to be provided to the Department; and

(2) the 20 most common outpatient surgical procedures shall be based upon the primary procedure code from the ambulatory surgical facilities and represent all occurrences of the surgical codes section of the CPT codes, then selecting the top 20 to be provided to the Department.

(b) All information required by this Rule shall be posted on the Department's website at: http://www.ncdhhs.gov/dhsr/ahc and may be accessed at no cost.

(c) In accordance with G.S. 131E-214.13, all licensed ambulatory surgical facilities shall report the data required in Paragraph (d) of this Rule related to the statewide 20 most common outpatient imaging procedures and the statewide 20 most common outpatient surgical procedures to the certified statewide data processor in a format provided by the certified statewide processor. This report shall include the related primary CPT and HCPCS codes. Commencing with the reporting period ending September 30, 2015, an annual data report shall be submitted. Each annual report shall be submitted by January 1.

(d) The report as described in Paragraph (c) of this Rule shall be specific to each reporting ambulatory surgical facility and shall include:

(1) the average gross charge for each CPT code or procedure without a public or private third party payer source;

(2) the average negotiated settlement on the amount that will be charged for each CPT code or procedure as required for patients defined in Subparagraph (d)(1) of this Rule. The average negotiated settlement shall be calculated using the average amount charged all patients eligible for the facility's financial assistance policy, including self-pay patients;

(3) the amount of Medicaid reimbursement for each CPT code or procedure, including all supplemental payments to and from the ambulatory surgical facility;

(4) the amount of Medicare reimbursement for each CPT code or procedure; and

(5) on behalf of patients who are covered by a Department of Insurance licensed third-party and teachers and State employees, the lowest, average, and highest amount of payments made for each CPT code or procedure by each of the facility's top five largest health insurers.

(A) each ambulatory surgical facility shall determine its five largest health insurers based on the dollar volume of payments received from those insurers;

(B) the lowest amount of payment shall be reported as the lowest payment from each of the five insurers on the CPT code or procedure;

(C) the average amount of payment shall be reported as the arithmetic average of each of the five health insurers payment amounts;

(D) the highest amount of payment shall be reported as the highest payment from each of the five insurers on the CPT code or procedure; and

(E) the identity of the top five largest health insurers shall be redacted prior to submission.

(e) The data reported, as defined in Paragraphs (c) and (d) of this Rule, shall reflect the payments received from patients and health insurers for all closed accounts. For the purpose of this Rule, "closed accounts" are patient accounts with a zero balance at the end of the data reporting period.

(f) A minimum of three data elements shall be required for reporting under Paragraph (c) of this Rule.

(g) The information submitted in the report shall be in compliance with the federal Health Insurance Portability and Accountability Act of 45 CFR Part 164.

(h) The Department shall provide all specific ambulatory surgical facility data reported pursuant to this Rule on its website.

History Note: *Authority G.S. 131E-147.1; 131E-214.4; 131E-214.13;*
Temporary Adoption Eff. December 31, 2014;
Eff. September 30, 2015;

Temporary Amendment Eff. March 31, 2016;
Amended Eff. January 31, 2017.

SECTION .0300 – GOVERNING AUTHORITY MANAGEMENT

10A NCAC 13C .0301 GOVERNING AUTHORITY

(a) The facility's governing authority shall adopt bylaws or other operating policies and procedures to assure that:

(1) a named individual is identified who is responsible for the overall operation and maintenance of the facility. The governing authority shall have methods in place for the oversight of the individual's performance;

(2) annual meetings of the governing authority shall be conducted if the governing authority consists of two or more individuals. Minutes shall be maintained of such meetings;

(3) a policy and procedure manual is created that is designed to ensure professional and safe care for the patients. The manual shall be reviewed annually and revised in accordance with facility policy. The manual shall include provisions for administration and use of the facility, compliance, personnel quality assurance, procurement of outside services and consultations, patient care policies, and services offered; and

(4) annual reviews and evaluations of the facility's policies, management, and operation are conducted.

(b) When services such as dietary, laundry, or therapy services are purchased from others, the governing authority shall be responsible for assuring the supplier meets the same local and State standards the facility would have to meet if it were providing those services using its own staff.

(c) The governing authority shall provide for the selection and appointment of the professional staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons.

(d) The governing authority shall establish written policies and procedures to assure billing and collection practices in accordance with G.S. 131E-91. These policies and procedures shall include:

(1) a financial assistance policy as defined in G.S. 131E-214.14(b)(3);

(2) how a patient may obtain an estimate of the charges for the statewide 20 most common outpatient imaging procedures and 20 most common outpatient surgical procedures based on the primary Current Procedure Terminology Code (CPT). The policy shall require that the information be provided to the patient in writing, either electronically or by mail, within three business days;

(3) how a patient or patient's representative may dispute a bill;

(4) issuance of a refund within 45 days of the patient receiving notice of the overpayment when a patient has overpaid the amount due to the facility;

(5) providing written notification to the patient or patient's representative, 30 days prior to submitting a delinquent bill to a collections agency;

(6) providing the patient or patient's representative with the facility's charity care and financial assistance policies, if the facility is required to file a Schedule H, federal form 990;

(7) the requirement that a collections agency, entity, or other assignee obtain written consent from the facility prior to initiating litigation against the patient or patient's representative;

(8) a policy for handling debts arising from the provision of care by the ambulatory surgical facility involving the doctrine of necessaries, in accordance with G.S. 131E-91(d)(5); and

(9) a policy for handling debts arising from the provision of care by the ambulatory surgical facility to a minor, in accordance with G.S. 131E-91(d)(6).

History Note: *Authority G.S. 131E-91; 131E-147.1; 131E-149; 131E-214.13(f); 131E-214.14;*
Eff. October 14, 1978;
Amended Eff. November 1, 1989; November 1, 1985; December 24, 1979;
Temporary Amendment Eff. May 1, 2014;
Amended Eff. November 1, 2014;
Readopted Eff. January 1, 2021.

10A NCAC 13C .0302 CHIEF EXECUTIVE OFFICER OR ADMINISTRATOR

(a) The governing authority shall appoint a qualified person as chief executive officer of the facility to represent the governing authority and shall define his authority and duties in writing. He shall be responsible for the management of the facility, implementation of the policies of the governing authority and authorized and empowered to carry out the provisions of these regulations.

(b) The chief executive officer shall designate, in writing, a qualified person to act in his behalf during his absence. In the absence of the chief executive officer, the person on the grounds of the facility who is designated by the chief executive officer to be in charge of the facility shall have reasonable access to all areas in the facility related to patient care and to the operation of the physical plant.

(c) When there is a planned change in ownership or in the chief executive officer, the governing authority of the facility shall notify the Department.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0304 SURGICAL PROCEDURES PERFORMED

A current listing of all types of surgical procedures offered by the facility shall be available.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0303 ADMINISTRATIVE RECORDS

(a) The following essential documents and references shall be on file in the administrative office of the facility:

(1) appropriate documents evidencing control and ownerships, such as deeds, leases, or corporation or partnership papers;
(2) bylaws of policies and procedures of the governing authority;
(3) minutes of the governing authority meetings if applicable;
(4) minutes of the facility's professional and administrative staff meetings;
(5) a current copy of these regulations;
(6) reports of inspections, reviews, and corrective actions taken related to licensure; and
(7) contracts and agreements related to licensure to which the facility is a party.

(b) All operating licenses, permits and certificates shall be appropriately displayed on the licensed premises.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0305 PERSONNEL

(a) Personnel Records

(1) A record of each employee shall be maintained which includes the following:

(A) employee's identification;

(B) resume of education and work experience;

(C) verification of valid license (if required), education, training, and prior employment experience; and

(D) verification of references.

(2) Personnel records shall be confidential.

(3) Notwithstanding the requirement found in Subparagraph (a)(2) of this Rule, representatives of the Department conducting an inspection of the facility shall have the right to inspect personnel records.

(b) Job Descriptions

(1) Every position shall have a written description which adequately describes the duties of the position.

(2) Each job description shall include position title, authority, specific responsibilities and minimum qualifications. Qualifications shall include education, training, experience, special abilities and license or certification required.

(3) Job descriptions shall be reviewed annually, kept current and given to each employee when assigned to the position and whenever the job description is changed.

(c) Orientation shall be provided to familiarize each new employee with the facility, its policies, and job responsibilities.

(d) All persons having direct responsibility for patient care shall be at least 18 years of age. All other employees working in the facility shall be not less than 16 years of age.

(e) The governing authority shall be responsible for insuring health standards for employees which are consistent with recognized professional practices for the prevention and transmission of communicable diseases.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Amended Eff. November 1, 1989; December 24, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0306 QUALITY ASSURANCE

(a) The governing authority shall establish a quality assurance program for the purpose of providing standards of care for the facility. The program shall include the establishment of a committee which shall evaluate:

(1) appropriateness and necessity of surgical procedures performed, and

(2) compliance with facility procedure and policies.

The committee shall determine corrective action if indicated.

(b) The committee shall consist of at least one physician or dentist (who is not an owner), the chief executive officer (or his designee), and other health professionals as indicated. There shall be at least one meeting of the committee quarterly.

(c) The functions of the committee shall include development of policies for selection of patients, review of credentials for staff privileges, peer review, tissue review, establishment of infection control procedures, and approval of additional surgical procedures to be performed in the facility.

(d) Records shall be kept of the activities of the committee. These records shall include as a minimum:

(1) reports made to the governing authority;

(2) minutes of committee meetings including date, time, persons attending, description and results of cases reviewed, and recommendations made by the committee; and

(3) information on any corrective action taken.

(e) Appropriate orientation, training or education programs shall be conducted as necessary to correct deficiencies which are uncovered as a result of the quality assurance program.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

SECTION .0400 - MEDICAL AND SURGICAL SERVICES

10A NCAC 13C .0401 MEDICAL SERVICES

(a) All patients admitted to the facility shall be under the direct care of a physician or dentist.

(b) The facility shall have available an anesthetist and he or she shall be available to administer regional or general anesthesia.

(c) Any patient undergoing general or regional anesthesia shall, prior to surgery, have a history and physical examination, relative to the intended procedure, performed by a licensed physician or a dentist who has successfully completed a postgraduate program in oral and maxillofacial surgery accredited by the American Dental Association. Results of the examination and the preoperative diagnosis shall be recorded in the patient's chart prior to surgery.

(d) The attending physician and dentist, prior to surgery, shall obtain written, informed consent of the patient or legal guardian for surgery and shall record this in the patient's medical record.

(e) The facility shall have the capability of obtaining blood and blood products to meet emergency situations.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Amended Eff. November 1, 1985;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0402 SURGICAL SERVICES

(a) The governing authority shall delineate surgical privileges for each physician and dentist performing surgery in accordance with criteria which it has established provided, however, that no physician or dentist may be given privileges to perform surgical procedures for which he or she does not have privileges to perform at the hospital with which the facility has a transfer agreement as provided in Paragraph (a) in Rule .0403 of this Section.

(b) A roster of medical personnel having surgical and anesthesia privileges at the facility specifying the privileges and limitations of each, shall be readily obtainable by the person in charge of the surgical suite.

(c) The administrator or his designee shall maintain a chronological register of all surgical procedures performed. This shall include type of procedure performed, type of anesthesia used, personnel participating, post operative diagnosis and any unusual or untoward occurrence.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Amended Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

SECTION .0500 - ANESTHESIA SERVICES

10A NCAC 13C .0501 PROVIDING ANESTHESIA SERVICES

Only a physician, dentist, qualified anesthetist, or qualified anesthesiologist as defined in Rule .0103 of this Subchapter, shall administer anesthetic agents. Podiatrists shall administer only local anesthesia. The governing authority shall establish written policies and procedures concerning the provision of anesthesia services, including the designation of those persons authorized to administer anesthetics in accordance with State law.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Readopted Eff. January 1, 2021.

10A NCAC 13C .0403 EMERGENCY CASES

(a) Each facility shall have a written plan for the transfer of emergency cases to a nearby hospital when hospitalization becomes necessary.

(b) There shall be procedures, personnel and suitable equipment to handle medical emergencies which may arise in connection with services provided by the facility.

(c) There shall be a written agreement between the facility and a nearby hospital to facilitate the transfer of patients who are in need of emergency care. A facility which has documentation of its efforts to establish such a transfer agreement with a hospital which provides emergency services and has been unable to secure such an agreement shall be considered to be in compliance with this Rule.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0502 EQUIPMENT

All equipment for the administration of anesthetics shall be readily available, kept clean or sterile, and maintained in good working condition.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0503 POST ANESTHESIA NOTE

Patient's anesthesiologist or anesthetist shall write a post anesthetic follow-up note prior to the patient's discharge. The note shall include the general condition of the patient and any instructions to the patient pertaining to his care and protection.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0504 REQUIREMENT OF PERSON TRAINED IN CPR

A person with training and experience in cardio-pulmonary resuscitation shall be on the premises of the facility until all surgical patients are discharged.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

SECTION .0600 - PATHOLOGY SERVICES

10A NCAC 13C .0601 PROVISION FOR LABORATORY TESTS

(a) Each facility shall have the capability of providing or obtaining laboratory tests required in connection with the surgery to be performed.

(b) The governing authority shall establish written policies requiring examination by a pathologist of all surgical specimens except for those types of specimens which the governing authority has determined do not require examination.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0602 DISPOSAL OF WASTE

Methods for the disposal of pathological waste, contaminated dressings and other similar material shall meet the approval of governing local and state authorities.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

SECTION .0700 - RADIOLOGY SERVICES

10A NCAC 13C .0701 PROVISION FOR RADIOLOGY SERVICES

Each facility shall have the capability of providing or obtaining diagnostic radiology services in connection with the surgery to be performed.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0702 REGULATIONS FOR PERFORMED SERVICES

Radiation protection shall be provided in accordance with the rules adopted by the Radiation Protection Commission found in 10A NCAC 15. Records shall be kept of annual checks and calibration of all ionizing radiation therapy equipment used in the facility.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;
Amended Eff. January 1, 2021.

SECTION .0800 - PHARMACEUTICAL SERVICES

10A NCAC 13C .0801 DRUG DISPENSING

The governing authority, with the advice of a registered pharmacist, shall assure that there are appropriate methods, procedures and controls for obtaining, dispensing, and administering drugs and biologicals.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0802 REGULATIONS FOR DISPENSING

When the facility maintains its own pharmaceutical services, it shall comply with applicable regulations adopted by the North Carolina Board of Pharmacy pursuant to General Statute 90-85.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;
Amended Eff. September 1, 2019.

SECTION .0900 - NURSING SERVICES

10A NCAC 13C .0901 NURSING ADMINISTRATION

(a) The facility shall have an organized nursing Department under the supervision of a director of nursing who is currently licensed as a registered nurse and who has responsibility and accountability for all nursing services.

(b) The director of nursing shall be responsible and accountable to the chief executive officer for:

(1) provision of nursing services to patients;

(2) developing a nursing policy and procedure manual and written job descriptions for nursing personnel.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Amended Eff. December 24, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .0902 NURSING PERSONNEL

(a) Licensed and ancillary nursing personnel shall be on duty to assure that staffing levels meet the nursing needs of patients in the facility and their individual nursing care needs.

(b) At least one registered nurse shall be in the facility during the hours of operation. Nursing personnel shall be assigned to duties consistent with their training and experience.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Readopted Eff. January 1, 2021.

SECTION .1000 - MEDICAL RECORDS SERVICES

10A NCAC 13C .1001 MEDICAL RECORD SYSTEM

The facility shall maintain a medical record system designed to provide readily available information on each patient. The medical record system shall be under the supervision of a designated qualified person.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .1002 INDIVIDUAL PATIENT RECORDS

(a) Each patient's medical record shall be maintained in accordance with professional standards and shall include at least the following information:

(1) patient's identification, including name, address, date of birth, next of kin and a patient number;
(2) admitting diagnosis;
(3) preoperative history and physical examination pertaining to the procedure to be performed;
(4) anesthesia report;
(5) surgeon's operative report;
(6) anesthesiologist's or anesthetist's report if applicable;
(7) pertinent laboratory, pathology and X-ray reports;
(8) postoperative orders and follow-up care;
(9) discharge summary, including discharge diagnosis;
(10) record of informed consent; and
(11) physician's, dentist's, and nurse's progress notes.

(b) The administrator shall be responsible for safeguarding information on the medical record against loss, tampering, or use by unauthorized persons.

(c) Medical records shall be the property of the facility and shall not be moved from the premises wherein they are filed except by subpoena or court order.

(d) For licensing purposes the length of time that medical records are to be retained is dependent upon the need for their use in continuing patient care and for legal, research, or educational purposes. This length of time shall not be less than 20 years.

(e) Should a facility cease operation, there shall be an arrangement for preservation of records to insure compliance with these regulations. The Department shall be notified, in writing, concerning the arrangements.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

SECTION .1100 - SURGICAL FACILITIES AND EQUIPMENT

10A NCAC 13C .1101 OPERATING SUITE

(a) Each operating suite shall be adequately equipped for the types of procedures to be performed.

(b) Each recovery area shall be adequately equipped for the proper care of post anesthesia recovery of surgical patients.

(c) The following equipment shall be available in the operating suite and recovery area:

(1) cardio-pulmonary resuscitation drugs and intubation equipment,
(2) cardiac monitor,
(3) resuscitator including oxygen and suction equipment,
(4) suitable surgical instruments customarily available for the planned surgical procedure,
(5) defibrillator, and
(6) tracheostomy set.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .1102 CARE OF OPERATING SUITE

(a) Dry sweeping and dusting shall be prohibited in treatment areas.

(b) Adequate and conveniently located spaces shall be provided for the storage of janitorial supplies and equipment.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

SECTION .1200 - FUNCTIONAL SAFETY

10A NCAC 13C .1201 GENERAL

(a) The governing authority shall develop written policies and procedures designed to enhance safety within the facility and on its grounds and minimize hazards to patients, staff and visitors.

(b) The policies and procedures shall include establishment of the following:

(1) safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs;

(2) provisions for reporting and the investigation of accidental events regarding patients, visitors and personnel (incidents) and corrective action taken;

(3) provision for dissemination of safety-related information to employees and users of the facility; and

(4) provision for syringe and needle storage, handling and disposal.

(c) Smoking shall be permitted only in designated areas which shall not include patient care and treatment areas.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Amended Eff. December 24, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .1202 PREVENTIVE MAINTENANCE

A schedule of preventive maintenance shall be developed for all of the medical and surgical equipment in the facility to assure satisfactory operation when needed.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Amended Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

SECTION .1300 - CONTROL AND SANITATION

10A NCAC 13C .1301 GENERAL

The governing authority shall employ procedures to minimize sources and transmission of infections. Professionally recognized surveillance methods shall be used. The governing authority shall provide space, equipment, and personnel to assure safe and aseptic treatment and protection of all patients and personnel against cross-infection.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Amended Eff. November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .1302 STERILIZATION PROCEDURES

(a) Policies and procedures shall be established in writing for storage, maintenance and distribution of sterile supplies and equipment.

(b) Sterile supplies and equipment shall not be mixed with unsterile supplies, and shall be stored in dust proof and moisture free units. They shall be properly labeled.

(c) Sterilizing equipment shall be available and of the necessary type and capacity to sterilize instruments and operating room materials, as well as laboratory equipment and supplies. The sterilizing equipment shall have design control and safety features intact. The accuracy of instrumentation and equipment shall be checked quarterly by any professionally recognized method and periodic calibration and preventive maintenance shall be provided as necessary, and a log maintained.

(d) The date of expiration shall be marked on all supplies sterilized in the facility.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Amended Eff. November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .1303 HOUSEKEEPING

Operating rooms shall be appropriately cleaned in accordance with established written procedures after each operation. Recovery rooms shall be maintained in a clean condition.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .1304 LINEN AND LAUNDRY

(a) An adequate supply of clean linen or disposable materials shall be maintained.

(b) Provisions for proper laundering of linen and washable goods shall be made. Soiled and clean linen shall be handled and stored separately.

(c) A sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each handwashing. Towels shall not be shared.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 13C .1305 SANITATION

(a) All parts of the facility, the premises and equipment shall be kept clean and free of insects, rodents, litter and rubbish.

(b) All garbage and waste shall be collected, stored and disposed of in a manner designed to prevent the transmission of disease. Containers shall be washed and sanitized before being returned to work areas. Disposable type containers shall not be reused.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

SECTION .1400 - PHYSICAL PLANT CONSTRUCTION

10A NCAC 13C .1401 DEFINITIONS

In addition to the definitions set forth in G.S. 131E-146, the following definitions shall apply in Section .1400 of this Subchapter:

(1) "Addition" means an extension or increase in floor area or height of a building.

(2) "Alteration" means any construction or renovation to an existing building other than construction of an addition.

(3) "Construction documents" means final building plans and specifications for the construction of a facility that a governing body submits to the Construction Section for approval as specified in Rule .0202 of this Subchapter.

(4) "Construction Section" means the Construction Section of the Division of Health Service Regulation.

(5) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.

(6) "Facility" means an ambulatory surgical facility as defined in G.S. 131E-146.

(7) "FGI Guidelines" means the Guidelines for Design and Construction of Outpatient Facilities that is incorporated by reference in Rule .1402 of this Section.

History Note: *Authority G.S. 131E-145; 131E-146; 131E-149;*
Eff. October 14, 1978;
Amended Eff. December 24, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;
Amended Eff. January 1, 2020.

10A NCAC 13C .1402 LIST OF REFERENCED GUIDELINES, CODES, STANDARDS, AND REGULATION

(a) The FGI Guidelines are incorporated herein by reference, including all subsequent amendments and editions; however, the following chapters of the FGI Guidelines shall not be incorporated herein by reference:

(1) Chapter 2.3;
(2) Chapter 2.4;
(3) Chapter 2.5;
(4) Chapter 2.6;
(5) Chapter 2.8;
(6) Chapter 2.10;
(7) Chapter 2.11;
(8) Chapter 2.12;
(9) Chapter 2.13; and
(10) Chapter 2.14.

Copies of the FGI Guidelines may be purchased from the Facility Guidelines Institute online at https://www.fgiguidelines.org/guidelines-main/purchase/ at a cost of two hundred dollars ($200.00) or accessed electronically free of charge at https://www.fgiguidelines.org/guidelines-main/.

(b) For the purposes of the rules of this Section, the following codes, standards, and regulation are incorporated herein by reference including subsequent amendments and editions. Copies of these codes, standards, and regulation may be obtained or accessed from the online addresses listed:

(1) the North Carolina State Building Codes with copies that may be purchased from the International Code Council online at https://shop.iccsafe.org/ at a cost of six hundred sixty-six dollars ($666.00) or accessed electronically free of charge at https://shop.iccsafe.org/state-and-local-codes/north-carolina.html;
(2) the following National Fire Protection Association standards, codes, and guidelines with copies of these standards, codes, and guidelines that may be accessed electronically free of charge at https://www.nfpa.org/Codes-and-Standards/All-Codes-and-Standards/List-of-Codes-and-Standards or may be purchased online at https://catalog.nfpa.org/Codes-and-Standards-C3322.aspx for the costs listed:
    (A) NFPA 22, Standard for Water Tanks for Private Fire Protection for a cost of fifty-four dollars ($54.00);
    (B) NFPA 53, Recommended Practice on Materials, Equipment, and Systems Used in Oxygen-Enriched Atmospheres for a cost of fifty-three dollars ($53.00);
    (C) NFPA 59A, Standard for the Production, Storage, and Handling of Liquefied Natural Gas for a cost of fifty-four dollars ($54.00);
    (D) NFPA 99, Health Care Facilities Code for a cost of seventy-seven dollars ($77.00);
    (E) NFPA 101, Life Safety Code for a cost of one hundred and five dollars and fifty cents ($105.50);
    (F) NFPA 255, Standard Method of Test of Surface Burning Characteristics of Building Materials for a cost of forty-two dollars ($42.00);
    (G) NFPA 407, Standard for Aircraft Fuel Servicing for a cost of forty-nine dollars ($49.00);
    (H) NFPA 705, Recommended Practice for a Field Flame Test for Textiles and Films for a cost of forty-two dollars ($42.00);
    (I) NFPA 780, Standard for the Installation of Lightning Protection Systems for a cost of sixty-three dollars and fifty cents ($63.50);
    (J) NFPA 801, Standard for Fire Protection for Facilities Handling Radioactive Materials for a cost of forty-nine dollars ($49.00); and
    (K) Fire Protection Guide to Hazardous Materials for a cost of one hundred and thirty-five dollars and twenty-five cents ($135.25).
(3) 42 CFR Part 416.54 Condition of participation: Emergency preparedness with copies of this regulation that may be accessed free of charge at https://www.gpo.gov/fdsys/pkg/CFR-2017-title42-vol5/xml/CFR-2017-title42-vol5-sec482-15.xml or purchased online at https://bookstore.gpo.gov/products/cfr-title-42-pt-482-end-code-federal-regulationspaper-201-7 for a cost of seventy-seven dollars ($77.00).

History Note: *Authority G.S. 131E-149;*

Eff. October 14, 1978;
Amended Eff. December 24, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;
Amended Eff. January 1, 2020.

10A NCAC 13C .1403 GENERAL AND EMERGENCY PREPAREDNESS

(a) A new facility or any addition or alterations to an existing facility whose construction documents were approved by the Construction Section on or after July 1, 2020 shall meet the requirements set forth in:

(1) the rules of this Section; and

(2) the FGI Guidelines.

(b) An existing facility whose construction documents were approved by the Construction Section prior to July 1, 2020 shall meet those standards established in the rules of this Section that were in effect at the time the construction documents were approved by the Construction Section. Previous versions of the rules of this Section can be accessed online at https://info.ncdhhs.gov/dhsr/const/index.html.

(c) The facility shall develop and maintain an emergency preparedness program as required by 42 CFR Part 416.54 Condition of Participation: Emergency Preparedness. The emergency preparedness program shall be developed with input from the local fire department and local emergency management agency. Documentation required to be maintained by 42 CFR Part 416.54 shall be maintained at the facility for at least three years and shall be made available to the Division during an inspection upon request.

(d) Any existing building converted from another use to a new facility shall meet the requirements of Paragraph (a) of this Rule.

History Note: *Authority G.S. 131E-149; 42 CFR Part 416.54;*
Eff. October 14, 1978;
Amended Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;
Amended Eff. January 1, 2020.

10A NCAC 13C .1404 EQUIVALENCY AND CONFLICTS WITH REQUIREMENTS

(a) The Division may grant an equivalency to allow an alternate design or functional variation from the requirements in the rules contained in this Section. The equivalency may be granted by the Division if a governing body submits a written equivalency request to the Division that indicates the following:

(1) the rule citation and the rule requirement that will not be met;
(2) the justification for the equivalency;
(3) how the proposed equivalency meets the intent of the corresponding rule requirement; and
(4) a statement by the governing body that the equivalency request will not reduce the safety and operational effectiveness of the facility design and layout.

The governing body shall maintain a copy of the approved equivalence issued by the Division.

(b) If the rules, codes, or standards contained in this Subchapter conflict, the most restrictive requirement shall apply.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Amended Eff. November 1, 1989; December 24, 1979;
Readopted Eff. January 1, 2020.

10A NCAC 13C .1411 ACCESS AND SAFETY

Projects involving replacement of, alterations of, and additions to existing licensed facilities shall be planned and phased so that construction will minimize disruptions of facility operations. Facility access, exit ways, safety provisions, and building and life safety systems shall be maintained so that the health and safety of the occupants will not be jeopardized during construction. Additional safety and operating measures shall be planned, documented, and executed to compensate for hazards related to construction or renovation activities to maintain an equivalent degree of health, safety, and operational effectiveness to that required by rules, standards, and codes for a facility not under construction or renovation.

History Note: *Authority G.S. 131E-149;*
Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

G.S. 150B-21.3A Report for 10A NCAC 13C, LICENSING OF AMBULATORY SURGICAL FACILITIES

Agency - Medical Care Commission

Comment Period - February 14, 2025 - April 15, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
SUBCHAPTER 13C – LICENSING OF AMBULATORY SURGICAL FACILITIES	**SECTION .0100 – GENERAL**	10A NCAC 13C .0103	DEFINITIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR §416.2 Subpart A	No	Necessary	Select One	Select One	Select One
	SECTION .0200 LICENSING PROCEDURES	10A NCAC 13C .0201	APPLICATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR §416.2 Subpart A	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0202	REQUIREMENTS FOR ISSUANCE OF LICENSE	Readopted Eff. January 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR §416.2 Subpart A	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0203	SUSPENSION OR REVOCATION: AMBULATORY SURGICAL FACILITY	Amended Eff. January 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0204	TYPE OF FACILITY DEEMED TO BE LICENSED	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0205	ITEMIZED CHARGES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.50	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0206	REPORTING REQUIREMENTS	Amended Eff. January 31, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .0300 – GOVERNING AUTHORITY MANAGEMENT	10A NCAC 13C .0301	GOVERNING AUTHORITY	Readopted Eff. January 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.41	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0302	CHIEF EXECUTIVE OFFICER OR ADMINISTRATOR	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.41	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0303	ADMINISTRATIVE RECORDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.41	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0304	SURGICAL PROCEDURES PERFORMED	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.41	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0305	PERSONNEL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.41	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0306	QUALITY ASSURANCE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.41 42 CFR Part §416.43	No	Necessary	Select One	Select One	Select One
	SECTION .0400 MEDICAL AND SURGICAL SERVICES	10A NCAC 13C .0401	MEDICAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.42 42 CFR Part §416.45 42 CFR Part §416.52	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0402	SURGICAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.42 42 CFR Part §416.45	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0403	EMERGENCY CASES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.41(b)	No	Necessary	Select One	Select One	Select One
	SECTION .0500 ANESTHESIA SERVICES	10A NCAC 13C .0501	PROVIDING ANESTHESIA SERVICES	Readopted Eff. January 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.41 42 CFR Part §416.42	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0502	EQUIPMENT	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.42 42 CFR Part §416.51	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0503	POST ANESTHESIA NOTE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.42	No	Necessary	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13C, LICENSING OF AMBULATORY SURGICAL FACILITIES

Agency - Medical Care Commission

Comment Period - February 14, 2025 - April 15, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		10A NCAC 13C .0504	REQUIREMENT OF PERSON TRAINED IN CPR	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.44(d)	No	Necessary	Select One	Select One	Select One
	SECTION .0600 PATHOLOGY SERVICES	10A NCAC 13C .0601	PROVISION FOR LABORATORY TESTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.49	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0602	DISPOSAL OF WASTE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.44 42 CFR Part §416.51	No	Necessary	Select One	Select One	Select One
	SECTION .0700 RADIOLOGY SERVICES	10A NCAC 13C .0701	PROVISION FOR RADIOLOGY SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.49 42 42 CFR Part §482.26(b)	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0702	REGULATIONS FOR PERFORMED SERVICES	Amended Eff. January 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.49	No	Necessary	Select One	Select One	Select One
	SECTION .0800 PHARMACEUTICAL SERVICES	10A NCAC 13C .0801	DRUG DISPENSING	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.48	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0802	REGULATIONS FOR DISPENSING	Amended Eff. September 1, 2019	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.48	No	Necessary	Select One	Select One	Select One
	SECTION .0900 NURSING SERVICES	10A NCAC 13C .0901	NURSING ADMINISTRATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.46	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .0902	NURSING PERSONNEL	Readopted Eff. January 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.46	No	Necessary	Select One	Select One	Select One
	SECTION .1000 MEDICAL RECORDS SERVICES	10A NCAC 13C .1001	MEDICAL RECORD SYSTEM	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.47	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .1002	INDIVIDUAL PATIENT RECORDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.47	No	Necessary	Select One	Select One	Select One
	SECTION .1100 SURGICAL FACILITIES AND EQUIPMENT	10A NCAC 13C .1101	OPERATING SUITE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.44	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .1102	CARE OF OPERATING SUITE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.44 42 CFR Part §416.51	No	Necessary	Select One	Select One	Select One
	SECTION .1200 FUNCTIONAL SAFETY	10A NCAC 13C .1201	GENERAL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.41 42 CFR Part §416.44	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .1202	PREVENTIVE MAINTENANCE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.43 42 CFR Part §416.44	No	Necessary	Select One	Select One	Select One
	SECTION .1300 CONTROL AND SANITATION	10A NCAC 13C .1301	GENERAL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.43 42 CFR Part §416.51	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .1302	STERILIZATION PROCEDURES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.44 42 CFR Part §416.51	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .1303	HOUSEKEEPING	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.44 42 CFR Part §416.51	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .1304	LINEN AND LAUNDRY	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.44 42 CFR Part §416.51	No	Necessary	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13C, LICENSING OF AMBULATORY SURGICAL FACILITIES

Agency - Medical Care Commission

Comment Period - February 14, 2025 - April 15, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		10A NCAC 13C .1305	SANITATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.44 42 CFR Part §416.51	No	Necessary	Select One	Select One	Select One
	SECTION .1400 PHYSICAL PLANT CONSTRUCTION	10A NCAC 13C .1401	DEFINITIONS	Amended Eff. January 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.44	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .1402	LIST OF REFERENCED GUIDELINES, CODES, STANDARDS, AND REGULATION	Amended Eff. January 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.44	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .1403	GENERAL AND EMERGENCY PREPAREDNESS	Amended Eff. January 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.44	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .1404	EQUIVALENCY AND CONFLICTS WITH REQUIREMENTS	Readopted Eff. January 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.44	No	Necessary	Select One	Select One	Select One
		10A NCAC 13C .1411	ACCESS AND SAFETY	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One

CHAPTER 14 - DIRECTOR, DIVISION OF HEALTH SERVICE REGULATION

SUBCHAPTER 14A – RULEMAKING

SECTION .0100 - RULEMAKING

10A NCAC 14A .0101 PETITIONS

(a) Any person wishing to submit a written petition requesting the adoption, amendment, or repeal of a rule by the Director of the Division of Health Service Regulation shall submit the petition addressed to the Director, Division of Health Service Regulation, 809 Ruggles Drive, 2701 Mail Service Center, Raleigh, North Carolina, 27699-2701.

(b) The petition shall contain the following information:

(1) the text of the proposed rule(s) for adoption or amendment and the statutory authority for the agency to promulgate the rule(s);
(2) a statement of the effect on existing rules or orders;
(3) a statement of the effect of the proposed rule(s) on existing practices in the area involved, if known; and
(4) the name(s) and address(es) of the petitioner(s).

(c) The petitioner may include the following information within the request:

(1) documents and any data supporting the petition;
(2) a statement of the reasons for adoption of the proposed rule(s), amendment or the repeal of an existing rule(s);
(3) a statement explaining the costs and computation of the cost factors, if known; and
(4) a description, including the names and addresses, if known, of those most likely to be affected by the proposed rule(s).

(d) The Director, based on a review of the facts stated in the petition, shall consider the following in his or her determination to grant the petition:

(1) whether he or she has authority to adopt the rule(s);
(2) the effect of the proposed rule(s) on existing rules, programs and practices;
(3) probable costs and cost factors of the proposed rule(s);
(4) the impact of the rule on the public and the regulated entities; and
(5) whether the public interest will be served by granting the petition.

(e) Petitions that do not contain the information required by Paragraph (b) of this Rule shall be returned to the petitioner by the Director of Division of Health Service Regulation.

History Note: *Authority G.S. 150B-20;*
Eff. June 10, 1977;
Readopted Eff. December 1, 1977;
Amended Eff. November 1, 1989;
Readopted Eff. July 1, 2019.

10A NCAC 14A .0103 DECLARATORY RULINGS

(a) The Director of the Division of Health Service Regulation may issue declaratory rulings. All requests for declaratory rulings shall be written and submitted to: the Director, Division of Health Service Regulation, 809 Ruggles Drive, 2701 Mail Service Center, Raleigh, North Carolina, 27699-2701.

(b) All requests for a declaratory ruling shall include the following information:

(1) the name and address of the petitioner;
(2) a statement of all relevant facts if the person aggrieved requests a declaratory ruling as to the applicability to a statute, rule, or order of the Division;
(3) the statute or rule to which the petition relates;
(4) a statement regarding the petitioner's opinion as to any conflict or inconsistencies, if any, within the Division regarding an interpretation of the law or a rule adopted by the Division to which the petition relates;
(5) a statement of the manner in which the petitioner is aggrieved by the rule or statute, or its potential application to him or her;
(6) the consequences of a failure to issue a declaratory ruling; and
(7) the petitioner's opinion as to the potential impact of the declaratory ruling on the public.

(c) Whenever the Director finds good cause exists to deny the request for declaratory ruling, he or she may deny the request to issue a declaratory ruling. In such a case, the Director shall notify the petitioner in writing of the decision to deny the request for declaratory ruling and shall state the reason for the denial.

(d) Good cause for the denial of a declaratory ruling request may include one of the following:

(1) the person submitting the request is not a person aggrieved;
(2) there is no conflict or inconsistency within the Division regarding an interpretation of the law or a rule adopted by the Division;
(3) a situation where there has been similar controlling factual determination in a contested case;
(4) if the request for declaratory ruling involves a factual context that was considered upon adoption of the rule being questioned as evidenced by the rulemaking record;
(5) the factual representations are not specific to the statute or rule being questioned;
(6) issuing the declaratory ruling will not serve the public interest; or
(7) if circumstances stated in the request or otherwise known to the agency show that a contested case hearing would be appropriate.

(e) A declaratory ruling procedure may consist of written submissions, oral hearings, or such other procedure as the Director may select in a particular case if additional information may assist in determining whether to grant or deny the petition.

(f) The Director may issue notice to persons who might be affected by the ruling that written comments may be submitted or oral presentations received at a scheduled hearing if the Director finds such comments or presentations may provide additional information that will assist in determining whether to grant or deny the petition.

History Note: *Authority G.S. 150B-4;*
Eff. November 1, 1989;
Amended Eff. November 1, 2010;
Readopted Eff. July 1, 2019.

SECTION .0300 - HEARINGS: TRANSFERS AND DISCHARGES

10A NCAC 14A .0301 DEFINITIONS

The following definitions apply throughout this Section:

(1) "Facility" is defined in 42 CFR 483.5, which is herein incorporated by reference, including subsequent amendments and editions. The Code of Federal Regulations may be accessed free of charge at http://www.access.gpo.gov/nara/cfr/waisidx_08/42cfr483_08.

(2) "Hearing Officer" means the person at the Hearing Unit designated to preside over hearings between residents and nursing facility providers regarding transfers and discharges.

(3) "Hearing Unit" means the Chief Hearing Officer and his or her staff in the Division of Medical Assistance of the Department of Health and Human Services.

(4) "Notice" means a written notification of transfer or discharge, as required by 42 CFR 483.15 (c), by the facility to the resident and the resident's representative as defined in 42 CFR 483.5.

(5) "Request for a Hearing" means a written expression by the resident, family member, or legal representative, that he or she wants the opportunity to present his or her case to the Hearing Officer.

(6) "Resident" means any person who is receiving treatment or long-term care in a facility.

(7) "Serve" means personal delivery, delivery by first class or certified United States Postal Service mail, or delivery by licensed overnight express mail, postage prepaid and addressed to the party at his or her last known address.

History Note: *Authority G.S. 143B-165(10); 42 U.S.C. 1395i-3(c)(2)(B)(iii); 42 U.S.C. 1396r(e)(3); 42 U.S.C. 1396r(f)(3); 42 CFR 483.15(c);*
Eff. August 3, 1992;
Readopted Eff. January 1, 2019.

10A NCAC 14A .0302 TRANSFER OR DISCHARGE HEARING REQUEST

Any resident who has been advised of the date of a transfer or discharge in writing may request that the Hearing Officer set a date for a hearing in accordance with these Rules. Hearing procedures shall be in accordance with rules in 10A NCAC 22H .0200, which are herein incorporated by reference, including subsequent amendments and editions. These Rules may be accessed free of charge at http://reports.oah.state.nc.us/ncac.asp.

History Note: *Authority G.S. 143B-165(10); 42 U.S.C. 1395i-3(c)(2)(B)(iii); 42 U.S.C. 1396r(e)(3); 42 U.S.C. 1396r(f)(3); 42 CFR 483.15(c);*
Eff. August 3, 1992;
Readopted Eff. January 1, 2019.

10A NCAC 14A .0303 FILING A REQUEST FOR HEARING

In order to initiate a hearing, a resident must first have been served by the facility administrator with a written notice and shall file a Request for Hearing in accordance with rules in 10A NCAC 22H .0200.

History Note: *Authority G.S. 143B-165(10); 42 U.S.C. 1395i-3(c)(2)(B)(iii); 42 U.S.C. 1396r(e)(3); 42 U.S.C. 1396r(f)(3); 42 CFR 483.15(c);*
Eff. August 3, 1992;
Readopted Eff. January 1, 2019.

Exhibit E/1

G.S. 150B-21.3A Report for 10A NCAC 14A, DIRECTOR, DIVISION OF HEALTH SERVICE REGULATION

Agency - DHHS - Secretary & Medical Care Commission

Comment Period - February 14, 2025 - April 15, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
SUBCHAPTER 14A – RULEMAKING	SECTION .0100 RULEMAKING	10A NCAC 14A .0101	PETITIONS	Readopted Eff. July 1, 2019	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 14A .0103	DECLARATORY RULINGS	Readopted Eff. July 1, 2019	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .0300 HEARINGS: TRANSFERS AND DISCHARGES	10A NCAC 14A .0301	DEFINITIONS	Readopted Eff. January 1, 2019	Necessary	Yes If yes, include the citation to the federal law	42 USCS 1396r(e)(3) and (f)(3); 42 CFR 483.5; 42 CFR 483.15	No	Necessary	Select One	Select One	Select One
		10A NCAC 14A .0302	TRANSFER OR DISCHARGE HEARING REQUEST	Readopted Eff. January 1, 2019	Necessary	Yes If yes, include the citation to the federal law	42 USCS 1396r(e)(3) and (f)(3); 42 CFR 483.15	No	Necessary	Select One	Select One	Select One
		10A NCAC 14A .0303	FILING A REQUEST FOR HEARING	Readopted Eff. January 1, 2019	Necessary	Yes If yes, include the citation to the federal law	42 USCS 1396r(e)(3) and (f)(3); 42 CFR 483.15	No	Necessary	Select One	Select One	Select One

SUBCHAPTER 13P – EMERGENCY MEDICAL SERVICES AND TRAUMA RULES

SECTION .0100 – DEFINITIONS

10A NCAC 13P .0101 ABBREVIATIONS

As used in this Subchapter, the following abbreviations mean:

(1) ACS: American College of Surgeons;
(2) AEMT: Advanced Emergency Medical Technician;
(3) AHA: American Heart Association;
(4) ASTM: American Society for Testing and Materials;
(5) CAAHEP: Commission on Accreditation of Allied Health Education Programs;
(6) CPR: Cardiopulmonary Resuscitation;
(7) ED: Emergency Department;
(8) EMD: Emergency Medical Dispatcher;
(9) EMDPRS: Emergency Medical Dispatch Priority Reference System;
(10) EMR: Emergency Medical Responder;
(11) EMS: Emergency Medical Services;
(12) EMS-NP: EMS Nurse Practitioner;
(13) EMS-PA: EMS Physician Assistant;
(14) EMT: Emergency Medical Technician;
(15) FAA: Federal Aviation Administration;
(16) FCC: Federal Communications Commission;
(17) ICD: International Classification of Diseases;
(18) ISS: Injury Severity Score;
(19) NHTSA: National Highway Traffic Safety Administration;
(20) OEMS: Office of Emergency Medical Services;
(21) OR: Operating Room;
(22) PSAP: Public Safety Answering Point;
(23) RAC: Regional Advisory Committee;
(24) RFP: Request For Proposal;
(25) SCTP: Specialty Care Transport Program;
(26) STEMI: ST Elevation Myocardial Infarction; and
(27) US DOT: United States Department of Transportation.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Readopted Eff. January 1, 2017;
Amended Eff. April 1, 2024; July 1, 2021.

10A NCAC 13P .0102 DEFINITIONS

In addition to the definitions in G.S. 131E-155, the following definitions apply throughout this Subchapter:

(1) "Affiliated EMS Provider" means the firm, corporation, agency, organization, or association identified with a specific county EMS system as a condition for EMS Provider Licensing as required by Rule .0204 of this Subchapter.

(2) "Affiliated Hospital" means a non-trauma center hospital that is owned by the Trauma Center or a hospital with a contract or other agreement to allow for the acceptance or transfer of the Trauma Center's patient population to the non-trauma center hospital.

(3) "Affiliate" or "Affiliation" means a reciprocal agreement and association that includes active participation, collaboration, and involvement in a process or system between two or more parties.

(4) "Alternative Practice Setting" means a practice setting that utilizes credentialed EMS personnel that may not be affiliated with or under the oversight of an EMS System or EMS System Medical Director.

(5) "Air Medical Ambulance" means an aircraft configured and medically equipped to transport patients by air. The patient care compartment of air medical ambulances shall be staffed by medical crew members approved for the mission by the Medical Director.

(6) "Air Medical Program" means a SCTP or EMS System utilizing rotary-wing or fixed-wing aircraft configured and operated to transport patients.

(7) "Assistant Medical Director" means a physician, EMS-PA, or EMS-NP who assists the Medical Director with the medical aspects of the management of a practice setting utilizing credentialed EMS personnel or medical crew members.

(8) "Bypass" means a decision made by the patient care technician to transport a patient from the scene of an accident or medical emergency past a receiving facility for the purposes of accessing a facility with a higher level of care, by a hospital of its own volition to reroute a patient from the scene of an accident or medical emergency or referring hospital to a facility with a higher level of care.

(9) "Community Paramedicine" means an EMS System utilizing credentialed personnel who have received additional training as determined by the EMS System Medical Director to provide knowledge and skills for the community needs beyond the 911 emergency response and transport operating guidelines defined in the EMS System plan.

(10) "Contingencies" mean conditions placed on a designation that, if unmet, may result in the loss or amendment of a designation.

(11) "Convalescent Ambulance" means an ambulance used on a scheduled basis solely to transport patients having a known non-emergency medical condition. Convalescent ambulances shall not be used in place of any other category of ambulance defined in this Subchapter.

(12) "Deficiency" means the failure to meet essential criteria for a designation that can serve as the basis for a focused review or denial of a designation.

(13) "Department" means the North Carolina Department of Health and Human Services.

(14) "Diversion" means the hospital is unable to accept a patient due to a lack of staffing or resources.

(15) "Educational Medical Advisor" means the physician responsible for overseeing the medical aspects of approved EMS educational programs.

(16) "EMS Care" means all services provided within each EMS System by its affiliated EMS agencies and personnel that relate to the dispatch, response, treatment, and disposition of any patient.

(17) "EMS Educational Institution" means any agency credentialed by the OEMS to offer EMS educational programs.

(18) "EMS Non-Transporting Vehicle" means a motor vehicle operated by a licensed EMS provider dedicated and equipped to move medical equipment and EMS personnel functioning within the scope of practice of an AEMT or Paramedic to the scene of a request for assistance. EMS nontransporting vehicles shall not be used for the transportation of patients on the streets, highways, waterways, or airways of the state.

(19) "EMS Peer Review Committee" means a committee as defined in G.S. 131E-155(6b).

(20) "EMS Provider" means those entities defined in G.S. 131E-155(13a) that hold a current license issued by the Department pursuant to G.S. 131E-155.1.

(21) "EMS System" means a coordinated arrangement of local resources under the authority of the county government (including all agencies, personnel, equipment, and facilities) organized to

respond to medical emergencies and integrated with other health care providers and networks including public health, community health monitoring activities, and special needs populations.

(22) "Essential Criteria" means those items that are the requirements for the respective level of trauma center designation (I, II, or III), as set forth in Rule .0901 of this Subchapter.

(23) "Focused Review" means an evaluation by the OEMS of corrective actions to remove contingencies that are a result of deficiencies following a site visit.

(24) "Ground Ambulance" means an ambulance used to transport patients with traumatic or medical conditions or patients for whom the need for specialty care, emergency, or non-emergency medical care is anticipated either at the patient location or during transport.

(25) "Hospital" means a licensed facility as defined in G.S. 131E-176 or an acute care in-patient diagnostic and treatment facility located within the State of North Carolina that is owned and operated by an agency of the United States government.

(26) "Inclusive Trauma System" means an organized, multi-disciplinary, evidence-based approach to provide quality care and to improve measurable outcomes for all defined injured patients. EMS, hospitals, other health systems, and clinicians shall participate in a structured manner through leadership, advocacy, injury prevention, education, clinical care, performance improvement, and research resulting in integrated trauma care.

(27) "Infectious Disease Control Policy" means a written policy describing how the EMS system will protect and prevent its patients and EMS professionals from exposure and illness associated with contagions and infectious disease.

(28) "Lead RAC Agency" means the agency (comprised of one or more Level I or II trauma centers) that provides staff support and serves as the coordinating entity for trauma planning.

(29) "Level I Trauma Center" means a hospital that has the capability of providing guidance, research, and total care for every aspect of injury from prevention to rehabilitation.

(30) "Level II Trauma Center" means a hospital that provides trauma care regardless of the severity of the injury, but may lack the comprehensive care as a Level I trauma center, and does not have trauma research as a primary objective.

(31) "Level III Trauma Center" means a hospital that provides assessment, resuscitation, emergency operations, and stabilization, and arranges for hospital transfer as needed to a Level I or II trauma center.

(32) "Medical Crew Member" means EMS personnel or other health care professionals who are licensed or registered in North Carolina and are affiliated with a SCTP.

(33) "Medical Director" means the physician responsible for the medical aspects of the management of a practice setting utilizing credentialed EMS personnel or medical crew members, or a Trauma Center.

(34) "Medical Oversight" means the responsibility for the management and accountability of the medical care aspects of a practice setting utilizing credentialed EMS personnel or medical crew members. Medical Oversight includes physician direction of the initial education and continuing education of EMS personnel or medical crew members; development and monitoring of both operational and treatment protocols; evaluation of the medical care rendered by EMS personnel or medical crew members; participation in system or program evaluation; and directing, by two-way voice communications, the medical care rendered by the EMS personnel or medical crew members.

(35) "Mobile Integrated Healthcare" means utilizing credentialed personnel who have received additional training as determined by the Alternative Practice Setting medical director to provide knowledge and skills for the healthcare provider program needs.

(36) "Office of Emergency Medical Services" means a section of the Division of Health Service Regulation of the North Carolina Department of Health and Human Services located at 1201 Umstead Drive, Raleigh, North Carolina 27603.

(37) "On-line Medical Control" means the medical supervision or oversight provided to EMS personnel through direct communication in-person, via radio, cellular phone, or other communication device during the time the patient is under the care of an EMS professional.

(38) "Operational Protocols" means the administrative policies and procedures of an EMS System or that provide guidance for the day-to-day operation of the system.

(39) "Physician" means a medical or osteopathic doctor licensed by the North Carolina Medical Board to practice medicine in the state of North Carolina.

(40) "Regional Advisory Committee" means a committee comprised of a lead RAC agency and a group representing trauma care providers and the community, for the purpose of regional planning, establishing, and maintaining a coordinated trauma system.

(41) "Request for Proposal" means a State document that must be completed by each hospital seeking initial or renewal trauma center designation.

(42) "Specialized Ambulance Protocol Summary (SAPS) means a document listing of all standard medical equipment, supplies, and medications, approved by the Specialty Care or Air Medical Program Medical Director as sufficient to manage the anticipated number and severity of injury or illness of the patients, for all vehicles used in the program based on the treatment protocols and approved by the OEMS.

(43) "Significant Failure to Comply" means a degree of non-compliance determined by the OEMS during compliance monitoring to exceed the ability of the local EMS System to correct, warranting enforcement action pursuant to Section .1500 of this Subchapter.

(44) "Specialty Care Transport Program" means a program designed and operated for the transportation of a patient by ground or air requiring specialized interventions, monitoring, and staffing by a paramedic who has received additional training as determined by the program Medical Director beyond the minimum training prescribed by the OEMS, or by one or more other healthcare professional(s) qualified for the provision of specialized care based on the patient's condition.

(45) "Specialty Care Transport Program Continuing Education Coordinator" means a Level I EMS Instructor within a SCTP who is responsible for the coordination of EMS continuing education programs for EMS personnel within the program.

(46) "Stretcher" means any wheeled or portable device capable of transporting a person in a recumbent position and may only be used in an ambulance vehicle permitted by the Department.

(47) "Stroke" means an acute cerebrovascular hemorrhage or occlusion resulting in a neurologic deficit.

(48) "System Continuing Education Coordinator" means the Level II EMS Instructor designated by the local EMS System who is responsible for the coordination of EMS continuing education programs.

(49) "System Data" means all information required for daily electronic submission to the OEMS by all EMS Systems using the EMS data set, data dictionary, and file format as specified in "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated herein by reference including subsequent amendments and editions. This document is available from the OEMS at https://oems.nc.gov/systems at no cost.

(50) "Trauma Center" means a hospital designated by the State of North Carolina and distinguished by its ability to manage, on a 24-hour basis, the severely injured patient or those at risk for severe injury.

(51) "Trauma Patient" means any patient with an ICD-CM discharge diagnosis as defined in the "North Carolina Trauma Registry Data Dictionary," incorporated herein by reference, including subsequent amendments and editions. This document is available from the OEMS online at https://oems.nc.gov/wp-content/uploads/2022/10/datadictionary.pdf at no cost.

(52) "Trauma Program" means an administrative entity that includes the trauma service and coordinates other trauma-related activities. It shall also include the trauma Medical Director, trauma program manager/trauma coordinator, and trauma registrar. This program's reporting structure shall give it the ability to interact with at least equal authority with other departments in the hospital providing patient care.

(53) "Trauma Registry" means a disease-specific data collection composed of a file of uniform data elements that describe the injury event, demographics, pre-hospital information, diagnosis, care, outcomes, and costs of treatment for injured patients collected and electronically submitted as defined by the OEMS. The elements of the Trauma Registry can be accessed online at https://oems.nc.gov/wp-content/uploads/2022/10/datadictionary.pdf at no cost.

(54) "Treatment Protocols" means a document approved by the Medical Directors of the local EMS System, Specialty Care Transport Program, Alternative Practice Setting, or Trauma Center and the OEMS specifying the diagnostic procedures, treatment procedures, medication administration, and patient-care-related policies that shall be completed by EMS personnel or medical crew members based upon the assessment of a patient.

SECTION .0200 – EMS SYSTEMS

10A NCAC 13P .0201 EMS SYSTEM REQUIREMENTS

(a) County governments shall establish EMS Systems. Each EMS System shall have:

(1) a defined geographical service area for the EMS System. The minimum service area for an EMS System shall be one county. There may be multiple EMS Provider service areas within an EMS System. The highest level of care offered within any EMS Provider service area shall be available to the citizens within that service area 24 hours a day, seven days a week;

(2) a defined scope of practice for all EMS personnel functioning in the EMS System within the parameters set forth by the North Carolina Medical Board pursuant to G.S. 143-514;

(3) written policies and procedures describing the dispatch, coordination, and oversight of all responders that provide EMS care, specialty patient care skills, and procedures as set forth in Rule .0301 of this Subchapter, and ambulance transport within the system;

(4) at least one licensed EMS Provider;

(5) a listing of permitted ambulances to provide coverage to the service area 24 hours a day, seven days a week;

(6) personnel credentialed to perform within the scope of practice of the system and to staff the ambulance vehicles as required by G.S. 131E-158. There shall be a written plan for the use of credentialed EMS personnel for all practice settings used within the system;

(7) written policies and procedures specific to the utilization of the EMS System's EMS Care data for the daily and on-going management of all EMS System resources;

(8) a written Infectious Disease Control Policy as defined in Rule .0102 of this Subchapter and written procedures that are approved by the EMS System Medical Director that address the cleansing and disinfecting of vehicles and equipment that are used to treat or transport patients;

(9) a listing of resources that will provide online medical direction for all EMS Providers operating within the EMS System;

(10) an EMS communication system that provides for:

(A) public access to emergency services by dialing 9-1-1 within the public dial telephone network as the primary method for the public to request emergency assistance. This number shall be connected to the PSAP with immediate assistance available such that no caller will be instructed to hang up the telephone and dial another telephone number. A person calling for emergency assistance shall not be required to speak with more than two persons to request emergency medical assistance;

(B) a PSAP operated by public safety telecommunicators with training in the management of calls for medical assistance available 24 hours a day, seven days a week;

(C) dispatch of the most appropriate emergency medical response unit or units to any caller's request for assistance. The dispatch of all response vehicles shall be in accordance with a written EMS System plan for the management and deployment of response vehicles including requests for mutual aid; and

(D) two-way radio voice communications from within the defined service area to the PSAP and to facilities where patients are transported. The PSAP shall maintain all required FCC radio licenses or authorizations;

(11) written policies and procedures for addressing the use of SCTP and Air Medical Programs resources utilized within the system;

(12) a written continuing education program for all credentialed EMS personnel, under the direction of a System Continuing Education Coordinator, developed and modified based on feedback from EMS Care system data, review, and evaluation of patient outcomes and quality management peer reviews, that follows the criteria set forth in Rule .0501 of this Subchapter;

(13) written policies and procedures to address management of the EMS System that includes:

(A) triage and transport of all acutely ill and injured patients with time-dependent or other specialized care issues including trauma, stroke, STEMI, burn, and pediatric patients that may require the bypass of other licensed health care facilities and that are based upon the expanded clinical capabilities of the selected healthcare facilities;

(B) triage and transport of patients to facilities outside of the system;

(C) arrangements for transporting patients to identified facilities when diversion or bypass plans are activated;

(D) reporting, monitoring, and establishing standards for system response times using system data;
(E) a disaster plan;
(F) a mass-gathering plan that includes how the provision of EMS standby coverage for the public-at-large will be provided;
(G) a mass-casualty plan;
(H) a weapons plan for any weapon as set forth in Rule .0216 of this Section;
(I) a plan on how EMS personnel shall report suspected child abuse pursuant to G.S. 7B-301;
(J) a plan on how EMS personnel shall report suspected abuse of the disabled pursuant to G.S. 108A-102;
(K) a plan on how each responding agency is to maintain a current roster of its personnel providing EMS care within the county under the provider number issued pursuant to Paragraph (c) of this Rule, in the OEMS credentialing and information database; and
(L) a plan on how each licensed hospital facility will use and maintain two-way radio communication for receiving in coming patient from EMS providers;

(14) affiliation as defined in Rule .0102 of this Subchapter with a trauma RAC as required by Rule .1101(b) of this Subchapter; and
(15) medical oversight as required by Section .0400 of this Subchapter.

(b) Each EMS System that utilizes emergency medical dispatching agencies applying the principles of EMD or offering EMD services, procedures, or programs to the public shall have:

(1) a defined service area for each agency;
(2) appropriate personnel within each agency, credentialed in accordance with the requirements set forth in Section .0500 of this Subchapter, to ensure EMD services to the citizens within that service area are available 24 hours per day, seven days a week, and a written policy describing how the agency will maintain a roster of credentialed EMD personnel in the OEMS credentialing and information database; and
(3) EMD responsibilities in special situations, such as disasters, mass-casualty incidents, or situations requiring referral to specialty hotlines; and
(4) EMD medical oversight as required in Section .0400 of this Subchapter.

(c) The EMS System shall obtain provider numbers from the OEMS for each entity that provides EMS Care within the county.

(d) An application to establish an EMS System shall be submitted by the county to the OEMS for review. When the system is comprised of more than one county, only one application shall be submitted. The proposal shall demonstrate that the system meets the requirements in Paragraph (a) of this Rule. System approval shall be granted for a period of six years. Systems shall apply to OEMS for reapproval no more than 90 days prior to expiration.

History Note: *Authority G.S. 131E-155(1); 131E-155(6); 131E-155(7); 131E-155(8); 131E-155(9); 131E-155(13a); 131E-155(15); 143-508(b); 143-508(d)(1); 143-508(d)(2); 143-508(d)(3); 143-508(d)(5); 143-508(d)(8); 143-508(d)(9); 143-508(d)(10); 143-508(d)(13); 143-517; 143-518;*
Temporary Adoption Eff. January 1, 2002;
Eff. August 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. April 1, 2024; July 1, 2018.

(55) "Triage" means the assessment and categorization of a patient to determine the level of EMS and healthcare facility based care required.

(56) "Water Ambulance" means a watercraft specifically configured and medically equipped to transport patients.

History Note: *Authority G.S. 131E-155(6b); 131E-162; 143-508(b); 143-508(d)(1); 143-508(d)(2); 143-508(d)(3); 143-508(d)(4); 143-508(d)(5); 143-508(d)(6); 143-508(d)(7); 143-508(d)(8); 143-508(d)(13); 143-518(a)(5);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. March 3, 2009 pursuant to E.O. 9, Beverly Perdue, March 3, 2009;
Pursuant to G.S. 150B-21.3(c), a bill was not ratified by the General Assembly to disapprove this rule;
Readopted Eff. January 1, 2017;
Amended Eff. April 1, 2024; July 1, 2021; September 1, 2019; July 1, 2018.

10A NCAC 13P .0203 SPECIAL SITUATIONS

(a) Upon written request from an EMS system or systems, tribal government, or federal jurisdiction having recognized province in North Carolina, the North Carolina Medical Care Commission may approve the furnishing and providing of services within the scope of practice of EMD, EMR, EMT, AEMT, or Paramedic in North Carolina.

(b) This approval shall be granted where the North Carolina Medical Care Commission concludes there exists an inability to address the criteria for EMS System development as set forth in Rule .0201 of this Section and the deficiency cannot be rectified due to insufficient resources or because of a lack of geographical access within the respective EMS system or systems.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004;
Readopted Eff. April 1, 2017.

10A NCAC 13P .0204 EMS PROVIDER LICENSE REQUIREMENTS

(a) Any firm, corporation, agency, organization, or association that provides non-transportation emergency medical services at the AEMT or Paramedic level shall be licensed by the Department as an EMS Provider by meeting and maintaining the criteria defined in Paragraph (b) of this Rule.

(b) Any firm, corporation, agency, organization, or association that provides emergency medical transportation services shall be licensed as an EMS Provider by meeting and maintaining the following criteria:

(1) be affiliated as defined in Rule .0102(3) of this Subchapter with each EMS System where there is to be a physical base of operation or where the EMS Provider will provide point-to-point patient transport within the system;

(2) present an application for a permit for any ambulance and EMS non-transporting vehicle that will be in service as required by G.S. 131E-156, and meet the requirements of Rules .0207 and .0213 of this Section;

(3) submit a written plan detailing how the EMS Provider will furnish credentialed personnel pursuant to G.S. 131E-158;

(4) where there are franchise ordinances pursuant to G.S. 153A-250 in effect that cover the proposed service areas of each EMS system of operation, provide written documentation reflecting a current franchise to operate, or of impending receipt of a franchise, from each county. In counties where there is no franchise ordinance in effect, present a signature from each EMS System representative authorizing the EMS Provider to affiliate as required by Subparagraph (b)(1) of this Rule;

(5) provide inspection, repair, cleaning, and maintenance of all EMS responding ground vehicles and maintain records for a period of time determined by the EMS System, and make available for inspection by the OEMS verifying compliance with this Subparagraph;

(6) collect and within 24 hours electronically submit to the OEMS EMS Care data that uses the EMS data set and data dictionary as specified in "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection;"

(7) develop and implement written operational protocols for the management of equipment, supplies, and medications and maintain records for a period of time determined by the EMS System, and make available for inspection by the OEMS verifying compliance with this Subparagraph. These protocols shall include a methodology:

(A) to assure that each vehicle contains the required equipment and supplies on each response;

(B) for cleaning and maintaining the equipment and vehicles; and

(C) to assure that supplies and medications are not used beyond the expiration date and stored in a temperature controlled atmosphere according to manufacturer's specifications.

(c) An EMS Provider may renew its license by presenting documentation to the OEMS that the Provider meets the criteria set forth in Paragraph (b) of this Rule.

(d) Air Medical Programs are exempt from the requirements set forth in Subparagraphs (b)(1) and (b)(4) of this Rule.

History Note: *Authority G.S. 131E-155.1(c); 143-508(d)(1); 143-508(d)(5); 143-508(d)(13);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004;
Amended Eff. March 3, 2009 pursuant to E.O. 9, Beverly Perdue, March 3, 2009;
Pursuant to G.S. 150B-21(c), a bill was not ratified by the General Assembly to disapprove this rule;
Readopted Eff. June 1, 2018.

10A NCAC 13P .0205 EMS PROVIDER LICENSE CONDITIONS

(a) Applications for an EMS Provider License must be received by the OEMS at least 30 days prior to the date that the EMS Provider proposes to initiate service. Applications for renewal of an EMS Provider License must be received by the OEMS at least 30 days prior to the expiration date of the current license.

(b) Only one license shall be issued to each EMS Provider. The Department shall issue a license to the EMS Provider following verification of compliance with applicable laws and rules.

(c) EMS Provider Licenses shall not be transferred.

(d) The license shall be posted in a prominent location accessible to public view at the primary business location of the EMS Provider.

(e) EMS Provider Licenses may not be issued by the Department to any firm, corporation, agency, organization or association that does not intend to provide emergency medical services as part of its operation to the citizens of North Carolina.

History Note: *Authority G.S. 131E-155.1(c);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. February 1, 2009; January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .0206 TERM OF EMS PROVIDER LICENSE

(a) EMS Provider Licenses remain in effect for six years unless any of the following occurs:

(1) the Department imposes an administrative sanction which specifies license expiration;
(2) the EMS Provider closes or goes out of business;
(3) the EMS Provider changes name or ownership; or
(4) failure to continue to comply with Rule .0204 of this Section.

(b) When the name or ownership of the EMS Provider changes, an EMS Provider License application shall be submitted to the OEMS at least 30 days prior to the effective date of the change.

History Note: *Authority G.S. 131E-155.1(c);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .0208 CONVALESCENT AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS

(a) To be permitted as a Convalescent Ambulance, a vehicle shall have:

(1) a patient compartment that meets the following interior dimensions:

(A) the length, measured on the floor from the back of the driver's compartment, driver's seat or partition to the inside edge of the rear loading doors, is at least 102 inches; and

(B) the height is at least 48 inches over the patient area, measured from the approximate center of the floor, exclusive of cabinets or equipment;

(2) patient care equipment and supplies as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. The equipment and supplies shall be clean, in working order, and secured in the vehicle;

(3) other equipment including:

(A) one fire extinguisher mounted in a quick release bracket that is either a dry chemical or all-purpose type and has a pressure gauge; and

(B) the availability of one pediatric restraint device to safely transport pediatric patients and children under 40 pounds in the patient compartment of the ambulance;

(4) permanently installed heating and air conditioning systems; and

(5) a copy of the EMS System patient care treatment protocols.

(b) Convalescent Ambulances shall:

(1) not be equipped, permanently or temporarily, with any emergency warning devices, audible or visual, other than those required by Federal Motor Vehicle Safety Standards;

(2) have the name of the EMS Provider permanently displayed on each side of the vehicle;

(3) not have emergency medical symbols, such as the Star of Life, block design cross, or any other medical markings, symbols, or emblems, including the word "EMERGENCY," on the vehicle;

(4) have the words "CONVALESCENT AMBULANCE" lettered on both sides and on the rear of the vehicle body; and

(5) have reflective tape affixed to the vehicle such that there is reflectivity on all sides of the vehicle.

(c) A two-way radio or radiotelephone device such as a cellular telephone shall be available to summon emergency assistance for a vehicle permitted as a convalescent ambulance.

(d) The convalescent ambulance shall not have structural or functional defects that may adversely affect the patient, the EMS personnel, or the safe operation of the vehicle.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .0207 GROUND AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS

(a) To be permitted as a Ground Ambulance, a vehicle shall have:

(1) a patient compartment that meets the following interior dimensions:
  (A) the length, measured on the floor from the back of the driver's compartment, driver's seat or partition to the inside edge of the rear loading doors, is at least 102 inches; and
  (B) the height is at least 48 inches over the patient area, measured from the approximate center of the floor, exclusive of cabinets or equipment;

(2) patient care equipment and supplies as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection." The equipment and supplies shall be clean, in working order, and secured in the vehicle;

(3) other equipment that includes:
  (A) one fire extinguisher mounted in a quick release bracket that is either a dry chemical or all-purpose type and has a pressure gauge; and
  (B) the availability of one pediatric restraint device to safely transport pediatric patients and children under 40 pounds in the patient compartment of the ambulance;

(4) the name of the EMS Provider permanently displayed on each side of the vehicle;

(5) reflective tape affixed to the vehicle such that there is reflectivity on all sides of the vehicle;

(6) emergency warning lights and audible warning devices mounted on the vehicle as required by G.S. 20-125. All warning devices shall function properly;

(7) no structural or functional defects that may adversely affect the patient, the EMS personnel, or the safe operation of the vehicle;

(8) an operational two-way radio that:
  (A) is mounted to the ambulance and installed for safe operation and controlled by the ambulance driver;
  (B) has the range, radio frequencies, and capabilities to establish and maintain two-way voice radio communication from within the defined service area of the EMS System to the emergency communications center or PSAP designated to direct or dispatch the deployment of the ambulance;
  (C) is capable of establishing two-way voice radio communication from within the defined service area to the emergency department of the hospital(s) where patients are routinely transported and to facilities that provide on-line medical direction to EMS personnel;
  (D) is equipped with a radio control device in the patient compartment capable of operation by the patient attendant to receive on-line medical direction; and
  (E) is licensed or authorized by the FCC;

(9) permanently installed heating and air conditioning systems; and

(10) a copy of the EMS System patient care treatment protocols.

(b) Ground ambulances permitted by the OEMS that do not back up the 911 EMS System shall be exempt from requirements for two-way radio communications as defined in Subparagraph (a)(8) of this Rule. A two-way radio or radiotelephone device such as a cellular telephone shall be available to summon emergency assistance.

(c) Communication instruments or devices such as data radio, facsimile, computer, or telemetry radio shall be in addition to the mission dedicated dispatch radio and shall function independently from the mission dedicated radio.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0209 AIR MEDICAL AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS

To be permitted as an Air Medical Ambulance, an aircraft shall meet the following requirements:

(1) configuration of the aircraft patient care compartment does not compromise the ability to provide care or prevent performing in-flight emergency patient care procedures as approved by the program Medical Director;

(2) the aircraft has on-board patient care equipment and supplies as defined in the treatment protocols for the program written by the Medical Director and approved by the OEMS. The equipment and supplies shall be clean, in working order, and secured in the aircraft;

(3) there is installed in the rotary-wing aircraft an internal voice communication system to allow for communication between the medical and flight crew;

(4) the program Medical Director designates the combination of medical equipment specified in Item (2) of this Rule that is carried on a mission based on anticipated patient care needs;

(5) the name of the EMS Provider is permanently displayed on each side of the aircraft;

(6) the rotary-wing aircraft is equipped with a two-way voice radio licensed by the FCC capable of operation on any frequency required to allow communications with public safety agencies such as fire departments, police departments, ambulance and rescue units, hospitals, and local government agencies, within the service area;

(7) in addition to equipment required by applicable air worthiness certificates and Federal Aviation Regulations 14 CFR Part 91 and Part 135 which are herein incorporated by reference, including all subsequent amendments and editions, any rotary-wing aircraft permitted shall have the following functioning equipment to help ensure the safety of patients, crew members, and ground personnel, patient comfort, and medical care:

  (a) Global Positioning System;

  (b) an external search light that can be operated from inside the aircraft;

  (c) survival gear appropriate for the service area and the number, age, and type of patients; and

  (d) permanently installed environmental control unit (ECU) capable of both heating and cooling the patient compartment of the aircraft;

(8) the availability of one pediatric restraint device to safely transport pediatric patients and children under 40 pounds in the patient compartment of the air medical ambulance;

(9) the aircraft has no structural or functional defects that may adversely affect the patient, or the EMS personnel; and

(10) a copy of the patient care treatment protocols set forth in Rules .0405 and .0406 of this Subchapter, either paper or electronic, carried aboard the aircraft.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004;
Amended Eff. March 3, 2009 pursuant to E.O. 9, Beverly Perdue, March 3, 2009;
Pursuant to G.S. 150B-21.3(c), a bill was not ratified by the General Assembly to disapprove this rule;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. January 1, 2017.

10A NCAC 13P .0210 WATER AMBULANCE: WATERCRAFT AND EQUIPMENT REQUIREMENTS

To be permitted as a Water Ambulance, a watercraft shall meet the following requirements:

(1) The watercraft shall have a patient care area that:
   (a) provides access to the head, torso, and lower extremities of the patient while providing sufficient working space to render patient care;
   (b) is covered to protect the patient and EMS personnel from the elements; and
   (c) has an opening of sufficient size to permit the safe loading and unloading of a person occupying a litter.

(2) The watercraft shall have on board patient care equipment and supplies as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. The equipment and supplies shall be clean, in working order, and secured in the vehicle.

(3) Water ambulances shall have the name of the EMS Provider permanently displayed on each side of the watercraft.

(4) Water ambulances shall have a 360-degree beacon warning light in addition to warning devices required in Chapter 75A, Article 1, of the North Carolina General Statutes.

(5) Water ambulances shall be equipped with:
   (a) two floatable rigid long backboards with proper accessories for securing infant, pediatric, and adult patients and stabilization of the head and neck;
   (b) one floatable litter with patient restraining straps and capable of being secured to the watercraft;
   (c) one fire extinguisher mounted in a quick release bracket that is either a dry chemical or all-purpose type and has a pressure gauge;
   (d) lighted compass;
   (e) radio navigational aids such as ADF (automatic directional finder), Satellite Global Navigational System, navigational radar, or other comparable radio equipment suited for water navigation;
   (f) marine radio; and
   (g) the availability of one pediatric restraint device to safely transport pediatric patients under 40 pounds in the patient compartment of the ambulance;

(6) The water ambulance shall not have structural or functional defects that may adversely affect the patient, the EMS personnel, or the safe operation of the watercraft.

(7) Water ambulances shall have a copy of the EMS System patient care treatment protocols.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .0211 AMBULANCE PERMIT CONDITIONS

(a) An EMS provider shall apply to the OEMS for the appropriate Ambulance Permit prior to placing an ambulance in service.

(b) The Department shall issue a permit for an ambulance following verification of compliance with applicable laws and rules.

(c) Only one Ambulance Permit shall be issued for each ambulance.

(d) An ambulance shall be permitted in only one category.

(e) Ambulance Permits shall not be transferred except in the case of Air Medical Ambulance replacement aircraft when the primary aircraft is out of service.

(f) The Ambulance Permit shall be posted as designated by the OEMS inspector.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .0212 TERM OF AMBULANCE PERMIT

Ambulance Permits remain in effect for two years unless any of the following occurs:

(1) The Department imposes an administrative sanction which specifies permit expiration;
(2) The EMS Provider closes or goes out of business;
(3) The EMS Provider changes name or ownership; or
(4) Failure to comply with the applicable Paragraphs of Rules .0207, .0208, .0209, or .0210 of this Section.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .0213 EMS NONTRANSPORTING VEHICLE REQUIREMENTS

(a) To be permitted as an EMS Nontransporting Vehicle, a vehicle shall:

(1) have patient care equipment and supplies as defined in the treatment protocols for the system. The equipment and supplies shall be clean, in working order, and secured in the vehicle.

(2) have the name of the EMS Provider permanently displayed on each side of the vehicle.

(3) have reflective tape affixed to the vehicle such that there is reflectivity on all sides of the vehicle.

(4) have emergency warning lights and audible warning devices mounted on the vehicle as required by G.S. 20-125 in addition to those required by Federal Motor Vehicle Safety Standards. All warning devices shall function properly.

(5) not have structural or functional defects that may adversely affect the EMS personnel or the safe operation of the vehicle.

(6) have one fire extinguisher that is a dry chemical or all-purpose type with a pressure gauge, mounted in a quick-release bracket.

(7) have an operational two-way radio that:

(A) is mounted to the EMS Nontransporting Vehicle and installed for safe operation and controlled by the driver;

(B) has sufficient range, radio frequencies, and capabilities to establish and maintain two-way voice radio communication from within the defined service area of the EMS System to the emergency communications center or PSAP designated to direct or dispatch the deployment of the ambulance;

(C) is capable of establishing two-way voice radio communication from within the defined service area to facilities that provide on-line medical direction to EMS personnel; and

(D) is licensed or authorized by the FCC.

(8) not use a radiotelephone device such as a cellular telephone as the only source of two-way radio voice communication.

(9) have a copy of the local EMS System patient care treatment protocols.

(b) Communication instruments or devices such as data radio, facsimile, computer, or telemetry radio shall be in addition to the mission dedicated dispatch radio and shall function independently from the mission-dedicated radio.

History Note: *Authority G.S. 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .0214 EMS NON-TRANSPORTING VEHICLE PERMIT CONDITIONS

(a) A licensed EMS provider shall apply to the OEMS for an EMS non-transporting Vehicle Permit prior to placing such vehicle in service.

(b) The OEMS shall issue a permit for a vehicle following verification of compliance with applicable laws and rules.

(c) Only one EMS Non-transporting Vehicle Permit shall be issued for each vehicle.

(d) EMS Non-transporting Vehicle Permits shall not be transferred.

(e) The EMS Non-transporting Vehicle Permit shall be posted on the vehicle by the OEMS inspector.

(f) Vehicles that are not owned or leased by the licensed EMS Provider are ineligible for permitting.

History Note: *Authority G.S. 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. January 1, 2017.

10A NCAC 13P .0215 TERM OF EMS NONTRANSPORTING VEHICLE PERMIT

EMS Nontransporting Vehicle Permits remain in effect for two years, unless any of the following occurs:

(1) The Department imposes an administrative sanction that specifies permit expiration;
(2) The EMS Provider closes or goes out of business;
(3) The EMS Provider changes name or ownership; or
(4) Failure to comply with Rule .0213 of this Section.

History Note: *Authority G.S. 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .0216 WEAPONS AND EXPLOSIVES FORBIDDEN

(a) Weapons, whether lethal or non-lethal, and explosives shall not be worn or carried aboard an ambulance or EMS non-transporting vehicle within the State of North Carolina when the vehicle is operating in any patient treatment or transport capacity or is available for such function.

(b) Conducted electrical weapons and chemical irritants such as mace, pepper (oleoresin capsicum) spray, and tear gas shall be considered weapons for the purpose of this Rule.

(c) This Rule shall apply whether such weapons and explosives are concealed or visible.

(d) If any weapon is found to be in the possession of a patient or person accompanying the patient during transportation, the weapon shall be safely secured in accordance with the weapons policy as set forth in Rule .0201 of this Section.

(e) Weapons authorized for use by EMS personnel attached to a law enforcement tactical team in accordance with the weapons policy as set forth in Rule .0201 of this Section may be secured in a locked, dedicated compartment or gun safe mounted within the ambulance or non-transporting vehicle for use when dispatched in support of the law enforcement tactical team, but are not to be worn or carried open or concealed by any EMS personnel in the performance of normal EMS duties under any circumstances.

(f) This Rule shall not apply to duly appointed law enforcement officers.

(g) Safety flares are authorized for use on an ambulance with the following restrictions:

(1) these devices are not stored inside the patient compartment of the ambulance; and

(2) these devices shall be packaged and stored to prevent accidental discharge or ignition.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Readopted Eff. January 1, 2017;
Amended Eff. April 1, 2024.

10A NCAC 13P .0217 MEDICAL AMBULANCE/EVACUATION BUS: VEHICLE AND EQUIPMENT REQUIREMENTS

(a) A Medical Ambulance/Evacuation bus is a multiple passenger vehicle configured and medically equipped for emergency and non-emergency transport of at least three stretcher bound patients with traumatic or medical conditions.

(b) To be permitted as a Medical Ambulance/Evacuation Bus, a vehicle shall have:

(1) a non-light penetrating sliding curtain installed behind the driver from floor-to-ceiling and from side-to-side to keep all light from the patient compartment from reaching the driver's area during vehicle operation at night;

(2) patient care equipment and supplies as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection." The equipment and supplies shall be clean, in working order, and secured in the vehicle;

(3) five-pound fire extinguishers mounted in a quick release bracket located inside the patient compartment at the front and rear of the vehicle that are either a dry chemical or all-purpose type and have pressure gauges;

(4) monitor alarms installed inside the patient compartment at the front and rear of the vehicle to warn of unsafe buildup of carbon monoxide;

(5) the name of the EMS provider permanently displayed on each side of the vehicle;

(6) reflective tape affixed to the vehicle such that there is reflectivity on all sides of the vehicle;

(7) emergency warning lights and audible warning devices mounted on the vehicle as required by G.S. 20-125. All warning devices shall function properly;

(8) no structural or functional defects that may adversely affect the patient, the EMS personnel, or the safe operation of the vehicle;

(9) an operational two-way radio that:

(A) is mounted to the ambulance and installed for safe operation and controlled by the ambulance driver;

(B) has the range, radio frequencies, and capabilities to establish and maintain two-way voice radio communication from within the defined service area of the EMS System to the emergency communications center or PSAP designated to direct or dispatch the deployment of the ambulance;

(C) is capable of establishing two-way voice radio communication from within the defined service area to the emergency department of the hospital(s) where patients are routinely transported and to facilities that provide on-line medical direction to EMS personnel;

(D) is equipped with a radio control device in the patient compartment capable of operation by the patient attendant to receive on-line medical direction; and

(E) is licensed or authorized by the FCC;

(10) permanently installed heating and air conditioning systems; and

(11) a copy of the EMS System patient care treatment protocols.

(c) A Medical Ambulance/Evacuation Bus shall not use a radiotelephone device such as a cellular telephone as the only source of two-way radio voice communication.

(d) Communication instruments or devices such as data radio, facsimile, computer, or telemetry radio shall be in addition to the mission dedicated dispatch radio and shall function independently from the mission dedicated radio.

(e) The EMS System medical director shall designate the combination of medical equipment as required in Subparagraph (b)(2) of this Rule that is carried on a mission based on anticipated patient care needs.

(f) The ambulance permit for this vehicle shall remain in effect for two years unless any of the following occurs:

(1) the Department imposes an administrative sanction which specifies permit expiration;

(2) the EMS Provider closes or goes out of business;

(3) the EMS Provider changes name or ownership; or

(4) failure to comply with the applicable Paragraphs of this Rule.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Eff. July 1, 2011;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0218 PEDIATRIC SPECIALTY CARE GROUND AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS

(a) A Pediatric Specialty Care Ground Ambulance is an ambulance used to transport only those patients 18 years old or younger with traumatic or medical conditions or for whom the need for specialty care or emergency or non-emergency medical care is anticipated during an inter-facility or discharged patient transport.

(b) To be permitted as a Pediatric Specialty Care Ground Ambulance, a vehicle shall have:

(1) a patient compartment that meets the following interior dimensions:
  (A) the length, measured on the floor from the back of the driver's compartment, driver's seat or partition to the inside edge of the rear loading doors, is at least 102 inches; and
  (B) the height is at least 48 inches over the patient area, measured from the center of the floor, exclusive of cabinets or equipment;

(2) patient care equipment and supplies as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection." The equipment and supplies shall be clean, in working order, and secured in the vehicle;

(3) one fire extinguisher mounted in a quick release bracket that is either a dry chemical or all-purpose type and has a pressure gauge;

(4) the name of the EMS Provider permanently displayed on each side of the vehicle;

(5) reflective tape affixed to the vehicle such that there is reflectivity on all sides of the vehicle;

(6) emergency warning lights and audible warning devices mounted on the vehicle as required by G.S. 20-125. All warning devices shall function properly;

(7) no structural or functional defects that may adversely affect the patient, the EMS personnel, or the safe operation of the vehicle;

(8) an operational two-way radio that:
  (A) is mounted to the ambulance and installed for safe operation and controlled by the ambulance driver;
  (B) has the range, radio frequencies, and capabilities to establish and maintain two-way voice radio communication from within the defined service area of the EMS System to the emergency communications center or PSAP designated to direct or dispatch the deployment of the ambulance;
  (C) is capable of establishing two-way voice radio communication from within the defined service area to the emergency department of the hospital(s) where patients are routinely transported and to facilities that provide on-line medical direction to EMS personnel;
  (D) is equipped with a radio control device in the patient compartment capable of operation by the patient attendant to receive on-line medical direction; and
  (E) is licensed or authorized by the FCC;

(9) permanently installed heating and air conditioning systems; and

(10) a copy of the EMS System patient care treatment protocols.

(c) Pediatric Specialty Care Ground ambulances shall not use a radiotelephone device such as a cellular telephone as the only source of two-way radio voice communication.

(d) Communication instruments or devices such as data radio, facsimile, computer, or telemetry radio shall be in addition to the mission dedicated dispatch radio and shall function independently from the mission dedicated radio.

(e) The Specialty Care Transport Program medical director shall designate the combination of medical equipment as required in Subparagraph (b)(2) of this Rule that is carried on a mission based on anticipated patient care needs.

(f) The ambulance permit for this vehicle shall remain in effect for two years unless any of the following occurs:

(1) the Department imposes an administrative sanction which specifies permit expiration;

(2) the EMS Provider closes or goes out of business;

(3) the EMS Provider changes name or ownership; or

(4) failure to comply with the applicable paragraphs of this Rule.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Eff. July 1, 2011;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0219 STAFFING FOR MEDICAL AMBULANCE/EVACUATION BUS VEHICLES

Medical Ambulance/Evacuation Bus Vehicles are exempt from the requirements of G.S. 131E-158(a). The EMS System Medical Director, as set forth in Rule .0403(8) of this Subchapter, shall determine the combination and number of EMT, AEMT, or Paramedic personnel that are sufficient to manage the anticipated number and severity of injury or illness of the patients transported in the Medical Ambulance/Evacuation Bus Vehicle.

History Note: *Authority G.S. 131E-158(b);*
Eff. July 1, 2011;
Readopted Eff. January 1, 2017.

10A NCAC 13P .0220 STAFFING FOR PEDIATRIC SPECIALTY CARE GROUND AMBULANCES

Pediatric Specialty Care Ground Ambulances operated within the approved Specialty Care Transport Program dedicated for inter-facility transport of non-emergent, emergent, and critically ill or injured or discharged Neonatal and Pediatric patients are exempt from the requirements of G.S. 131E-158(a). The Specialty Care Program Medical Director shall determine the staffing that is sufficient to manage the severity of illness or injury of the patients transported in the Pediatric Specialty Care Ground Ambulance.

History Note: *Authority G.S. 131E-158(b);*
Eff. July 1, 2011;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .0221 PATIENT TRANSPORTATION BETWEEN HOSPITALS

(a) For the purpose of this Rule, hospital means those facilities as defined in Rule .0102 of this Subchapter.

(b) Every ground ambulance when transporting a patient between hospitals shall be occupied by all of the following:

(1) one person who holds a credential issued by the OEMS as an emergency medical responder or higher who is responsible for the operation of the vehicle and rendering assistance to the patient caregiver when needed; and

(2) at least one of the following individuals as determined by the transferring physician to manage the anticipated severity of injury or illness of the patient who is responsible for the medical aspects of the mission:

(A) emergency medical technician;
(B) advanced EMT;
(C) paramedic;
(D) nurse practitioner;
(E) physician;
(F) physician assistant;
(G) registered nurse; or
(H) respiratory therapist.

(c) Information shall be provided to the OEMS by the licensed EMS provider in the application:

(1) describing the intended staffing pursuant to Rule .0204 of this Section; and

(2) showing authorization pursuant to Rule .0204 of this Section by the county where the EMS provider license is issued to use the staffing in Paragraph (b) of this Rule.

(d) Ambulances used for patient transports between hospitals shall contain all medical equipment, supplies, and medications approved by the Medical Director, based upon the NCCEP treatment protocol guidelines. These protocol guidelines set forth in Rules .0405 and .0406 of this Subchapter are available online at no cost at https://oems.nc.gov.

History Note: *Authority G.S. 131E-155.1; 131E-158(b); 143-508(d)(1); 143-508(d)(8);*
Eff. July 1, 2012;
Readopted Eff. January 1, 2017;
Amended Eff. April 1, 2024; September 1, 2019.

10A NCAC 13P .0222 TRANSPORT OF STRETCHER BOUND PATIENTS

(a) Any person transported on a stretcher as defined in Rule .0102 of this Subchapter meets the definition of patient as defined in G.S. 131E-155(16).

(b) Stretchers may only be utilized for patient transport in an ambulance permitted by the OEMS in accordance with G.S. 131E-156 and Rule .0211 of this Section.

(c) The Medical Care Commission exempts wheeled chair devices used solely for the transportation of mobility impaired persons seated in an upright position in non-permitted vehicles from the definition of stretcher.

History Note: *Authority G.S. 131E-156; 131E-157; 143-508(d)(8);*
Eff. January 1, 2017;
Amended Eff. July 1, 2021; July 1, 2018.

10A NCAC 13P .0223 REQUIRED DISCLOSURE AND REPORTING INFORMATION

(a) Applicants for initial and renewal EMS Provider licensing shall disclose the following background information:

(1) any prior name(s) used for providing emergency medical services in North Carolina or any other state;

(2) any felony criminal charges and convictions, under Federal or State law, and any civil actions taken against the applicant or any of its owners or officers in North Carolina or any other state;

(3) any misdemeanor or felony conviction, under Federal or State law, relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance;

(4) any misdemeanor or felony conviction, under Federal or State law, related to theft, fraud, embezzlement, breach of fiduciary duty, or other financial misconduct in connection with the delivery of EMS care or service;

(5) any current or prior investigations, including outcomes, for alleged Medicare, Medicaid, or other insurance fraud, tax evasion, and fraud;

(6) any revocation or suspension of accreditation; and

(7) any revocation or suspension by any State licensing authority of a license to provide EMS.

(b) Within 30 days of occurrence, a licensed EMS provider shall disclose any changes in the information set forth in Paragraph (a) of this Rule that was provided to the OEMS in its most recent application.

History Note: *Authority G.S. 131E-155.1(c); 131E-159; 143-508(d)(1); 143-508(d)(5);*
Eff. January 1, 2017.

10A NCAC 13P .0224 GROUND AMBULANCE VEHICLE MANUFACTURING STANDARDS

(a) In addition to the terms defined in Rule .0102 of this Subchapter, the following definitions apply to this Rule:

(1) "Remounted" means a ground ambulance patient compartment module that has been removed from its original chassis and mounted onto a different chassis.

(2) "Refurbished" means upgrading or repairing an existing ground ambulance patient care module or chassis that may not involve replacement of the chassis.

(b) "Ground ambulances" as defined in Rule .0102 of this Subchapter manufactured after July 1, 2018, or remounted after July 1, 2025, that are based and operated in North Carolina shall meet one of the following manufacturing standards:

(1) the Commission on Accreditation of Ambulance Services (CAAS) "Ground Vehicle Standard for Ambulances, which is incorporated herein by reference including all subsequent amendments and editions. This document is available online at no cost at www.groundvehiclestandard.org; or

(2) the National Fire Protection Association (NFPA) 1917-2016 "Standard for Automotive Ambulances," which is incorporated herein by reference including all subsequent amendments and editions. This document is available for purchase online at www.nfpa.org for a cost of seventy-eight dollars ($78.00).

(c) The following shall be exempt from the criteria set forth in Paragraph (b) of this Rule:

(1) ambulances owned and operated by an agency of the United States government;

(2) ambulances manufactured prior to July 1, 2018;

(3) ambulances remounted prior to July 1, 2025;

(4) "convalescent ambulances" as defined in Rule .0102 of this Subchapter;

(5) refurbished ambulances; or

(6) Medical Ambulance/Evacuation/Bus as set forth in Rule .0217 of this Section.

(d) Effective July 1, 2018, the National Highway Traffic Safety Administration (NHTSA) KKK-A-1822F-Ambulance Manufacturing Standard shall no longer meet the manufacturing standards for new ground ambulances as set forth in Paragraph (b) of the Rule.

(e) Ground ambulances that do not meet the criteria set forth in this Rule shall be ineligible for permitting as set forth in Rule .0211 of this Section.

History Note: *Authority G.S. 131E-156; 131E-157; 143-508(d)(8);*
Eff. January 1, 2018;
Amended Eff. April 1, 2024.

SECTION .0300 – SPECIALTY CARE TRANSPORT PROGRAMS

10A NCAC 13P .0301 SPECIALTY CARE TRANSPORT PROGRAM CRITERIA

(a) EMS Providers seeking designation to provide specialty care transports shall submit an application for program approval to the OEMS at least 60 days prior to field implementation. The application shall document that the program has:

(1) a defined service area that identifies the specific transferring and receiving facilities the program is intended to service;
(2) written policies and procedures implemented for medical oversight meeting the requirements of Section .0400 of this Subchapter;
(3) service available on a 24 hour a day, seven days a week basis;
(4) the capability to provide the patient care skills and procedures as specified in "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection;"
(5) a written continuing education program for EMS personnel, under the direction of the Specialty Care Transport Program Continuing Education Coordinator, developed and modified based upon feedback from program data, review and evaluation of patient outcomes, and quality management review that follows the criteria set forth in Rule .0501 of this Subchapter;
(6) a communication system that provides two-way voice communications for transmission of patient information to medical crew members anywhere in the service area of the program. The SCTP Medical Director shall verify that the communications system is satisfactory for on-line medical direction;
(7) medical crew members that have completed training conducted every six months regarding:
    (A) operation of the EMS communications system used in the program; and
    (B) the medical and patient safety equipment specific to the program;
(8) written operational protocols for the management of equipment, supplies, and medications. These protocols shall include:
    (A) a Specialized Ambulance Protocol Summary document listing of all standard medical equipment, supplies, and medications, approved by the Medical Director as sufficient to manage the anticipated number and severity of injury or illness of the patients, for all vehicles and aircraft used in the program based on the treatment protocols and approved by the OEMS; and
    (B) a methodology to ensure that each ground vehicle and aircraft contains the required equipment, supplies, and medications on each response; and
(9) written policies and procedures specifying how EMS Systems will dispatch and utilize the ground ambulances and aircraft operated by the program.

(b) When transporting patients, staffing for the ground ambulance and aircraft used in the SCTP shall be approved by the SCTP Medical Director as medical crew members, using any of the following as determined by the transferring physician who is responsible for the medical aspects of the mission to manage the anticipated severity of injury or illness of the patient:

(1) paramedic;
(2) nurse practitioner;
(3) physician;
(4) physician assistant;
(5) registered nurse; or
(6) respiratory therapist.

(c) SCTP as defined in Rule .0102 of this Subchapter are exempt from the staffing requirements defined in G.S. 131E-158(a).

(d) SCTP approval is valid for six years. Programs shall apply to the OEMS for reapproval no more than 90 days prior to expiration.

History Note: *Authority G.S. 131E-155.1(b); 131E-158; 143-508;*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004;
Amended Eff. January 1, 2004;
Amended Eff. March 3, 2009 pursuant to E.O. 9, Beverly Perdue, March 3, 2009;

Pursuant to G.S. 150B-21.3(c), a bill was not ratified by the General Assembly to disapprove this rule;
Readopted Eff. January 1, 2017;
Amended Eff. April 1, 2024; July 1, 2018.

10A NCAC 13P .0302 AIR MEDICAL SPECIALTY CARE TRANSPORT PROGRAM CRITERIA FOR LICENSED EMS PROVIDERS USING ROTARY-WING AIRCRAFT

(a) Air Medical Programs using rotary-wing aircraft shall document that the program has:

(1) medical crew members that have all completed training regarding:
  (A) altitude physiology; and
  (B) the operation of the EMS communications system used in the program;
(2) written policies and procedures for transporting patients to designated facilities when diversion or bypass plans are activated;
(3) written policies and procedures specifying how EMS Systems will dispatch and utilize aircraft operated by the program;
(4) written triage protocols for trauma, stroke, STEMI, burn, and pediatric patients reviewed and approved by the OEMS Medical Director;
(5) written policies and procedures specifying how EMS Systems will receive the Specialty Care Transport Services offered under the program when the aircraft are unavailable for service; and
(6) written policies and procedures specifying how mutual aid assistance will be obtained from both in-state and bordering out-of-state air medical programs.

(b) All patient response, re-positioning, and mission flight legs shall be conducted under FAA part 135 regulations.

History Note: *Authority G.S. 143-508;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. March 3, 2009 pursuant to E.O. 9, Beverly Perdue, March 3, 2009;
Pursuant to G.S. 150B-21.3(c), a bill was not ratified by the General Assembly to disapprove this rule;
Readopted Eff. January 1, 2017.

10A NCAC 13P .0305 AIR MEDICAL SPECIALTY CARE TRANSPORT PROGRAM CRITERIA FOR LICENSED EMS PROVIDERS USING FIXED-WING AIRCRAFT

(a) In addition to the general requirements of Specialty Care Transport Programs in Rule .0301 of this Section, Air Medical Programs using fixed-wing aircraft shall document that:

(1) Medical crew members have all completed training regarding:
  (A) Altitude physiology; and
  (B) The operation of the EMS communications system used in the program;
(2) Written policies and procedures specifying how ground ambulance services are utilized by the program for patient delivery and receipt on each end of the transport; and
(3) There is a copy of the Specialty Care Treatment Program patient care protocols.

(b) All patient, re-positioning, and mission flight legs must be conducted under FAA part 135 regulations.

History Note: *Authority G.S. 143-508(d)(1), (d)(3);*
Eff. March 3, 2009 pursuant to E.O. 9, Beverly Perdue, March 3, 2009;
Pursuant to G.S. 150B-21.3(c), a bill was not ratified by the General Assembly to disapprove this rule;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

SECTION .0400 - MEDICAL OVERSIGHT

10A NCAC 13P .0401 COMPONENTS OF MEDICAL OVERSIGHT FOR EMS SYSTEMS

Each EMS System shall have the following components in place to assure medical oversight of the system:

(1) a medical director for adult and pediatric patients appointed, either directly or by written delegation, by the county responsible for establishing the EMS System. Systems may elect to appoint one or more assistant medical directors. The medical director and assistant medical directors shall meet the criteria defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection;"

(2) written treatment protocols for adult and pediatric patients for use by EMS personnel;

(3) for systems providing EMD service, an EMDPRS approved by the medical director;

(4) an EMS Peer Review Committee; and

(5) written procedures for use by EMS personnel to obtain on-line medical direction. On-line medical direction shall:

(a) be restricted to medical orders that fall within the scope of practice of the EMS personnel and within the scope of approved system treatment protocols;

(b) be provided only by a physician, EMS-NP, or EMS-PA. Only physicians may deviate from written treatment protocols; and

(c) be provided by a system of two-way voice communication that can be maintained throughout the treatment and disposition of the patient.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0402 COMPONENTS OF MEDICAL OVERSIGHT FOR SPECIALTY CARE TRANSPORT PROGRAMS

Each Specialty Care Transport Program shall have the following components in place to assure Medical Oversight of the system:

(1) a medical director. The administration of the SCTP shall appoint a medical director following the criteria for medical directors of Specialty Care Transport Programs as defined by the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection." The program administration may elect to appoint one or more assistant medical directors;

(2) treatment protocols for adult and pediatric patients for use by medical crew members;

(3) an EMS Peer Review Committee; and

(4) a written protocol for use by medical crew members to obtain on-line medical direction. On-line medical direction shall:

(a) be restricted to medical orders that fall within the scope of practice of the medical crew members and within the scope of approved program treatment protocols;

(b) be provided only by a physician, EMS-NP, or EMS-PA. Only physicians may deviate from written treatment protocols; and

(c) be provided by a system of two-way voice communication that can be maintained throughout the treatment and disposition of the patient.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0403 RESPONSIBILITIES OF THE MEDICAL DIRECTOR FOR EMS SYSTEMS

(a) The Medical Director for an EMS System is responsible for the following:

(1) ensuring that medical control as set forth in Rule .0401(5) of this Section is available 24 hours a day, seven days a week;

(2) the establishment, approval, and annual updating of adult and pediatric treatment protocols as set forth in Rule .0405 of this Section;

(3) EMD programs, the establishment, approval, and annual updating of the EMDPRS, including subsequent editions published by the EMDPRS program utilized by the EMS System;

(4) medical supervision of the selection, system orientation, continuing education and performance of all EMS personnel;

(5) medical supervision of a scope of practice performance evaluation for all EMS personnel in the system based on the treatment protocols for the system;

(6) the medical review of the care provided to patients;

(7) providing guidance regarding decisions about the equipment, medical supplies, and medications that will be carried on all ambulances and EMS nontransporting vehicles operating within the system;

(8) determining the combination and number of EMS personnel sufficient to manage the anticipated number and severity of injury or illness of the patients transported in Medical Ambulance/Evacuation Bus Vehicles defined in Rule .0219 of this Subchapter; and

(9) keeping the care provided up-to-date with current medical practice.

(b) Any tasks related to Paragraph (a) of this Rule may be completed, through the Medical Director's written delegation, by assisting physicians, physician assistants, nurse practitioners, registered nurses, EMDs, or paramedics. The EMS System Medical Director may delegate physician medical oversight for a licensed EMS provider at the EMT level of service that does not back up the emergency 911 EMS System. Any decision delegating medical oversight for a licensed provider shall comply with the EMS System franchise requirements in Rule .0204 of this Subchapter. Medical oversight delegated for a licensed EMS provider shall meet the following requirements:

(1) a medical director for adult and pediatric patients. The medical director and assistant medical directors shall meet the criteria defined in "The North Carolina College of Emergency Physicians: Standards for Medical Oversight and Collection;"

(2) treatment protocols must be adopted in their original form from the standard adult and pediatric treatment protocols as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection;" and

(3) establish an agency peer review committee that meets quarterly. The agency peer review committee minutes shall be reported to the EMS System peer review committee.

(c) The Medical Director may suspend temporarily, pending review, any EMS personnel from further participation in the EMS System when he or she determines that the individual's actions are detrimental to the care of the patient, the individual committed unprofessional conduct, or the individual failed to comply with credentialing requirements. During the review process, the Medical Director may:

(1) restrict the EMS personnel's scope of practice pending completion of remediation on the identified deficiencies;

(2) continue the suspension pending completion of remediation on the identified deficiencies; or

(3) permanently revoke the EMS personnel's participation in the EMS System.

History Note: *Authority G.S. 143-508(b); 143-508(d)(3); 143-508(d)(7);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Readopted Eff. January 1, 2017;
Amended Eff. April 1, 2024.

10A NCAC 13P .0404 RESPONSIBILITIES OF THE MEDICAL DIRECTOR FOR SPECIALTY CARE TRANSPORT PROGRAMS

(a) The medical director for a Specialty Care Transport Program is responsible for the following:

(1) the establishment, approval, and updating of adult and pediatric treatment protocols as set forth in Rule .0406 of this Section;

(2) medical supervision of the selection, program orientation, continuing education, and performance of medical crew members;

(3) medical supervision of a scope of practice performance evaluation for all medical crew members in the program based on the treatment protocols for the program;

(4) the medical review of the care provided to patients;

(5) keeping the care provided up to date with current medical practice;

(6) approving the Specialized Ambulance Protocol Summary (SAPS) document listing of all medications, equipment, and supplies for all Specialty Care level ground vehicles and aircraft permitted by the OEMS; and

(7) in air medical programs, determination and specification of the medical equipment required in Rule .0209 of this Subchapter that is carried on a mission based on anticipated patient care needs.

(b) Any tasks related to Paragraph (a) of this Rule may be completed, through written delegation, by assisting physicians, physician assistants, nurse practitioners, registered nurses, or medical crew members.

(c) The medical director may suspend temporarily, pending due process review, any medical crew members from further participation in the Specialty Care Transport Program when it is determined the activities or medical care rendered by such personnel may be detrimental to the care of the patient, constitute unprofessional conduct, or result in non-compliance with credentialing requirements. During the review process, the medical director may:

(1) restrict the EMS personnel's scope of practice pending completion of remediation on the identified deficiencies;

(2) continue the suspension pending completion of remediation on the identified deficiencies; or

(3) permanently revoke the EMS personnel's participation in the Specialty Care Transport Program.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0405 REQUIREMENTS FOR ADULT AND PEDIATRIC TREATMENT PROTOCOLS FOR EMS SYSTEMS

(a) Treatment Protocols used in EMS Systems shall:

(1) Be adopted in their original form from the standard adult and pediatric treatment protocols as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost; and

(2) Not contain medical procedures, medications, or intravenous fluids that exceed the scope of practice defined by the North Carolina Medical Board pursuant to G.S. 143-514 for the level of care offered in the EMS System and any other applicable health care licensing board.

(b) Individual adult and pediatric treatment protocols may be modified locally by EMS Systems if there is a change in a specific protocol which will optimize care within the local community which adds additional medications or medical procedures, or rearranges the order of care provided in the protocol contained within the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection" as described in Paragraph (a) of this Rule. Additional written Treatment Protocols may be developed by any EMS System in addition to the required protocols contained within the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection" as required by the EMS System. All North Carolina College of Emergency Physicians Policies and Procedures must be included and may be modified at the local level. All EMS System Treatment Protocols which have been added or changed by the EMS System shall be submitted to the OEMS Medical Director for review and approval at least 30 days prior to the implementation of the change.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .0406 REQUIREMENTS FOR ADULT AND PEDIATRIC TREATMENT PROTOCOLS FOR SPECIALTY CARE TRANSPORT PROGRAMS

(a) Adult and pediatric treatment protocols used by medical crew members within a Specialty Care Transport Program shall:

(1) be approved by the OEMS Medical Director and incorporate all skills, medications, equipment, and supplies for Specialty Care Transport Programs as defined by the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost; and

(2) not contain medical procedures, medications, or intravenous fluids that exceed the scope of practice of the medical crew members.

(b) All adult and pediatric treatment protocols shall be reviewed annually, and any change in the treatment protocols shall be submitted to the OEMS Medical Director for review and approval at least 30 days prior to the implementation of the change.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .0407 REQUIREMENTS FOR EMERGENCY MEDICAL DISPATCH PRIORITY REFERENCE SYSTEM

(a) EMDPRS used by an EMD within an approved EMD program shall:

(1) be approved by the OEMS Medical Director and meet or exceed the statewide standard for EMDPRS as defined by the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection;"

(2) not exceed the EMD scope of practice defined by the North Carolina Medical Board pursuant to G.S. 143-514;

(3) have a written plan how the agency is to maintain a current roster of EMD personnel in the OEMS credentialing and information database;

(4) have a written plan how the emergency medical dispatching agency applying the principles of EMD or offering EMD services, procedures, or program will comply with subsequent editions and compliance standards defined by the EMDPRS program and the EMS System; and

(5) participate and report compliance data at EMS System peer review meetings.

(b) An EMDPRS developed locally shall be reviewed and updated annually and submitted to the OEMS Medical Director for approval. Any change in the EMDPRS shall be submitted to the OEMS Medical Director for review and approval at least 30 days prior to the implementation of the change.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0408 EMS PEER REVIEW COMMITTEE FOR EMS SYSTEMS

The EMS Peer Review Committee for an EMS System shall:

(1) be composed of membership as defined in G.S. 131E-155(6b).
(2) appoint a physician as chairperson;
(3) meet at least quarterly;
(4) use information gained from the analysis of system data submitted to the OEMS to evaluate the ongoing quality of patient care and medical direction within the system;
(5) use information gained from the analysis of system data submitted to the OEMS to make recommendations regarding the content of continuing education programs for all EMS personnel functioning within the EMS system;
(6) review adult and pediatric treatment protocols of the EMS System and make recommendations to the medical director for changes;
(7) establish and implement a written procedure to guarantee due process reviews for EMS personnel temporarily suspended by the medical director;
(8) record and maintain minutes of committee meetings throughout the approval period of the EMS System;
(9) establish and implement EMS system performance improvement guidelines that meet or exceed the statewide standard as defined by the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost; and
(10) adopt written guidelines that address:
    (a) structure of committee membership;
    (b) appointment of committee officers;
    (c) appointment of committee members;
    (d) length of terms of committee members;
    (e) frequency of attendance of committee members;
    (f) establishment of a quorum for conducting business; and
    (g) confidentiality of medical records and personnel issues.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .0409 EMS PEER REVIEW COMMITTEE FOR SPECIALTY CARE TRANSPORT PROGRAMS

(a) The EMS Peer Review Committee for a Specialty Care Transport Program shall:

(1) be composed of membership as defined in G.S. 131E-155(6b);
(2) appoint a physician as chairperson;
(3) meet at least quarterly;
(4) analyze program data to evaluate the ongoing quality of patient care and medical direction within the program;
(5) use information gained from program data analysis to make recommendations regarding the content of continuing education programs for medical crew members;
(6) review adult and pediatric treatment protocols of the Specialty Care Transport Programs and make recommendations to the Medical Director for changes;
(7) establish and implement a written procedure to guarantee due process reviews for medical crew members temporarily suspended by the Medical Director;
(8) record and maintain minutes of committee meetings throughout the approval period of the Specialty Care Transport Program;
(9) establish and implement EMS system performance improvement guidelines that meet or exceed the statewide standard as defined by the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection;" and
(10) adopt written guidelines that address:
(A) structure of committee membership;
(B) appointment of committee officers;
(C) appointment of committee members;
(D) length of terms of committee members;
(E) frequency of attendance of committee members;
(F) establishment of a quorum for conducting business; and
(G) confidentiality of medical records and personnel issues.

(b) County government representation is not required for committee membership for approved Air Medical Programs.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004;
Amended Eff. March 3, 2009 pursuant to E.O. 9, Beverly Perdue, March 3, 2009;
Pursuant to G.S. 150B-21.3(c), a bill was not ratified by the General Assembly to disapprove this rule;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. January 1, 2017.

10A NCAC 13P .0410 COMPONENTS OF MEDICAL OVERSIGHT FOR AIR MEDICAL PROGRAMS

(a) Licensed EMS providers seeking to offer rotary-wing or fixed-wing air medical program services within North Carolina shall receive approval from the OEMS prior to beginning operation.

(b) Licensed EMS providers seeking to offer multiple air medical programs under separate medical oversight processes as set forth in Paragraph (c) of this Rule shall make application for each program and receive approval from the OEMS as set forth in Paragraph (a) of this Rule.

(c) Each Air Medical Program providing services within North Carolina shall meet the following requirements for the provision of medical oversight:

(1) a Medical Director as set forth in Rules .0402 and .0404 of this Section;
(2) treatment protocols approved by the OEMS, to be utilized by the provider as required by Rule .0406 of this Section;
(3) a peer review committee as required by Rule .0409 of this Section;
(4) notify all North Carolina EMS Systems where services will be provided to enable each EMS System to include the provider in their EMS System plan, as set forth in Rule .0201 of this Subchapter;
(5) all aircrafts used within North Carolina shall comply with Rule .0209 of this Subchapter;
(6) populate and maintain a roster in the North Carolina database for all air medical crew members, Medical Directors, and staff identified by the program to serve as primary and secondary administrative contacts;
(7) all medical crew members operating in North Carolina shall maintain a North Carolina license or credential in accordance with the rules and regulations of the respective state licensing or credentialing body;
(8) active membership in each Trauma RAC containing the majority of hospitals where the program transports patients for admission;
(9) submit patient care data electronically, within 24 hours, to the OEMS EMS care database as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Collection" for all interstate and intrastate transports as set forth in Rule .0204 of this Subchapter;
(10) provide information regarding procedures performed during transport within North Carolina to OEMS for quality management review as required by the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection;"
(11) submit peer review materials to the receiving hospital's peer review committee for each patient transported for admission; and
(12) a method providing for the coordinated dispatch of resources between air medical programs for scene safety, ensuring that only the number of air medical resources needed respond to the incident location are provided, and arranging for the receiving hospital to prepare for the incoming patient.

(d) In addition to the requirements set forth in Paragraph (c) of this Rule, Air Medical Program whose base of operation is outside of North Carolina who operate fixed-wing or rotary-wing air medical programs within the State shall meet the following requirements for the provision of medical oversight:

(1) submit to the OEMS all existing treatment protocols utilized by the program in the state that it is based for comparison with North Carolina standards as set forth in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," and make any modifications identified by the OEMS to comply with the standards as set forth in Subparagraph (c)(2) of this Rule;
(2) all aircrafts used within North Carolina shall comply with Rule .0209 of this Subchapter, inspections to be conducted at a location inside North Carolina at a time agreed upon by the Department and the Air Medical Program;
(3) submit written notification to the Department within three business days of receiving notice of any arrests or regulatory investigations for the diversion of drugs or patient care issues involving a North Carolina credentialed or licensed medical crew member; and
(4) any medical crew member suspended by the Department shall be barred from patient contact when operating in North Carolina until such time as the case involving the medical crew member has been adjudicated or resolved as set forth in Rule .1507 of this Subchapter;

(e) Significant failure to comply with the criteria set forth in this Rule shall result in revocation of the Air Medical Program as set forth in Rule .1503 of this Subchapter.

History Note: *Authority G.S. 131E-155.1; 131E-156; 131E-157(a); 131E-161; 143-508(d)(8);*
Eff. January 1, 2018;
Amended Eff. April 1, 2024.

SECTION .0500 – EMS PERSONNEL

10A NCAC 13P .0501 EDUCATIONAL PROGRAMS

(a) EMS educational programs that qualify credentialed EMS personnel to perform within their scope of practice shall be offered by an EMS educational institution as set forth in Section .0600 of this Subchapter, or by an EMS educational institution in another state where the education and credentialing requirements have been approved for legal recognition by the Department pursuant to G.S. 131E-159 as determined using the professional judgment of OEMS staff following comparison of out-of-state standards with the program standards set forth in this Rule.

(b) Educational programs approved to qualify EMS personnel for credentialing shall meet the educational content of the "US DOT NHTSA National EMS Education Standards," which is hereby incorporated by reference, including subsequent amendments and editions. This document is available online at no cost at www.ems.gov/education.html.

(c) Educational programs approved to qualify EMS personnel for initial AEMT and Paramedic credentialing shall meet the requirements of Paragraph (b) of this Rule and possess verification of accreditation or a valid letter of review from the Commission on Accreditation of Allied Health Education Programs (CAAHEP) or other accrediting agency determined using the professional judgment of OEMS staff following a comparison of standards. The Department shall not approve initial AEMT or Paramedic courses for educational programs that fail to meet accreditation requirements by January 1, 2023.

(d) Educational programs approved to qualify EMD personnel for credentialing shall conform with the "ASTM F1258 – 95(2014): Standard Practice for Emergency Medical Dispatch," which is hereby incorporated by reference including subsequent amendments and editions. This document is available from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428-2959 USA, at a cost of forty eight dollars ($48.00) per copy.

(e) Instructional methodology courses approved to qualify Level I EMS instructors shall conform with the "US DOT NHTSA 2002 National Guidelines for Educating EMS Instructors," which is hereby incorporated by reference including subsequent amendments and additions. This document is available online at no cost at www.ems.gov/education.html.

(f) Continuing educational programs approved by the OEMS to qualify EMS personnel for renewal of credentials shall be approved by demonstrating the ability to assess cognitive competency in the skills and medications for the level of application as defined by the North Carolina Medical Board pursuant to G.S. 143-514.

(g) Refresher courses shall comply with the requirements defined in Rule .0513 of this Section.

History Note: *Authority G.S. 143-508(d)(3); 143-508(d)(4); 143-514;*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004;
Amended Eff. January 1, 2009;
Readoption Eff. January 1, 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0502 INITIAL CREDENTIALING REQUIREMENTS FOR EMR, EMT, AEMT, PARAMEDIC, AND EMD

(a) In order to be credentialed by the OEMS as an EMR, EMT, AEMT, or Paramedic, individuals shall:

(1) Be at least 18 years of age. An examination may be taken at age 17; however, the EMS credential shall not be issued until the applicant has reached the age of 18.

(2) Complete an approved educational program as set forth in Rule .0501 of this Section for their level of application.

(3) Complete a scope of practice performance evaluation that uses performance measures based on the cognitive, psychomotor, and affective educational objectives set forth in Rule .0501 of this Section and that is consistent with their level of application, and approved by the OEMS. This scope of practice evaluation shall be completed no more than one year prior to examination. This evaluation shall be conducted by a Level I or Level II EMS Instructor credentialed at or above the level of application or under the direction of the primary credentialed EMS instructor or educational medical advisor for the approved educational program.

(4) Within 90 days from their course graded date as reflected in the OEMS credentialing database, complete a written examination administered by the OEMS. If the applicant fails to register and complete a written examination within the 90-day period, the applicant shall obtain a letter of authorization to continue eligibility for testing from his or her EMS Educational Institution's program coordinator to qualify for an extension of the 90-day requirement set forth in this Paragraph. If the EMS Educational Institution's program coordinator declines to provide a letter of authorization, the applicant shall be disqualified from completing the credentialing process. Following a review of the applicant's specific circumstances, OEMS staff will determine, based on professional judgment, if the applicant qualifies for EMS credentialing eligibility. The OEMS shall notify the applicant in writing within 10 business days of the decision.

(A) a maximum of three attempts within six months shall be allowed.

(B) if unable to pass the written examination requirement after three attempts, the educational program shall become invalid and the individual may only become eligible for credentialing by repeating the requirements set forth in Rule .0501 of this Section.

(5) Submit to a criminal background history check as set forth in Rule .0511 of this Section.

(6) Submit evidence of completion of all court conditions resulting from any misdemeanor or felony conviction(s).

(b) An individual seeking credentialing as an EMR, EMT, AEMT, or Paramedic may qualify for initial credentialing under the legal recognition option set forth in G.S. 131E-159(c). Individuals seeking credentialing as an AEMT or Paramedic shall submit documentation that the credential being used for application is from an educational program meeting the requirements as set forth in Rule .0501 of this Section.

(c) In order to be credentialed by the OEMS as an EMD, individuals shall:

(1) be at least 18 years of age;

(2) complete the educational requirements set forth in Rule .0501 of this Section;

(3) complete, within one year prior to application, an AHA CPR course or a course determined by the OEMS to be equivalent to the AHA CPR course, including infant, child, and adult CPR;

(4) submit to a criminal background history check as defined in Rule .0511 of this Section;

(5) submit evidence of completion of all court conditions resulting from any misdemeanor or felony conviction(s); and

(6) possess an EMD nationally recognized credential pursuant to G.S. 131E-159(d).

(d) Pursuant to G.S. 131E-159(h), the Department shall not issue an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159(a); 131E-159(b); 131E-159(g); 131E-159(h); 143-508(d)(3); 143B-952;*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0503 TERM OF CREDENTIALS FOR EMS PERSONNEL

EMR, EMT, AEMT, Paramedic, and Instructor credentials shall be valid for a period of four years, and the EMD credential shall be valid for a period of two years, barring any delay in expiration as set forth in Rule .0504 of this Section.

History Note: *Authority G.S. 131E-159(a);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. April 1, 2024; January 1, 2017.

10A NCAC 13P .0504 RENEWAL OF CREDENTIALS FOR EMR, EMT, AEMT, PARAMEDIC, AND EMD

(a) EMR, EMT, AEMT, and Paramedic applicants shall renew credentials by meeting the following criteria:

(1) presenting documentation to the OEMS or an approved EMS educational institution or program as set forth in Rule .0601 or .0602 of this Subchapter that they have completed an approved educational program as described in Rule .0501 of this Section;

(2) submit to a criminal background history check as set forth in Rule .0511 of this Section;

(3) submit evidence of completion of all court conditions resulting from applicable misdemeanor or felony conviction(s); and

(4) be a resident of North Carolina or affiliated with an EMS provider approved by the Department.

(b) An individual may renew credentials by presenting documentation to the OEMS that he or she holds a valid EMS credential for his or her level of application issued by the National Registry of Emergency Medical Technicians or by another state where the education and credentialing requirements have been determined by OEMS staff in their professional judgment to be equivalent to the educations and credentialing requirements set forth in this Section.

(c) EMD applicants shall renew credentials by presenting documentation to the OEMS that he or she holds a valid EMD credential issued by a national credentialing agency using the education criteria set forth in Rule .0501 of this Section.

(d) Upon request, an EMS professional may renew at a lower credentialing level by meeting the requirements defined in Paragraph (a) of this Rule. To restore the credential held at the higher level, the individual shall meet the requirements set forth in Rule .0512 of this Section.

(e) EMS credentials may not be renewed through a local credentialed institution or program more than 90 days prior to the date of expiration.

(f) Pursuant to G.S. 150B-3(a), if an applicant makes a timely and sufficient application for renewal, the EMS credential shall not expire until a decision on the credential is made by the Department. If the application is denied, the credential shall remain effective until the last day for applying for judicial review of the Department's order.

(g) Pursuant to G.S. 131E-159(h), the Department shall not renew the EMS credential for any person listed on the North Carolina Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159(a); 131E-159(g); 131E-159(h); 143-508(d)(3); 143B-952; 150B-3(a);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0505 SCOPE OF PRACTICE FOR EMS PERSONNEL

EMS Personnel educated in approved programs, credentialed by the OEMS, and functioning under physician medical oversight may perform acts and administer intravenous fluids and medications as allowed by the North Carolina Medical Board pursuant to G.S. 143-514.

History Note: *Authority G.S. 143-508(d)(6); 143-514;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. July 1, 2018.

10A NCAC 13P .0506 PRACTICE SETTINGS FOR EMS PERSONNEL

(a) Credentialed EMS Personnel may function in the following practice settings in accordance with the protocols approved by the OEMS and by the Medical Director of the EMS System or Specialty Care Transport Program with which they are affiliated:

(1) at the location of a physiological or psychological illness or injury;
(2) at public or community health facilities in conjunction with public and community health initiatives;
(3) in hospitals and clinics;
(4) in residences, facilities, or other locations as part of wellness or injury prevention initiatives within the community and the public health system;
(5) at mass gatherings or special events; and
(6) community paramedicine programs.

(b) Individuals functioning in an alternative practice setting as defined in Rule .0102 of this Subchapter consistent with the areas identified in Subparagraphs (a)(1) through (a)(5) of this Rule that are not affiliated with an EMS System shall:

(1) be under the medical oversight of a physician licensed by the North Carolina Medical Board that is associated with the practice setting where the individual will function; and
(2) be restricted to performing within the scope of practice as defined by the North Carolina Medical Board pursuant to G.S. 143-514 for the individual's level of EMS credential.

(c) Individuals holding a valid EMR or EMT credential that are not affiliated with an approved first responder program or EMS agency and that do not administer medications or utilize advanced airway devices are approved to function as a member of an industrial or corporate first aid safety team without medical oversight or EMS System affiliation.

History Note: *Authority G.S. 143-508(d)(7);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. July 1, 2018; January 1, 2017.

10A NCAC 13P .0507 INITIAL CREDENTIALING REQUIREMENTS FOR LEVEL I EMS INSTRUCTORS

(a) Applicants for credentialing as a Level I EMS Instructor shall:

(1) be currently credentialed by the OEMS as an EMT, AEMT, or Paramedic;

(2) have completed post-secondary level education equal to or exceeding a minimum of an Associate Degree from an institution accredited by an approved agency listed on the U.S. Department of Education website, www.ed.gov:

(A) The Department shall accept degrees from programs accredited by the Accreditation Commission for Education in Nursing (ACEN) and the Commission on Accreditation of Allied Health Education Programs.

(B) Additional degrees may be accepted based on the professional judgment of OEMS staff following a comparison of standards;

(3) have three years experience at the scope of practice for the level of application;

(4) within one year prior to application, complete an in-person evaluation that demonstrates the applicant's ability to provide didactic and clinical instruction based on the cognitive, psychomotor, and affective educational objectives in Rule .0501 of this Section consistent with their level of application and approved by the OEMS:

(A) for a credential to teach at the EMT level, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application; and

(B) for a credential to teach at the AEMT or Paramedic level, this evaluation shall be conducted under the direction of the educational medical advisor, or a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor;

(5) have 100 hours of teaching experience at or above the level of application in an approved EMS educational program or a program determined by OEMS staff in their professional judgment equivalent to an EMS education program;

(6) complete an educational program as described in Rule .0501 of this Section; and

(7) within one year prior to application, attend an OEMS Instructor workshop sponsored by the OEMS. A listing of scheduled OEMS Instructor workshops is available from the OEMS at https://info.ncdhhs.gov/dhsr/ems.

(b) An individual seeking credentialing for Level I EMS Instructor may qualify for initial credentialing under the legal recognition option defined in G.S. 131E-159(c).

(c) The credential of a Level I EMS Instructor shall be valid for four years, or less pursuant to G.S. 131E-159(c), unless any of the following occurs:

(1) the OEMS imposes an administrative action against the instructor credential; or

(2) the instructor fails to maintain a current EMT, AEMT, or Paramedic credential at the highest level that the instructor is approved to teach.

(d) Pursuant to the provisions of G.S. 131E-159(h), the Department shall not issue an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159; 143-508(d)(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. January 1, 2022; September 1, 2019.

10A NCAC 13P .0508 INITIAL CREDENTIALING REQUIREMENTS FOR LEVEL II EMS INSTRUCTORS

(a) Applicants for credentialing as a Level II EMS Instructor shall:

(1) be currently credentialed by the OEMS as an EMT, AEMT, or Paramedic;

(2) be currently credentialed by the OEMS as a Level I Instructor at the EMT, AEMT, or Paramedic level;

(3) have completed post-secondary level education equal to or exceeding a Bachelor's Degree from an institution accredited by an approved agency listed on the U.S. Department of Education website, www.ed.gov:

(A) The Department shall accept degrees from programs accredited by the Accreditation Commission for Education in Nursing (ACEN) and the Commission on Accreditation of Allied Health Education Programs.

(B) Additional degrees may be accepted based on the professional judgment of OEMS staff following a comparison of standards;

(4) within one year prior to application, complete an in-person evaluation that demonstrates the applicant's ability to provide didactic and clinical instruction based on the cognitive, psychomotor, and affective educational objectives in Rule .0501 of this Section consistent with their level of application and approved by the OEMS:

(A) for a credential to teach at the EMT level, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application; and

(B) for a credential to teach at the AEMT or Paramedic level, this evaluation shall be conducted under the direction of the educational medical advisor, or a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor;

(5) a minimum two concurrent years teaching experience as a Level I EMS Instructor at or above the level of application, or as a Level II EMS Instructor at a lesser credential level applying for a higher level in an approved EMS educational program, or teaching experience determined by OEMS staff in their professional judgment to be equivalent to an EMS Level I education program;

(6) complete the "EMS Education Administration Course" conducted by a North Carolina Community College or the National Association of EMS Educators Level II Instructor Course that is valid for the duration of the active Level II Instructor credential; and

(7) within one year prior to application, attend an OEMS Instructor workshop sponsored by the OEMS. A listing of scheduled OEMS Instructor workshops is available from the OEMS at https://info.ncdhhs.gov/dhsr/ems.

(b) An individual seeking credentialing for Level II EMS Instructor may qualify for initial credentialing under the legal recognition option defined in G.S. 131E-159(c).

(c) The credential of a Level II EMS Instructor is valid for four years, or less pursuant to G.S. 131E-159(c), unless any of the following occurs:

(1) the OEMS imposes an administrative action against the instructor credential; or

(2) the instructor fails to maintain a current EMT, AEMT, or Paramedic credential at the highest level that the instructor is approved to teach.

(d) Pursuant to the provisions of G.S. 131E-159(h) the Department shall not issue an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159; 143-508(d)(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. January 1, 2022; September 1, 2019.

10A NCAC 13P .0509 CREDENTIALING OF INDIVIDUALS TO ADMINISTER LIFESAVING TREATMENT TO PERSONS SUFFERING AN ADVERSE REACTION TO AGENTS THAT MIGHT CAUSE ANAPHYLAXIS

(a) To become credentialed by the North Carolina Medical Care Commission to administer epinephrine to persons who suffer adverse reactions to agents that might cause anaphylaxis, a person shall meet the following:

(1) Be 18 years of age or older; and

(2) successfully complete an educational program taught by a physician licensed to practice medicine in North Carolina or designee of the physician. The educational program shall instruct individuals in the appropriate use of procedures for the administration of epinephrine to pediatric and adult victims who suffer adverse reactions to agents that might cause anaphylaxis and shall include the following:

(A) definition of anaphylaxis;

(B) agents that might cause anaphylaxis and the distinction between them, including drugs, insects, foods, and inhalants;

(C) recognition of symptoms of anaphylaxis for both pediatric and adult victims;

(D) appropriate emergency treatment of anaphylaxis as a result of agents that might cause anaphylaxis;

(E) availability and design of packages containing equipment for administering epinephrine to victims suffering from anaphylaxis as a result of agents that might cause anaphylaxis;

(F) pharmacology of epinephrine including indications, contraindications, and side effects;

(G) discussion of legal implications of rendering aid; and

(H) instruction that treatment is to be utilized only in the absence of the availability of physicians or other practitioners who are authorized to administer the treatment.

(b) A credential to administer epinephrine to persons who suffer adverse reactions to agents that might cause anaphylaxis shall be issued by the North Carolina Medical Care Commission upon receipt of a completed application signed by the applicant and the physician who taught or was responsible for the educational program. Applications may be obtained from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707. All credentials shall be valid for a period of four years.

(c) This Rule enables only those individuals who do not hold a North Carolina EMS credential and are not associated or affiliated with an EMS system, EMS agency, or emergency response provider to provide care pending arrival of the emergency responders dispatched through a 911 center to an EMS event involving a person suffering an anaphylactic reaction.

History Note: *Authority G.S. 143-508(d)(11); 143-509(9);*
Temporary Adoption Eff. January 1, 2003; January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; February 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .0510 RENEWAL OF CREDENTIALS FOR LEVEL I AND LEVEL II EMS INSTRUCTORS

(a) Level I and Level II EMS Instructor applicants shall renew credentials by presenting documentation to the OEMS that they:

(1) are credentialed by the OEMS as an EMT, AEMT, or Paramedic;

(2) within one year prior to application, complete an evaluation that demonstrates the applicant's ability to provide didactic and clinical instruction based on the cognitive, psychomotor, and affective educational objectives in Rule .0501 of this Section consistent with their level of application and approved by the OEMS:

(A) to renew a credential to teach at the EMT level, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application; and

(B) to renew a credential to teach at the AEMT or Paramedic level, this evaluation shall be conducted under the direction of the educational medical advisor, or a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor;

(3) completed 96 hours of EMS instruction at the level of application. Individuals identified as EMS program coordinators or positions as determined by OEMS staff in their professional judgment to the equivalent to an EMS program coordinator may provide up to 72 hours related to the institution's needs, with the remaining 24 hours in EMS instruction;

(4) completed 24 hours of educational professional development as defined by the educational institution that provides for:

(A) enrichment of knowledge;

(B) development or change of attitude in students; or

(C) acquisition or improvement of skills; and

(5) within one year prior to renewal application, attend an OEMS Instructor workshop sponsored by the OEMS.

(b) An individual may renew a Level I or Level II EMS Instructor credential under the legal recognition option defined in G.S. 131E-159(c).

(c) The credential of a Level I or Level II EMS Instructor is valid for four years, or less pursuant to G.S. 131E-159(c) unless any of the following occurs:

(1) the OEMS imposes an administrative action against the instructor credential; or

(2) the instructor fails to maintain a current EMT, AEMT, or Paramedic credential at the highest level that the instructor is approved to teach.

(d) Pursuant to the provisions of G.S. 131E-159(h), the Department shall not issue an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159(a); 131E-159(b); 143-508(d)(3);*
Eff. February 1, 2004;
Amended Eff. February 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0511 CRIMINAL HISTORIES

(a) The criminal background histories for all individuals who apply for, seek to renew, or hold EMS credentials shall be reviewed pursuant to G.S. 131E-159(g).

(b) In addition to Paragraph (a) of this Rule, the OEMS shall carry out the following for all EMS Personnel whose primary residence is outside North Carolina, individuals who have resided in North Carolina for 60 months or less, and individuals under investigation by the OEMS who may be subject to administrative enforcement action by the Department under the provisions of Rule .1507 of this Subchapter:

(1) obtain a signed consent form for a criminal history check;
(2) obtain fingerprints on an SBI identification card or live scan electronic fingerprinting system at an agency approved by the North Carolina Department of Public Safety;
(3) obtain the criminal history from the Department of Public Safety; and
(4) collect any processing fees from the individual identified in Paragraph (a) or (b) of this Rule as required by the Department of Public Safety pursuant to G.S. 143B-952 prior to conducting the criminal history background check.

(c) An individual who makes application for renewal of a current EMS credential or advancement to a higher level EMS credential who has previously submitted a criminal background history required under the criteria contained in Paragraph (b) of this Rule may be exempt from the residency requirements of Paragraph (b) of this Rule if determined by OEMS that no other circumstances warrant another criminal history check as set forth in Paragraph (b) of this Rule.

(d) An individual shall not be eligible for initial or renewal of EMS credentials if the applicant refuses to consent to any criminal history check as required by G.S. 131E-159(g). Since payment is required before the fingerprints may be processed by the Department of Public Safety, failure of the applicant or credentialed EMS personnel to pay the required fee in advance shall be considered a refusal to consent for the purposes of issuance or retention of an EMS credential.

History Note: *Authority G.S. 131E-159(g); 143-508(d)(3); 143-508(10); 143B-952;*
Eff. January 1, 2009;
Amended Eff. January 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. January 1, 2017.

10A NCAC 13P .0512 REINSTATEMENT OF LAPSED EMS CREDENTIAL

(a) EMS personnel enrolled in an OEMS approved continuing education program as set forth in Rule .0601 of this Subchapter and who were eligible for renewal of an EMS credential prior to expiration, may request the EMS educational institution submit documentation of the continuing education record to the OEMS. OEMS shall renew the EMS credential to be valid for four years from the previous expiration date.

(b) An individual with a lapsed North Carolina EMS credential is eligible for reinstatement through the legal recognition option defined in G.S. 131E-159(c) and Rule .0502 of this Section.

(c) EMR, EMT, AEMT, and Paramedic applicants for reinstatement of an EMS credential, lapsed up to 12 months, shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c);
(2) be a resident of North Carolina or affiliated with a North Carolina EMS provider or employed with an alternative practice setting in compliance with Rule .0506 of this Section;
(3) at the time of application, present evidence that renewal education requirements were met prior to expiration or complete a refresher course at the level of application taken following expiration of the credential;
(4) complete an OEMS administered written examination for the individual's level of credential application;
(5) undergo a criminal history check performed by the OEMS as defined in Rule .0511 of this Section; and
(6) submit evidence of completion of all court conditions resulting from applicable misdemeanor or felony conviction(s).

(d) EMR, EMT, AEMT, and Paramedic applicants for reinstatement of an EMS credential, lapsed more than 12 months shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c);
(2) be a resident of North Carolina, affiliated with a North Carolina EMS Provider, or employed with an alternative practice setting in compliance with Rule .0506 of this Section;
(3) at the time of application, complete a refresher course at the level of application taken following expiration of the credential;
(4) complete an OEMS administered written examination for the level of credential application;
(5) undergo a criminal history check performed by the OEMS as defined in Rule .0511 of this Section; and
(6) submit evidence of completion of all court conditions resulting from applicable misdemeanor or felony conviction(s).

(e) EMT, AEMT, and Paramedic applicants for reinstatement of an EMS Instructor Credential, lapsed up to 12 months, shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c);
(2) be a resident of North Carolina or affiliated with a North Carolina EMS Provider; and
(3) at the time of application, present evidence that renewal requirements were met prior to expiration or within six months following the expiration of the Instructor credential.

(f) EMT, AEMT, and Paramedic applicants for reinstatement of an EMS Instructor credential, lapsed greater than 12 months, shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c); and
(2) meet the requirements for initial Instructor credentialing set forth in Rules .0507 and .0508 of this Section. Degree requirements that were not applicable to EMS Instructors initially credentialed prior to July 1, 2021 shall be required for reinstatement of a lapsed credential.

(g) EMD applicants shall renew a lapsed credential by meeting the requirements for initial credentialing set forth in Rule .0502 of this Section.

(h) Pursuant to G.S. 131E-159(h), the Department shall not issue or renew an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159; 143-508(d)(3); 143B-952;*
Eff. January 1, 2017;
Amended Eff. April 1, 2024; July 1, 2021.

10A NCAC 13P .0513 REFRESHER COURSES

(a) Approved EMS educational institutions as set forth in Rule .0601 and .0602 of this Subchapter may develop refresher courses for the renewal or reinstatement of EMS credentials.

(b) The application for OEMS approval of a refresher course shall include:

(1) course objectives, content outline, and time allocation to topics of the course;

(2) teaching methodologies for measuring the student's abilities to perform at his or her level of application; and

(3) the method to be used to conduct a technical scope of practice evaluation for students seeking reinstatement of a lapsed EMS credential for their level of application.

(c) EMR, EMT, AEMT and paramedic refresher courses developed for the renewal or reinstatement of an EMS credential shall meet the following criteria:

(1) an application for approval of a refresher course shall be completed at least 30 days prior to the expected date of enrollment and shall include evidence of complying with the requirements of Paragraph (b) of this Rule for refresher courses.

(A) refresher course approval shall be for a period not to exceed two years; and

(B) any changes in curriculum shall be approved by the OEMS prior to implementation.

(2) course curricula shall:

(A) meet the National Registry of Emergency Medical Technicians' recertification requirements, which is hereby incorporated by reference including subsequent amendments and additions. This document is available from the National Registry of Emergency Medical Technicians, online at www.nremt.org/rwd/public/document/recertification at no cost; and

(B) demonstrate the ability to assess student knowledge and competency in the skills and medications as defined by the North Carolina Medical Board pursuant to G.S. 143-514 for the proposed level of EMS credential application.

History Note: *Authority G.S. 143-508(d)(3); 143B-952;*
Eff. January 1, 2017.

SECTION .0600 – EMS EDUCATIONAL INSTITUTIONS AND PROGRAMS

10A NCAC 13P .0601 CONTINUING EDUCATION EMS EDUCATIONAL PROGRAM REQUIREMENTS

(a) Continuing Education EMS Educational Programs shall be credentialed by the OEMS to provide only EMS continuing education. An application for credentialing as an approved EMS continuing education program shall be submitted to the OEMS for review.

(b) Continuing Education EMS Educational Programs shall have:

(1) at least a Level I EMS Instructor as program coordinator and shall hold a Level I EMS Instructor credential at a level equal to or greater than the highest level of continuing education program offered in the EMS System, Specialty Care Transport Program, or Agency;

(2) a continuing education program shall be consistent with the services offered by the EMS System, Specialty Care Transport Program, or Agency;

(A) In an EMS System, the continuing education programs shall be reviewed and approved by the system continuing education director and Medical Director;

(B) In a Specialty Care Transport Program, the continuing education program shall be reviewed and approved by Specialty Care Transport Program Continuing Education director and the Medical Director; and

(C) In an Agency not affiliated with an EMS System or Specialty Care Transport Program, the continuing education program shall be reviewed and approved by the Agency Program Medical Director;

(3) written educational policies and procedures to include each of the following;

(A) the delivery of educational programs in a manner where the content and material is delivered to the intended audience, with a limited potential for exploitation of such content and material;

(B) the record-keeping system of student attendance and performance;

(C) the selection and monitoring of EMS instructors; and

(D) student evaluations of faculty and the program's courses or components, and the frequency of the evaluations;

(4) access to instructional supplies and equipment necessary for students to complete educational programs as defined in Rule .0501 of this Subchapter;

(5) meet the educational program requirements as defined in Rule .0501 of this Subchapter;

(6) Upon request, the approved EMS continuing education program shall provide records to the OEMS in order to verify compliance and student eligibility for credentialing; and

(7) approved education program credentials are valid for a period not to exceed four years.

(c) Program directors shall attend an OEMS Program Coordinator workshop annually. A listing of scheduled OEMS Program Director Workshops is available at https://emspic.org. Newly appointed program directors who have not attended an OEMS Program Director Workshop within the past year shall attend a workshop within one year of appointment as the program director.

(d) Assisting physicians delegated by the EMS System Medical Director as authorized by Rule .0403 of this Subchapter or SCTP Medical Director as authorized by Rule .0404 of this Subchapter for provision of medical oversight of continuing education programs shall meet the Education Medical Advisor criteria as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight."

History Note: *Authority G.S. 143-508(d)(4); 143-508(d)(13);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. April 1, 2024; July 1, 2021.

10A NCAC 13P .0602 BASIC AND ADVANCED EMS EDUCATIONAL INSTITUTION REQUIREMENTS

(a) Basic and Advanced EMS Educational Institutions may offer educational programs for which they have been credentialed by the OEMS.

(1) EMS Educational Institutions shall complete a minimum of two initial courses at the highest level educational program approved for the Educational Institution's credential approval period.

(2) EMS Educational Institutions that do not complete two initial courses for each educational program approved shall be subject to action as set forth in Rule .1505 of this Subchapter.

(b) For initial courses, Basic EMS Educational Institutions shall meet all of the requirements for continuing EMS educational programs defined in Rule .0601 of this Section and shall have:

(1) a Level I or higher EMS Instructor as each lead course instructor for all courses. The lead course instructor must be credentialed at a level equal to or higher than the course and shall meet the lead instructor responsibilities of the CAAHEP Standards and Guidelines for the Accreditation of Educational Programs in the Emergency Medical Services Professions as set forth in Rule .0501 of this Subchapter. The lead instructor shall:
   (A) perform duties assigned under the direction and delegation of the program director.
   (B) assist in coordination of the didactic, lab, clinical, and field internship instruction.

(2) a lead EMS educational program director. This individual shall be a Level II EMS Instructor credentialed at or above the highest level of course offered by the institution. Newly appointed program directors who have not attended an OEMS Program Coordinator Workshop with the past year shall attend a workshop within one year of appointment as the program director; and:
   (A) have EMS or related allied health education, training, and experience;
   (B) be knowledgeable about methods of instruction, testing, and evaluation of students;
   (C) have field experience in the delivery of pre-hospital emergency care;
   (D) have academic training and preparation related to emergency medical services, at least equivalent to that of a paramedic; and
   (E) be knowledgeable of current versions of the National EMS Scope of Practice and National EMS Education Standards as defined by USDOT NHTSA National EMS, evidence-informed clinical practice, and incorporated by Rule .0501 of this Subchapter;

(3) a lead EMS educational program director responsible for the following:
   (A) the administrative oversight, organization, and supervision of the program;
   (B) the continuous quality review and improvement of the program;
   (C) the long-range planning on ongoing development of the program;
   (D) evaluating the effectiveness of the instruction, faculty, and overall program;
   (E) the collaborative involvement with the Education Medical Advisor;
   (F) the training and supervision of clinical and field internship preceptors; and
   (G) the effectiveness and quality of fulfillment of responsibilities delegated to another qualified individual;

(4) written educational policies and procedures that include:
   (A) the written educational policies and procedures set forth in Rule .0601 of this Section;
   (B) the delivery of cognitive and psychomotor examinations in a manner that will protect and limit the potential for exploitation of such content and material;
   (C) the exam item validation process utilized for the development of validated cognitive examinations;
   (D) the selection and monitoring of all in-state and out-of-state clinical education and field internship sites;
   (E) the selection and monitoring of all educational institutionally approved clinical education and field internship preceptors;
   (F) utilization of EMS preceptors providing feedback to the student and EMS program;
   (G) the evaluation of preceptors by their students, including the frequency of evaluations;
   (H) the evaluation of the clinical education and field internship sites by their students, including the frequency of evaluations;
   (I) completion of an annual evaluation of the program to identify any correctable deficiencies;

(J) the program annually assesses goals and learning domains that include how program staff identify and respond to changes in the needs or expectations of the community's interests; and

(K) an advisory committee representing all practice settings utilizing EMS personnel, including clinical preceptor sites, shall assist the program to monitor community needs and expectations and provide guidance to revise goals and responsiveness to change. The advisory committee shall meet no less than annually.

(5) an Educational Medical Advisor that meets the criteria as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection" who is responsible for the following;

(A) medical oversight of the program;

(B) collaboration to provide appropriate and updated educational content for the program curriculum;

(C) establishing minimum requirements for program completion;

(D) oversight of student evaluation, monitoring, and remediation as needed;

(E) ensuring entry level competence;

(F) ensuring interaction of physician and students; and

(6) written educational policies and procedures describing the delivery of educational programs, the record-keeping system detailing student attendance and performance, and the selection and monitoring of EMS instructors.

(c) For initial courses, Advanced Educational Institutions shall meet all requirements set forth in Paragraph (b) of this Rule, Standard III of the CAAHEP Standards and Guidelines for the Accreditation of Educational Programs in the Emergency Medical Services Professions shall apply, and;

(1) The faculty must be knowledgeable in course content and effective in teaching their assigned subjects, and capable through academic preparation, training, and experience to teach the courses or topics to which they are assigned.

(2) A faculty member to assist in teaching and clinical coordination in addition to the program coordinator.

(d) The educational institution shall notify the OEMS within 10 business days of a change to the program director or Medical Advisor position. The educational institution shall submit the change to the OEMS as an addendum to the approved Educational Institution application within 30 days of the effective date of the position change.

(e) Basic and Advanced EMS Educational Institution credentials shall be valid for a period of four years, unless the institution is accredited in accordance with Rule .0605 of this Section.

History Note: *Authority G.S. 143-508(d)(4); 143-508(d)(13);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. April 1, 2024; July 1, 2021.

10A NCAC 13P .0605 ACCREDITED EMS EDUCATIONAL INSTITUTION REQUIREMENTS

(a) EMS Educational Institutions who already possess accreditation by the CAAHEP shall be credentialed by the OEMS by presenting:

(1) an application for credentialing;
(2) evidence of current CAAHEP accreditation;
(3) a copy of the self study;
(4) a copy of the executive analysis; and
(5) documentation reflecting compliance with Rule .0602(b) and (c) of this Section.

(b) Accredited EMS Educational Institutions may offer initial and renewal educational programs for EMS personnel as defined in Rule .0501 of this Subchapter.

(c) Accredited EMS Educational Institutions maintaining CAAHEP accreditation shall renew credentials no more than 12 months prior to expiration of the OEMS credentials by providing the information detailed in Paragraph (a) of this Rule.

(d) Accredited EMS Educational Institutions that fail to maintain CAAHEP accreditation shall be subject to the credentialing and renewal criteria set forth in Rule .0602 of this Section.

(e) Accredited EMS Educational Institution credentials are valid for a period of five years.

History Note: *Authority G.S. 143-508(d)(4); 143-508(d)(13);*
Eff. January 1, 2017.

SECTION .0900 - TRAUMA CENTER STANDARDS AND APPROVAL

10A NCAC 13P .0901 TRAUMA CENTER CRITERIA

To receive designation as a Level I, Level II, or Level III Trauma Center, a hospital shall:

(1) have a trauma program and a trauma service that have been operational for at least 12 months prior to application for designation;

(2) at least 12 months prior to submitting a RFP, have membership in and inclusion of all trauma patient records in the North Carolina Trauma Registry, in accordance with the North Carolina Trauma Registry Data Dictionary incorporated by reference including subsequent amendments and editions. This document is available from the OEMS online at https://info.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html at no cost;

(3) meet the verification criteria for designation as a Level I, Level II, or Level III Trauma Center, as defined in the "American College of Surgeons: Resources for Optimal Care of the Injured Patient," which is hereby incorporated by reference, including subsequent amendments and editions. This document can be downloaded at no cost online at www.facs.org; and

(4) meet all requirements of the designation level applied for initial designation set forth in Rule .0904 of this Section or for renewal designation set forth in Rule .0905 of this Section.

History Note: *Authority G.S. 131E-162; 143-508(d)(2);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Readopted Eff. January 1, 2017;
Amended Eff. September 1, 2019.

10A NCAC 13P .0904 INITIAL DESIGNATION PROCESS

(a) For initial Trauma Center designation or changing the level of Trauma Center designation, the hospital shall request a consult visit by OEMS and the consult shall occur within one year prior to submission of the RFP.

(b) A hospital interested in pursuing Trauma Center designation shall submit a letter of intent 180 days prior to the submission of an RFP to the OEMS. The letter shall define the hospital's primary trauma catchment area. Simultaneously, Level I or II applicants shall also demonstrate the need for the Trauma Center designation by submitting one original and three copies of documents that include:

(1) the population to be served and the extent that the population is underserved for trauma care with the methodology used to reach this conclusion;

(2) geographic considerations, to include trauma primary and secondary catchment area and distance from other Trauma Centers; and

(3) evidence the Trauma Center will admit 1200 or more trauma patients annually or show that its trauma service will be taking care of at least 240 trauma patients with an ISS greater than or equal to 15 yearly. These criteria shall be met without compromising the quality of care or cost effectiveness of any other designated Level I or II Trauma Center sharing all or part of its catchment area or by jeopardizing the existing Trauma Center's ability to meet this same 240-patient minimum.

(c) The hospital shall be participating in the State Trauma Registry as defined in Rule .0102 of this Subchapter, and submit data weekly to the OEMS of 12 months or more prior to application that includes all the Trauma Center's trauma patients as defined in Rule .0102 of this Subchapter who are:

(1) diverted to an affiliated hospital;

(2) admitted to the Trauma Center for greater than 24 hours from an ED or hospital;

(3) die in the ED;

(4) are DOA; or

(5) are transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital).

(d) OEMS shall review the regional Trauma Registry data from both the applicant and the existing trauma center(s), and ascertain the applicant's ability to satisfy the justification of need information required in Paragraph (b) of this Rule. The OEMS shall notify the applicant's primary RAC of the application and provide the regional data submitted by the applicant in Paragraph (b) of this Rule for review and comment. The RAC shall be given 30 days to submit written comments to the OEMS.

(e) OEMS shall notify the respective Board of County Commissioners in the applicant's primary catchment area of the request for initial designation to allow for comment during the same 30 day comment period.

(f) OEMS shall notify the hospital in writing of its decision to allow submission of an RFP. If approved, the RAC and Board of County Commissioners in the applicant's primary catchment area shall also be notified by the OEMS that an RFP will be submitted.

(g) Once the hospital is notified that an RFP will be accepted, the hospital shall complete and submit an electronic copy of the completed RFP with signatures to the OEMS no later than 45 days prior to the proposed site visit date.

(h) The RFP shall demonstrate that the hospital meets the standards for the designation level applied for as found in Rule .0901 of this Section.

(i) If OEMS does not recommend a site visit based upon failure to comply with Rule .0901 of this Section, the OEMS shall send the written reasons to the hospital within 30 days of the decision. The hospital may reapply for designation within six months following the submission of an updated RFP. If the hospital fails to respond within six months, the hospital shall reapply following the process outlined in Paragraphs (a) through (h) of this Rule.

(j) If after review of the RFP, the OEMS recommends the hospital for a site visit, the OEMS shall notify the hospital within 30 days. The hospital and the OEMS shall agree on the date of the site visit.

(k) Except for OEMS representatives, reviewers for a Level I or II visit shall be from outside the local or adjacent RAC, unless mutually agreed upon by the OEMS and the trauma center seeking designation where the hospital is located. The composition of a Level I or II site survey team shall be as follows:

(1) one trauma surgeon who is a Fellow of the ACS, experienced as a site surveyor, who shall be the primary reviewer;

(2) one emergency physician who currently works in a designated trauma center, is a member of the American College of Emergency Physicians or American Academy of Emergency Medicine, and is boarded in emergency medicine by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine;

(3) one trauma surgeon;

(4) one trauma program manager; and
(5) OEMS Staff.

(l) All site team members for a Level III visit except for the OEMS representatives, shall be from outside the local or adjacent RAC where the hospital is located. The composition of a Level III state site survey team shall be as follows:

(1) one trauma surgeon who is a Fellow of the ACS and shall be the primary reviewer;
(2) one emergency physician who currently works in a designated trauma center and is boarded in emergency medicine by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine;
(3) one trauma program manager; and
(4) OEMS Staff.

(m) The hospital shall make available all requested patient medical charts.

(n) The primary reviewer of the site review team shall give a verbal post-conference report representing a consensus of the site review team. The primary reviewer shall complete and submit to the OEMS a written consensus report within 30 days of the site visit.

(o) The report of the site survey team and the staff recommendations shall be reviewed by the State Emergency Medical Services Advisory Council at its next regularly scheduled meeting following the site visit. Based upon the site visit report and the staff recommendation, the State Emergency Medical Services Advisory Council shall recommend to the OEMS that the request for Trauma Center designation be approved or denied.

(p) All criteria defined in Rule .0901 of this Section shall be met for initial designation at the level requested.

(q) Hospitals with a deficiency(ies) resulting from the site visit shall be given up to 12 months to demonstrate compliance. Satisfaction of deficiency(ies) may require an additional site visit. The need for an additional site visit shall be determined on a case-by-case basis based on the type of deficiency. If compliance is not demonstrated within the time period set by OEMS, the hospital shall submit a new application and updated RFP and follow the process outlined in Paragraphs (a) through (h) of this Rule.

(r) The final decision regarding Trauma Center designation shall be rendered by the OEMS.

(s) The OEMS shall notify the hospital in writing of the State Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the Advisory Council meeting.

(t) If a trauma center changes its trauma program administrative structure such that the trauma service, trauma Medical Director, trauma program manager, or trauma registrar are relocated on the hospital's organizational chart at any time, it shall notify OEMS of this change in writing within 30 days of the occurrence.

(u) Initial designation as a trauma center shall be valid for a period of three years.

History Note: *Authority G.S. 131E-162; 143-508(d)(2);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. April 1, 2024; July 1, 2018.

10A NCAC 13P .0905 RENEWAL DESIGNATION PROCESS

(a) Hospitals may utilize one of two options to achieve Trauma Center renewal:
- (1) undergo a site visit conducted by OEMS to obtain a four-year renewal designation; or
- (2) undergo a verification visit by the ACS, in conjunction with the OEMS, to obtain a three-year renewal designation.

(b) For hospitals choosing Subparagraph (a)(1) of this Rule:
- (1) prior to the end of the designation period, the OEMS shall forward to the hospital an RFP for completion. The hospital shall, within 10 business days of receipt of the RFP, define for OEMS the Trauma Center's trauma primary catchment area.
- (2) hospitals shall complete and submit an electronic copy of the RFP to the OEMS and the specified site surveyors at least 30 days prior to the site visit. The RFP shall include information that supports compliance with the criteria contained in Rule .0901 of this Section as it relates to the Trauma Center's level of designation.
- (3) all criteria defined in Rule .0901 of this Section, as it relates to the Trauma Center's level of designation, shall be met for renewal designation.
- (4) a site visit shall be conducted within 120 days prior to the end of the designation period. The hospital and the OEMS shall agree on the date of the site visit.
- (5) the composition of a Level I or II site survey team shall be the same as that specified in Rule .0904 of this Section.
- (6) the composition of a Level III site survey team shall be the same as that specified in Rule .0904 of this Section.
- (7) on the day of the site visit, the hospital shall make available all requested patient medical charts.
- (8) the primary reviewer of the site review team shall give a verbal post-conference report representing a consensus of the site review team. The primary reviewer shall complete and submit to the OEMS a written consensus report within 30 days of the site visit.
- (9) the report of the site survey team and a staff recommendation shall be reviewed by the NC Emergency Medical Services Advisory Council at its next regularly scheduled meeting following the site visit. Based upon the site visit report and the staff recommendation, the NC Emergency Medical Services Advisory Council shall recommend to the OEMS that the request for Trauma Center renewal be:
  - (A) approved;
  - (B) approved with a contingency(ies) due to a deficiency(ies) requiring a focused review;
  - (C) approved with a contingency(ies) not due to a deficiency(ies) requiring a consultative visit; or
  - (D) denied.
- (10) hospitals with a deficiency(ies) shall have up to 10 business days prior to the NC Emergency Medical Services Advisory Council meeting to provide documentation to demonstrate compliance. If the hospital has a deficiency that cannot be corrected in this period prior to the NC Emergency Medical Services Advisory Council meeting, the hospital shall be given 12 months by the OEMS to demonstrate compliance and undergo a focused review that may require an additional site visit. The need for an additional site visit is on a case-by-case basis based on the type of deficiency. The hospital shall retain its Trauma Center designation during the focused review period. If compliance is demonstrated within the prescribed time period, the hospital shall be granted its designation for the four-year period from the previous designation's expiration date. If compliance is not demonstrated within the 12 month time period, the Trauma Center designation shall not be renewed. To become redesignated, the hospital shall submit an updated RFP and follow the initial applicant process outlined in Rule .0904 of this Section.
- (11) the final decision regarding trauma center renewal shall be rendered by the OEMS.
- (12) the OEMS shall notify the hospital in writing of the NC Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the NC Emergency Medical Services Advisory Council meeting.
- (13) hospitals with a deficiency(ies) shall submit an action plan to the OEMS to address the deficiency(ies) within 10 business days following receipt of the written final decision on the trauma recommendations.

(c) For hospitals choosing Subparagraph (a)(2) of this Rule:

(1) at least six months prior to the end of the Trauma Center's designation period, the trauma center shall notify the OEMS of its intent to undergo an ACS verification visit. It shall simultaneously define in writing to the OEMS its trauma primary catchment area. Trauma Centers choosing this option shall then comply with all the ACS' verification procedures, as well as any additional state criteria as defined in Rule .0901 of this Section, that apply to their level of designation.

(2) when completing the ACS' documentation for verification, the Trauma Center shall ensure access to the ACS on-line PRQ (pre-review questionnaire) to OEMS. The Trauma Center shall simultaneously complete any documents supplied by OEMS and forward these to the OEMS.

(3) the Trauma Center shall make sure the site visit is scheduled to ensure that the ACS' final written report, accompanying medical record reviews and cover letter are received by OEMS at least 30 days prior to a regularly scheduled NC Emergency Medical Services Advisory Council meeting to ensure that the Trauma Center's state designation period does not terminate without consideration by the NC Emergency Medical Services Advisory Council.

(4) any in-state review for a hospital choosing Subparagraph (a)(2) of this Rule, except for the OEMS staff, shall be from outside the local or adjacent RAC in which the hospital is located.

(5) the composition of a Level I, II, or III site survey team for hospitals choosing Subparagraph (a)(2) of this Rule shall be as follows:

(A) one trauma surgeon who is a Fellow of the ACS, experienced as a site surveyor, who shall be the primary reviewer;

(B) one emergency physician who works in a designated trauma center, is a member of the American College of Emergency Physicians or the American Academy of Emergency Medicine, and is boarded in emergency medicine by the American Board of Emergency Physicians or the American Osteopathic Board of Emergency Medicine;

(C) one trauma program manager; and

(D) OEMS staff.

(6) the date, time, and all proposed members of the site visit team shall be submitted to the OEMS for review at least 45 days prior to the site visit. The OEMS shall approve the site visit schedule if the schedule does not conflict with the ability of attendance by required OEMS staff. The OEMS shall approve the proposed site visit team members if the OEMS determines there is no conflict of interest, such as previous employment, by any site visit team member associated with the site visit.

(7) all state Trauma Center criteria shall be met as defined in Rule .0901 of this Section for renewal of state designation. ACS' verification is not required for state designation. ACS' verification does not ensure a state designation.

(8) The ACS final written report and supporting documentation described in Subparagraph (c)(4) of this Rule shall be used to generate a report following the post conference meeting for presentation to the NC Emergency Medical Services Advisory Council for renewal designation.

(9) the final written report issued by the ACS' verification review committee, the accompanying medical record reviews from which all identifiers shall be removed and cover letter shall be forwarded to OEMS within 10 business days of its receipt by the Trauma Center seeking renewal.

(10) the OEMS shall present its summary of findings report to the NC Emergency Medical Services Advisory Council at its next regularly scheduled meeting. The NC Emergency Medical Services Advisory Council shall recommend to the Chief of the OEMS that the request for Trauma Center renewal be:

(A) approved;

(B) approved with a contingency(ies) due to a deficiency(ies) requiring a focused review;

(C) approved with a contingency(ies) not due to a deficiency(ies); or

(D) denied.

(11) the OEMS shall send the hospital written notice of the NC Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the NC Emergency Medical Services Advisory Council meeting.

(12) the final decision regarding trauma center designation shall be rendered by the OEMS.

(13) hospitals with contingencies as the result of a deficiency(ies), as determined by OEMS, shall have up to 10 business days prior to the NC Emergency Medical Services Advisory Council meeting to provide documentation to demonstrate compliance. If the hospital has a deficiency that cannot be corrected in this time period, the hospital, may undergo a focused review to be conducted by the OEMS whereby the Trauma Center shall be given 12 months by the OEMS to demonstrate

compliance. Satisfaction of contingency(ies) may require an additional site visit. The need for an additional site visit is on a case-by-case basis based on the type of deficiency. The hospital shall retain its Trauma Center designation during the focused review period. If compliance is demonstrated within the prescribed time period, the hospital shall be granted its designation for the three-year period from the previous designation's expiration date. If compliance is not demonstrated within the 12 month time period, the Trauma Center designation shall not be renewed. To become redesignated, the hospital shall submit a new RFP and follow the initial applicant process outlined in Rule .0904 of this Section.

(14) hospitals with a deficiency(ies) shall submit an action plan to the OEMS to address the deficiency(ies) within 10 business days following receipt of the written final decision on the trauma recommendations.

(d) If a Trauma Center currently using the ACS' verification process chooses not to renew using this process, it must notify the OEMS at least six months prior to the end of its state trauma center designation period of its intention to exercise the option in Subparagraph (a)(1) of this Rule. Upon notification, the OEMS shall extend the designation for one additional year to ensure consistency with hospitals using Subparagraph (a)(1) of this Rule.

History Note: *Authority G.S. 131E-162; 143-508(d)(2);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. April 1, 2009; January 1, 2009; January 1, 2004;
Readoption Eff. January 1, 2017;
Amended Eff. April 1, 2024; July 1, 2021.

10A NCAC 13P .1003 MISREPRESENTATION OF DESIGNATION

(a) Hospitals shall not represent themselves as trauma centers unless they are currently designated by the Department pursuant to Section .0900 of this Subchapter.

(b) Designation applies only to the hospital that submitted the RFP and underwent the formal site survey and does not extend to its satellite facilities or affiliates.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

SECTION .1100 - TRAUMA SYSTEM DESIGN

10A NCAC 13P .1101 STATE TRAUMA SYSTEM

(a) The State trauma system shall consist of regional plans, policies, guidelines, and performance improvement initiatives by the RACs to create an Inclusive Trauma System monitored by the OEMS.

(b) Each hospital and EMS System shall affiliate as defined in Rule .0102 of this Subchapter and participate with the RAC that includes the Level I or II Trauma Center where the majority of trauma patient referrals and transports occur. Each hospital and EMS System shall submit to the OEMS upon request patient transfer patterns from data sources that support the choice of their primary RAC affiliation. Each RAC shall include at least one Level I or II Trauma Center.

(c) Each Lead RAC Coordinator shall update and submit RAC affiliation membership for hospitals and EMS Systems to the OEMS no later than July 1 of each year. Each hospital or EMS System shall submit written notification to the OEMS for any RAC affiliation change. RAC affiliation may be changed only if supported by a change in the majority of transfer patterns to a Level I or Level II Trauma Center. Documentation of these new transfer patterns shall be included in the request to change affiliation.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. July 1, 2021; January 1, 2017.

10A NCAC 13P .1102 REGIONAL TRAUMA SYSTEM PLAN

(a) After consultation with all Level I and II Trauma Centers within their catchment areas, a Level I or II Trauma Center shall be selected as the lead RAC agency by the OEMS to facilitate development of and provide RAC staff support that includes the following:

(1) the trauma Medical Director(s) from the lead RAC agency;
(2) a trauma nurse coordinator(s) or program manager(s) from the lead RAC agency; and
(3) an individual to coordinate RAC activities.

(b) The RAC membership shall include the following:

(1) the trauma Medical Director(s) and the trauma nurse coordinator(s) or program manager(s) from the lead RAC agency;
(2) if on staff, the outreach coordinator(s), or designee(s) from the lead RAC agency;
(3) if on staff, an injury prevention coordinator(s), or designees(s) from the lead RAC agency;
(4) the RAC registrar or designee(s) from the lead RAC agency;
(5) a senior level hospital administrator from the lead RAC agency;
(6) an emergency physician from the lead RAC agency;
(7) a representative from each EMS system participating in the RAC;
(8) a representative from each hospital participating in the RAC;
(9) community representatives from the lead RAC agency's catchment area; and
(10) An EMS System Medical Director or Assistant Medical Director from the lead RAC agency's catchment area.

(c) The lead RAC agency shall develop a plan within one year of notification of the RAC membership a regional trauma system plan containing:

(1) organizational structures, including the roles of the members of the system;
(2) goals and objectives, including the orientation of the providers to the regional system;
(3) RAC membership list, rules of order, terms of office, and meeting schedule. Meetings shall be held at least two times per year;
(4) information required by the OEMS as set forth in Rule .1103 of this Section;
(5) the regional trauma system evaluation tools to be utilized;
(6) written verification of regional support from members of the RAC for the regional trauma system plan; and
(7) performance improvement activities, including utilization of regional trauma system patient care data.

(d) The RAC shall prepare an annual progress report no later than July 1 of each year that assesses compliance with the regional trauma system plan and specifies any updates to the plan. This report shall be made available to the OEMS for review upon request.

(e) Upon OEMS' receipt of a letter of intent for initial Level I or II Trauma Center designation by a hospital in the lead RAC agency's catchment area as set forth in Rule .0904(b) of this Subchapter, the applicant's lead RAC agency shall be provided the applicant's data from the OEMS for distribution to all RAC members for review and comment, as set forth in Rule .0904(d) of this Subchapter.

(f) The RAC membership has 30 days to comment on the request for initial designation. All comments shall be sent from each RAC member directly to the OEMS, with the lead RAC agency provided a copy of their response, within this 30 day comment period.

(g) The OEMS shall notify the regional RAC of the OEMS approval of a hospital to submit an RFP for trauma center designation.

History Note: *Authority G.S. 131E-162; 143-508(d)(5); 143-508(d)(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. January 1, 2017.

10A NCAC 13P .1103 REGIONAL TRAUMA SYSTEM POLICY DEVELOPMENT

The RAC shall oversee the development, implementation, and evaluation of the regional trauma system that includes:

(1) A public information and education program to include system access and injury prevention;

(2) Written trauma system guidelines addressing the following:

(a) Regional communications;

(b) Triage;

(c) Treatment at the accident scene, and in the pre-hospital, inter-hospital, and Emergency Department to include guidelines to facilitate the rapid assessment and initial resuscitation of the severely injured patient. Criteria addressing management during transport shall include continued assessment and management of airway, cervical spine, breathing, circulation, neurologic and secondary parameters, communication, and documentation;

(d) Transport to determine the appropriate mode of transport and level of care required to transport, considering patient condition, requirement for trauma center resources, family requests, and capability of transferring entity;

(e) Bypass procedures that define:

(i) circumstances and criteria for bypass decisions;

(ii) time and distance criteria; and

(iii) mode of transport which bypasses closer facilities; and

(f) Accident scene and inter-hospital diversion procedures that include delineation of specific factors such as hospital census or acuity, physician availability, staffing issues, disaster status, or transportation which would require routing of a patient to another hospital or Trauma Center;

(3) Transfer agreements (including those with other hospitals, as well as specialty care facilities such as burn, pediatrics, spinal cord, and rehabilitation) which shall outline mutual understandings between facilities to transfer/accept certain patients. These shall specify responsible parties, documentation requirements, and minimum care requirements; and

(4) A performance improvement plan that includes:

(a) A regional trauma peer review committee of the RAC:

(i) whose membership and responsibilities are defined in G.S. 131E-162; and

(ii) that continuously evaluates the regional trauma system through structured review of process of care and outcomes; and

(b) Utilization of patient care data.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

SECTION .1400 - RECOVERY AND REHABILITATION OF CHEMICALLY DEPENDENT EMS PERSONNEL

10A NCAC 13P .1401 CHEMICAL ADDICTION OR ABUSE RECOVERY PROGRAM REQUIREMENTS

(a) The OEMS shall provide a monitoring program for aiding in the recovery of EMS personnel subject to disciplinary action for being unable to perform as credentialed EMS personnel with reasonable skill and safety to patients and the public by reason of use of alcohol, drugs, chemicals, or any other type of material as set forth in Rule .1507 of this Subchapter.

(b) This program requires:

(1) an initial assessment by a healthcare professional specializing in chemical dependency approved by the program;

(2) a treatment plan developed by a healthcare professional specializing in chemical dependency for the individual using the findings of the initial assessment. The Department and individual will enter into a consent agreement based upon the treatment plan; and

(3) monitoring by OEMS program staff of the individual for compliance with the consent agreement entered into by the Department and the individual entering the program.

History Note: *Authority G.S. 131E-159(f); 143-508(b); 143-508(d)(10);*
Eff. October 1, 2010;
Readopted Eff. January 1, 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .1402 PROVISIONS FOR PARTICIPATION IN THE CHEMICAL ADDICTION OR ABUSE RECOVERY PROGRAM

The OEMS shall use the screening criteria set forth in this Section to determine whether an individual may enter the treatment program established by Rule .1401 of this Section. The individual may enter the program if the individual:

(1) acknowledges, in writing, the actions that violated the performance requirements found in this Subchapter;

(2) has not been charged or convicted at any time in his or her past, of diverting chemicals for the purpose of distribution, dealing, or selling illicit drugs;

(3) is not under current criminal investigation or subject to pending criminal charges by law enforcement;

(4) ceases in the direct delivery of any patient care and surrenders all EMS credentials until either the individual is eligible for issuance of an encumbered EMS credential pursuant to Rule .1403 of this Section, or has completed the treatment program established in Rule .1401 of this Section; and

(5) agrees to accept responsibility for all costs including assessment, treatment, monitoring, and body fluid screening.

History Note: *Authority G.S. 131E-159(f); 143-508(b); 143-508(d)(10);*
Eff. October 1, 2010;
Readopted Eff. January 1, 2017.

10A NCAC 13P .1403 CONDITIONS FOR RESTRICTED PRACTICE WITH LIMITED PRIVILEGES

(a) In order to assist in determining eligibility for an individual to return to restricted practice, completion of all requirements outlined in the individual's consent agreement with the Department as described in Rule .1401 of this Section shall be presented to the Chief of the OEMS.

(b) Individuals who have surrendered his or her EMS credential(s) as a condition of entry into the recovery program, as required in Rule .1402 of this Section, shall be reviewed by the OEMS Chief to determine if issuance of an encumbered EMS credential is warranted by the Department.

(c) In order to obtain an encumbered credential with limited privileges, an individual shall:

(1) be compliant for a minimum of 90 consecutive days with the treatment program described in Rule .1401 of this Section; and

(2) be recommended in writing for review by the individual's recovery healthcare professional overseeing the treatment plan developed as described in Rule .1401 of this Section.

(d) The individual shall agree to sign a consent agreement with the OEMS that details the practice restrictions and privilege limitations of the encumbered EMS credential, and that contains the consequences of failure to abide by the terms of this agreement.

(e) The individual shall be issued the encumbered credential by the OEMS within 10 business days following execution of the consent agreement described in Paragraph (d) of this Rule.

(f) The encumbered EMS credential shall be valid for a period not to exceed four years.

History Note: *Authority G.S. 131E-159(f); 143-508(b); 143-508(d)(10);*
Eff. October 1, 2010;
Readopted Eff. January 1, 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .1404 REINSTATEMENT OF AN UNENCUMBERED EMS CREDENTIAL

Reinstatement of an unencumbered EMS credential is dependent upon the individual completing all requirements of the consent agreement as set forth in Rule .1401 of this Section.

History Note: *Authority G.S. 131E-159(f); 143-508(d)(10); 143-509(13);*
Eff. October 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. July 1, 2021.

10A NCAC 13P .1405 FAILURE TO COMPLETE THE CHEMICAL ADDICTION OR ABUSE RECOVERY PROGRAM

Individuals who fail to complete the consent agreement established in Rule .1401 of this Section, upon review by the OEMS, are subject to revocation of their EMS credential.

History Note: *Authority G.S. 131E-159(f); 143-508(b); 143-508(d)(10);*
Eff. October 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. July 1, 2021; January 1, 2017.

SECTION .1500 - DENIAL, SUSPENSION, AMENDMENT, OR REVOCATION

10A NCAC 13P .1501 ENFORCEMENT DEFINITIONS

Notwithstanding Section .0100 of this Subchapter, for the purpose of this Section, the following definitions apply to Rules .1502, .1503, .1504, and .1506 for EMS Systems, Licensed EMS Providers, Specialty Care Transport Programs, and EMS Educational Institutions:

(1) "Contingencies" mean conditions placed on an initial or renewal designation, approval or license that, if unmet, can result in the loss or amendment of the designation, approval, or license.

(2) "Deficiency" means the failure to meet essential criteria for credentialing, approval, or licensing as specified in Sections .0200, .0300 or .0600 of this Subchapter that can serve as the basis for a focused review or denial of a designation, approval or license.

(3) "Essential Criteria" means those items listed in Sections .0200, .0300 or .0600 of this Subchapter that are the minimum requirements for the respective application for initial or renewal designation, approval, or licensing.

(4) "Focused Review" means an evaluation by the OEMS of a regulated entity's corrective actions to remove contingencies that are a result of deficiencies placed upon it following review of an application for renewal.

History Note: *Authority G.S. 131E-155(13a); 143-508(b),(d)(1),(d)(4),(d)(13);*
Eff. January 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .1502 LICENSED EMS PROVIDERS

(a) The OEMS shall deny an initial or renewal EMS Provider license for any of the following reasons:

(1) significant failure to comply, as defined in Rule .0102 of this Subchapter, with the applicable licensing requirements in Rule .0204 of this Subchapter;

(2) making false statements or representations to the OEMS or willfully concealing information in connection with an application for licensing;

(3) tampering with or falsifying any record used in the process of obtaining an initial license or in the renewal of a license; or

(4) disclosing information as defined in Rule .0223 of this Subchapter that is determined by OEMS staff, based upon review of documentation, to disqualify the applicant from licensing.

(b) The Department shall amend any EMS Provider license by amending it to reduce the license from a full license to a provisional license whenever the Department finds that:

(1) the licensee failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that Article;

(2) there is a probability that the licensee can take corrective measures to resolve the issue of non-compliance with Rule .0204 of this Subchapter, and be able to remain in compliance within a reasonable length of time determined by OEMS staff on a case-by-case basis; and

(3) there is a probability, determined by OEMS staff using their professional judgment, based upon analysis of the licensee's ability to take corrective measures to resolve the issue of non-compliance with the licensure rules, that the licensee will be able thereafter to remain in compliance with the licensure rules.

(c) The Department shall give the licensee written notice of the amendment of the EMS Provider license. This notice shall be given personally or by certified mail and shall set forth:

(1) the duration of the provisional EMS Provider license;

(2) the factual allegations;

(3) the statutes or rules alleged to be violated; and

(4) notice of the EMS provider's right to a contested case hearing, as set forth in Rule .1509 of this Subchapter, on the amendment of the EMS Provider license.

(d) The provisional EMS Provider license is effective upon its receipt by the licensee and shall be posted in a location at the primary business location of the EMS Provider, accessible to public view, in lieu of the full license. Pursuant to G.S. 131E-155.1(d), the provisional license remains in effect until the Department:

(1) restores the licensee to full licensure status; or

(2) revokes the licensee's license.

(e) The Department shall revoke or suspend an EMS Provider license whenever the Department finds that the licensee:

(1) failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that Article and it is not probable that the licensee can remedy the licensure deficiencies within 12 months or less;

(2) failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that Article and, although the licensee may be able to remedy the deficiencies, it is not probable that the licensee will be able to remain in compliance with licensure rules;

(3) failed to comply with the provision of G.S. 131E, Article 7, and the rules adopted under that Article that endanger the health, safety, or welfare of the patients cared for or transported by the licensee;

(4) obtained or attempted to obtain an ambulance permit, EMS nontransporting vehicle permit, or EMS Provider license through fraud or misrepresentation;

(5) continues to repeat the same deficiencies placed on the licensee in previous compliance site visits;

(6) has recurring failure to provide emergency medical care within the defined EMS service area in a manner as determined by the EMS System;

(7) failed to disclose or report information in accordance with Rule .0223 of this Subchapter;

(8) was deemed by OEMS to place the public at risk because the owner, any officer, or agent was convicted in any court of a crime involving fiduciary misconduct or a conviction of a felony;

(9) altered, destroyed, attempted to destroy, withheld, or delayed release of evidence, records, or documents needed for a complaint investigation being conducted by the OEMS; or

(10) continues to operate within an EMS System after a Board of County Commissioners terminated its affiliation with the licensee, resulting in a violation of the licensing requirement set forth in Rule .0204 of this Subchapter.

(f) The Department shall give the EMS Provider written notice of revocation. This notice shall be given personally or by certified mail and shall set forth:

(1) the factual allegations;

(2) the statutes or rules alleged to be violated; and

(3) notice of the EMS Provider's right to a contested case hearing, as set forth in Rule .1509 of this Section, on the revocation of the EMS Provider's license.

(g) The issuance of a provisional EMS Provider license is not a procedural prerequisite to the revocation or suspension of a license pursuant to Paragraph (e) of this Rule.

History Note: *Authority G.S. 131E-155.1(d); 143-508(d)(10);*
Eff. January 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. July 1, 2018; January 1, 2017.

10A NCAC 13P .1503 SPECIALTY CARE TRANSPORT PROGRAMS

(a) The Department shall deny the initial or renewal approval, without first allowing a focused review, of a SCTP for any of the following reasons:

(1) failure to comply with the provisions of G.S.131E, Article 7 and the rules adopted under that Article;
(2) obtaining or attempting to obtain approval through fraud or misrepresentation;
(3) endangerment to the health, safety, or welfare of patients cared for by the SCTP; or
(4) repeated deficiencies placed on the program in previous site visits.

(b) When an SCTP is required to have a focused review, it must demonstrate compliance with the provisions of G.S. 131E, Article 7 and the rules adopted under that Article within 12 months or less.

(c) The Department shall revoke an SCTP approval at any time or deny a request for renewal of approval whenever the Department finds that the SCTP failed to comply with the provisions of G.S.131E, Article 7 and the rules adopted under that Article; and

(1) it is not probable that the SCTP can remedy the deficiencies within 12 months or less;
(2) although the SCTP may be able to remedy the deficiencies, it is not probable that the SCTP shall be able to remain in compliance with designation rules for the foreseeable future;
(3) the SCTP fails to meet the requirements of a focused review;
(4) endangerment to the health, safety, or welfare of patients cared for or transported by the SCTP;
(5) fails to provide SCTP services within the defined service area in a timely manner as determined by the Department;
(6) continues to operate within an EMS System after a Board of County Commissioners has terminated its affiliation with the SCTP; or
(7) alters, destroys or attempts to destroy evidence needed for a complaint investigation.

(d) The Department shall give the SCTP written notice of revocation. This notice shall be given personally or by certified mail and shall set forth:

(1) the factual allegations;
(2) the statutes or rules alleged to be violated; and
(3) notice of the program's right to a contested case hearing on the revocation of the approval.

(e) Focused review is not a procedural prerequisite to the revocation of an approval pursuant to Paragraph (c) of this Rule.

History Note: *Authority 143-508(d)(10), (d)(13);*
Eff. January 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .1504 TRAUMA CENTERS

(a) The Department shall deny the initial or renewal designation, without first allowing a focused review, of a trauma center for any of the following reasons:

(1) failure to comply with G.S. 131E-162 and the rules adopted under that Statute;
(2) obtaining or attempting to obtain a trauma center designation through fraud or misrepresentation;
(3) endangerment to the health, safety, or welfare of patients cared for in the hospital; or
(4) repeated deficiencies placed on the trauma center in previous site visits.

(b) When a trauma center is required to have a focused review, it must demonstrate compliance with the provisions of G.S. 131E-162 and the rules adopted under that Statute within 12 months or less.

(c) The Department shall revoke a trauma center designation at any time or deny a request for renewal of designation, whenever the Department finds that the trauma center has failed to comply with the provisions of G.S. 131E-162 and the rules adopted under that Statute; and

(1) it is not probable that the trauma center can remedy the deficiencies within 12 months or less;
(2) although the trauma center may be able to remedy the deficiencies it is not probable that the trauma center shall be able to remain in compliance with designation rules for the foreseeable future;
(3) the trauma center failed to meet the requirements of a focused review;
(4) failure to comply endangers the health, safety, or welfare of patients cared for in the trauma center; or
(5) the trauma center altered, destroyed or attempted to destroy evidence needed for a complaint investigation.

(d) The Department shall give the trauma center written notice of revocation. This notice shall be given personally or by certified mail and shall set forth:

(1) the factual allegations;
(2) the statutes or rules alleged to be violated; and
(3) notice of the hospital's right to a contested case hearing on the revocation of the designation.

(e) Focused review is not a procedural prerequisite to the revocation of a designation pursuant to Paragraph (c) of this Rule.

(f) A trauma center may voluntarily withdraw its designation for a maximum of one year by submitting a written request to the Department. This request shall include the reasons for withdrawal and a plan for resolution of the issues. To reactivate the designation, the facility shall provide to the Department written documentation of compliance. Voluntary withdrawal does not affect the original expiration date of the trauma center's designation.

(g) If the trauma center fails to resolve the issues which resulted in a voluntary withdrawal within one year, the Department shall revoke the trauma center designation.

(h) In the event of a revocation or voluntary withdrawal, the Department shall provide written notification to all hospitals and emergency medical services providers within the trauma center's defined trauma primary catchment area. The Department shall provide written notification to all hospitals and emergency medical services providers within the trauma center's defined trauma primary catchment area if, and when, the voluntary withdrawal reactivates to full designation.

History Note: *Authority G.S. 131E-162; 143-508(d)(10);*
Eff. January 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .1505 EMS EDUCATIONAL INSTITUTIONS

(a) For the purpose of this Rule, "focused review" means an evaluation by the OEMS of an educational institution's corrective actions to remove contingencies that are a result of deficiencies identified in the initial or renewal application process.

(b) The Department shall deny the initial or renewal designation, without first allowing a focused review, of an EMS Educational Institution. An Educational Institution denied initial designation shall not be eligible to reapply to the OEMS for two years. Reasons for denial are:

(1) significant failure to comply with the provisions of Sections .0500 and .0600 of this Subchapter; or

(2) attempting to obtain an EMS Educational Institution designation through fraud or misrepresentation.

(c) When an EMS Educational Institution is required to have a focused review, it shall demonstrate compliance with the provisions of Sections .0500 and .0600 of this Subchapter within six months or less.

(d) The Department shall amend, suspend, or revoke an EMS Educational Institution designation at any time whenever the Department finds that the EMS Educational Institution has significant failure to comply, as defined in Rule .0102 of this Subchapter, with the provisions of Section .0600 of this Subchapter, and:

(1) it is not probable that the EMS Educational Institution can remedy the deficiencies within six months or less as determined by OEMS staff based upon analysis of the educational institution's ability to take corrective measures to resolve the issue of non-compliance with Section .0600 of this Subchapter;

(2) although the EMS Educational Institution may be able to remedy the deficiencies, it is not probable that the EMS Educational Institution shall be able to remain in compliance with credentialing rules;

(3) failure to produce records upon request as required in Rule .0601 of this Subchapter;

(4) the EMS Educational Institution failed to meet the requirements of a focused review within six months, as set forth in Paragraph (c) of this Rule;

(5) the failure to comply endangered the health, safety, or welfare of patients cared for as part of an EMS educational program as determined by OEMS staff in their professional judgment based upon a complaint investigation, in consultation with the Department and Department of Justice, to verify the results of the investigations are sufficient to initiate enforcement action pursuant to G.S. 150B; or

(6) the EMS Educational Institution altered, destroyed, or attempted to destroy evidence needed for a complaint investigation.

(e) The Department shall give the EMS Educational Institution written notice of action taken on the Institution designation. This notice shall be given personally or by certified mail and shall set forth:

(1) the factual allegations;

(2) the statutes or rules alleged to be violated; and

(3) notice of the EMS Educational Institution's right to a contested case hearing, set forth in Rule .1509 of this Section, on the revocation of the designation.

(f) Focused review is not a procedural prerequisite to the revocation of a designation as set forth in Rule .1509 of this Section.

(g) If determined by the educational institution that suspending its approval to offer EMS educational programs is necessary, the EMS Educational Institution may voluntarily surrender its credential without explanation by submitting a written request to the OEMS stating its intention. The voluntary surrender shall not affect the original expiration date of the EMS Educational Institution's designation. To reactivate the designation:

(1) the institution shall provide OEMS written documentation requesting reactivation; and

(2) the OEMS shall verify the educational institution is compliant with all credentialing requirements set forth in Section .0600 of this Subchapter prior to reactivation of the designation by the OEMS.

(h) If the institution fails to resolve the issues that resulted in a voluntary surrender, the Department shall revoke the EMS Educational Institution designation.

(i) In the event of a revocation or voluntary surrender, the Department shall provide written notification to all EMS Systems within the EMS Educational Institution's defined service area. The Department shall provide written notification to all EMS Systems within the EMS Educational Institution's defined service area when the voluntary surrender reactivates to full credential.

(j) When an accredited EMS Educational Institution as defined in Rule .0605 of this Subchapter has administrative action taken against its accreditation, the OEMS shall determine if the cause of action is sufficient for revocation of

the EMS Educational Institution designation or imposing a focused review pursuant to Paragraphs (b) and (c) of this Rule is warranted.

History Note: *Authority G.S. 143-508(d)(4); 143-508(d)(10);*
Eff. January 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. April 1, 2024; July 1, 2021; July 1, 2018; January 1, 2017.

10A NCAC 13P .1506 EMS VEHICLE PERMITS

(a) The Department shall deny, suspend, or revoke the permit of an ambulance or EMS nontransporting vehicle if the EMS Provider:

(1) failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that Article;
(2) obtained or attempted to obtain a permit through fraud or misrepresentation;
(3) has continued deficiencies identified as repeated from previous compliance site visits;
(4) failed to provide emergency medical care within the defined EMS service area in a timely manner as determined by the EMS System;
(5) continued to operate the ambulance or nontransporting vehicle in a county after written notification by a Board of Commissioners to cease operations in that county;
(6) altered, destroyed or attempted to destroy evidence needed for a complaint investigation; or
(7) does not possess a valid EMS Provider License.

(b) In lieu of suspension or revocation, the Department shall issue a temporary permit for an ambulance or EMS nontransporting vehicle whenever the Department finds that:

(1) the EMS Provider to which that vehicle is assigned has failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that Article;
(2) there is a reasonable probability that the EMS Provider can remedy the permit deficiencies within a length of time determined by the Department; and
(3) there is a reasonable probability that the EMS Provider will be willing and able to remain in compliance with the rules regarding vehicle permits for the foreseeable future.

(c) The Department shall give the EMS Provider written notice of the temporary permit. This notice shall be given personally or by certified mail and shall set forth:

(1) the duration of the temporary permit not to exceed 60 days;
(2) a copy of the vehicle inspection form;
(3) the statutes or rules alleged to be violated; and
(4) notice of the EMS Provider's right to a contested case hearing on the temporary permit.

(d) The temporary permit is effective immediately upon its receipt by the EMS Provider and remains in effect until the earlier of the expiration date of the permit or until the Department:

(1) restores the vehicle to full permitted status; or
(2) suspends or revokes the vehicle permit.

History Note: *Authority G.S. 131E-156(c),(d); 131E-157(c);*
Eff. January 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .1507 EMS PERSONNEL CREDENTIALS

(a) Any EMS credential that has been forfeited under G.S. 15A-1331.1 may not be reinstated until the person has complied with the court's requirements, has petitioned the Department for reinstatement, has completed the disciplinary process, and has received Department reinstatement approval.

(b) The Department shall amend, deny, suspend, or revoke the credentials of EMS personnel for any of the following:

(1) significant failure to comply with the applicable performance and credentialing requirements as found in this Subchapter;

(2) making false statements or representations to the Department, or concealing information in connection with an application for credentials;

(3) making false statements or representations, concealing information, or failing to respond to inquiries from the Department during a complaint investigation;

(4) tampering with, or falsifying any record used in the process of obtaining an initial EMS credential, or in the renewal of an EMS credential;

(5) in any manner or using any medium, engaging in the stealing, manipulating, copying, reproducing, or reconstructing of any written EMS credentialing examination questions, or scenarios;

(6) cheating, or assisting others to cheat while preparing to take, or when taking a written EMS credentialing examination;

(7) altering an EMS credential, using an EMS credential that has been altered, or permitting or allowing another person to use his or her EMS credential for the purpose of alteration. "Altering" includes changing the name, expiration date, or any other information appearing on the EMS credential;

(8) unprofessional conduct, including a significant failure to comply with the rules relating to the function of credentialed EMS personnel contained in this Subchapter, or the performance of or attempt to perform a procedure that is detrimental to the health and safety of any person, or that is beyond the scope of practice of credentialed EMS personnel or EMS instructors;

(9) being unable to perform as credentialed EMS personnel with reasonable skill and safety to patients and the public by reason of illness that will compromise skill and safety, use of alcohol, drugs, chemicals, or any other type of material, or by reason of any physical impairment;

(10) conviction in any court of a crime involving moral turpitude, a conviction of a felony, a conviction requiring registering on a sex offender registry, or conviction of a crime involving the scope of practice of credentialed EMS personnel;

(11) by theft or false representations, obtaining or attempting to obtain, money or anything of value from a patient, EMS Agency, or educational institution;

(12) adjudication of mental incompetence;

(13) lack of competence to practice with a reasonable degree of skill and safety for patients, including a failure to perform a prescribed procedure, failure to perform a prescribed procedure competently, or performance of a procedure that is not within the scope of practice of credentialed EMS personnel or EMS instructors;

(14) performing as a credentialed EMS personnel in any EMS System in which the individual is not affiliated and authorized to function;

(15) performing or authorizing the performance of procedures, or administration of medications detrimental to a student or individual;

(16) delay or failure to respond when on-duty and dispatched to a call for EMS assistance;

(17) testing positive, whether for-cause or at random, through urine, blood, or breath sampling, for any substance, legal or illegal, that is likely to impair the physical or psychological ability of the credentialed EMS personnel to perform all required or expected functions while on duty;

(18) failure to comply with G.S. 143-518 regarding the use or disclosure of records or data associated with EMS Systems, Specialty Care Transport Programs, Alternative Practice Settings, or patients;

(19) refusing to consent to any criminal history check required by G.S. 131E-159;

(20) abandoning or neglecting a patient who is in need of care, without making arrangements for the continuation of such care;

(21) falsifying a patient's record or any controlled substance records;

(22) harassing, abusing, or intimidating a patient, EMS personnel, other allied healthcare personnel, student, educational institution staff, members of the public, or OEMS staff, either physically, verbally, or in writing;

10A NCAC 13P .1508 SUMMARY SUSPENSION

In accordance with G.S. 150B-3(c) an EMS Provider License, EMS Vehicle Permit, or EMS credential may be summarily suspended if the public health, safety, or welfare requires emergency action. This determination is delegated to the Chief of the OEMS. For EMS credentials, this determination shall be made following review by the EMS Disciplinary Committee pursuant to G.S. 131E-159(f). Such a finding shall be incorporated with the order of the Department and the order is effective on the date specified in the order or on service of the certified copy of the order at the last known address of the affected party, whichever is later, and continues to be effective during the proceedings. Failure to receive the order because of refusal of service or unknown address does not invalidate the order.

History Note: *Authority G.S. 131E-159(f); 150B-3(c);*
Eff. January 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

(23) engaging in any activities of a sexual nature with a patient, including kissing, fondling, or touching while responsible for the care of that individual;
(24) any criminal arrests that involve charges that have been determined by the Department to indicate a necessity to seek action in order to further protect the public pending adjudication by a court;
(25) altering, destroying, or attempting to destroy evidence needed for a complaint investigation being conducted by the OEMS;
(26) significant failure to comply with a condition to the issuance of an encumbered EMS credential with limited and restricted practices for persons in the chemical addiction or abuse treatment program;
(27) unauthorized possession of lethal or non-lethal weapons, chemical irritants to include mace, pepper (oleoresin capsicum) spray and tear gas, or explosives while in the performance of providing emergency medical services;
(28) significant failure to comply to provide EMS care records to the licensed EMS provider for submission to the OEMS as required by Rule .0204 of this Subchapter;
(29) continuing to provide EMS care after local suspension of practice privileges by the local EMS System, Medical Director, or Alternative Practice Setting;
(30) representing or allowing others to represent that the credentialed EMS personnel has a credential that the credentialed EMS personnel does not in fact have;
(31) diversion of any medication requiring medical oversight for credentialed EMS personnel;
(32) filing a knowingly false complaint against an individual, EMS Agency, or educational institution; or
(33) failure to comply with educational requirements defined in Sections .0500 and .0600 of this Subchapter.

(c) Pursuant to the provisions of G.S. 131E-159(h), the OEMS shall not issue an EMS credential for any person listed on the North Carolina Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when the registration would have been required by law.

(d) Pursuant to the provisions of G.S. 50-13.12, upon notification by the court, the OEMS shall revoke an individual's EMS credential until the Department has been notified by the court that evidence has been obtained of compliance with a child support order. The provisions of G.S. 50-13.12 supersede the requirements of Paragraph (f) of this Rule.

(e) When a person who is credentialed to practice as an EMS professional is also credentialed in another jurisdiction and the other jurisdiction takes disciplinary action against the person, the Department shall summarily impose the same or lesser disciplinary action upon receipt of the other jurisdiction's action. The EMS professional may request a hearing before the EMS Disciplinary Committee. At the hearing the issues shall be limited to:

(1) whether the person against whom action was taken by the other jurisdiction and the Department are the same person;
(2) whether the conduct found by the other jurisdiction also violates the rules of the N.C. Medical Care Commission; and
(3) whether the sanction imposed by the other jurisdiction is lawful under North Carolina law.

(f) The OEMS shall provide written notification of the amendment, denial, suspension, or revocation. This notice shall be given personally or by certified mail, and shall set forth:

(1) the factual allegations;
(2) the statutes or rules alleged to have been violated; and
(3) notice of the individual's right to a contested hearing, set forth in Rule .1509 of this Section, on the revocation of the credential.

(g) The OEMS shall provide written notification to the EMS professional within five business days after information has been entered into the National Practitioner Data Bank and the Healthcare Integrity and Protection Integrity Data Bank.

(h) The EMS System Administrator, Primary Agency Contact, Medical Director, Educational Institution Program Coordinator, or Medical Advisor shall notify the OEMS of any violation listed in Paragraph (b) of this Rule within 30 days of discovery of the violation or upon completion of the internal agency or EMS system investigation.

History Note: *Authority G.S. 131E-159; 143-508(d)(10); 143-519;*
Eff. January 1, 2013;
Readopted Eff. January 1, 2017;

Amended Eff. April 1, 2024; July 1, 2021.

10A NCAC 13P .1509 PROCEDURES FOR DENIAL, SUSPENSION, AMENDMENT, OR REVOCATION

The procedures for contested cases in G.S. 150B, Article 3, apply to the denial, suspension, amendment or revocation of credentials, licenses, permits, approvals, or designations.

History Note: *Authority G.S. 143-508(d)(10);*
Eff. January 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 13P .1510 PROCEDURES FOR THE VOLUNTARY SURRENDER OR MODIFICATION OF THE LEVEL OF AN EMS CREDENTIAL

(a) An individual who holds a valid North Carolina EMS credential may request to voluntarily surrender the credential to the OEMS by:

(1) providing written notice stating the individual's desire to surrender the credential and explaining the circumstances surrounding the request; and

(2) returning the pocket credential and wall certificate to the OEMS upon notification the request has been approved.

(b) An individual who holds a valid North Carolina EMS credential may request to voluntarily modify the current credentialing level from a higher level to a lower level by the OEMS by:

(1) providing written notice stating the individual's desire to lower his or her current level and explaining the circumstances surrounding the request and stating the desired level of credentialing; and

(2) returning the pocket credential and wall certificate to the OEMS upon notification the request has been approved.

(c) The OEMS shall provide a written response to the individual within 10 business days following receipt of the request either approving or denying the request. This response shall describe the reason(s) for approval or denial.

(d) If the individual seeks to restore the credential to the previous status, the individual shall:

(1) wait a minimum of six months from the date the action was taken;

(2) provide written notice stating the individual's desire to restore the previous credential;

(3) provide evidence of continuing education at a minimum of two hours per month at the level of the EMS credential being sought; and

(4) undergo a criminal history background check.

(e) If the OEMS denies the individual's request for restoration of the EMS credential, the OEMS shall provide in writing the reason(s) for denial and inform the individual of the procedures for contested case hearing as set forth in Rule .1509 of this Section.

History Note: *Authority G.S. 131E-159(g); 143-508(d)(3); 143-508(d)(10); Eff. January 1, 2017.*

10A NCAC 13P .1511 PROCEDURES FOR QUALIFYING FOR AN EMS CREDENTIAL FOLLOWING ENFORCEMENT ACTION

(a) Any individual who has been subject to suspension, revocation, or amendment of an EMS credential shall submit in writing to the OEMS a request for review to determine eligibility for credentialing.

(b) Factors the Department shall consider when determining eligibility shall include:

(1) the reason for administrative action, including:
  (A) criminal history;
  (B) patient care;
  (C) substance abuse; and
  (D) failure to meet credentialing requirements;
(2) the length of time since the administrative action was taken; and
(3) any mitigating or aggravating factors relevant to obtaining a valid EMS credential.

(c) In order to be considered for eligibility, the individual shall:

(1) wait a minimum of 36 months following administrative action before seeking review; and
(2) undergo a criminal history background check. If the individual has been charged or convicted of a misdemeanor or felony in this or any other state or country within the previous 36 months, the 36 month waiting period shall begin from the date of the latest charge or conviction.

(d) If determined to be eligible, the Department shall grant authorization for the individual to begin the process for EMS credentialing as set forth in Rule .0502 of this Subchapter.

(e) Prior to enrollment in an EMS educational program, the individual shall disclose the prior administrative action taken against the individual's credential in writing to the EMS Educational Institution.

(f) An individual who has undergone administrative action against his or her EMS credential is not eligible for legal recognition as defined in G.S. 131E-159(d) or issuance of a temporary EMS credential as defined in G.S. 131E-159(e).

(g) For a period of 10 years following restoration of the EMS credential, the individual shall disclose the prior administrative action taken against his or her credential to every EMS System, Medical Director, EMS Provider, and EMS Educational Institution where he or she is affiliated and provide a letter to the OEMS from each verifying disclosure.

(h) If the Department determines the individual is ineligible for EMS credentialing pursuant to this Rule, the Department shall provide in writing the reason(s) for denial and inform him or her of the procedures for contested case hearing as set forth in Rule .1509 of this Section.

History Note: *Authority G.S. 131E-159(g); 143-508(d)(3); 143-508(d)(10);*
Eff. January 1, 2017;
Amended Eff. July 1, 2021.

G.S. 150B-21.3A Report for 10A NCAC 13P, EMERGENCY MEDICAL SERVICES AND TRAUMA RULES

Agency - Medical Care Commission

Comment Period - February 14, 2025 - April 15, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
SUBCHAPTER 13P – EMERGENCY MEDICAL SERVICES AND TRAUMA RULES	**SECTION .0100 – DEFINITIONS**	10A NCAC 13P .0101	ABBREVIATIONS	Amended Eff. April 1, 2024	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0102	DEFINITIONS	Amended Eff. April 1, 2024	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .0200 – EMS SYSTEMS	10A NCAC 13P .0201	EMS SYSTEM REQUIREMENTS	Amended Eff. April 1, 2024	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0203	SPECIAL SITUATIONS	Readopted Eff. April 1, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0204	EMS PROVIDER LICENSE REQUIREMENTS	Readopted Eff. June 1, 2018	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0205	EMS PROVIDER LICENSE CONDITIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0206	TERM OF EMS PROVIDER LICENSE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0207	GROUND AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS	Amended Eff. April 1, 2024	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0208	CONVALESCENT AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0209	AIR MEDICAL AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS	Amended Eff. January 1, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0210	WATER AMBULANCE: WATERCRAFT AND EQUIPMENT REQUIREMENTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0211	AMBULANCE PERMIT CONDITIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0212	TERM OF AMBULANCE PERMIT	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0213	EMS NONTRANSPORTING VEHICLE REQUIREMENTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0214	EMS NON-TRANSPORTING VEHICLE PERMIT CONDITIONS	Amended Eff. January 1, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0215	TERM OF EMS NONTRANSPORTING VEHICLE PERMIT	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0216	WEAPONS AND EXPLOSIVES FORBIDDEN	Amended Eff. April 1, 2024	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0217	MEDICAL AMBULANCE/EVACUATION BUS: VEHICLE AND EQUIPMENT REQUIREMENTS	Amended Eff. April 1, 2024	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0218	PEDIATRIC SPECIALTY CARE GROUND AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS	Amended Eff. April 1, 2024	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0219	STAFFING FOR MEDICAL AMBULANCE/EVACUATION BUS VEHICLES	Readopted Eff. January 1, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0220	STAFFING FOR PEDIATRIC SPECIALTY CARE GROUND AMBULANCES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0221	PATIENT TRANSPORTATION BETWEEN HOSPITALS	Amended Eff. April 1, 2024	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0222	TRANSPORT OF STRETCHER BOUND PATIENTS	Amended Eff. July 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13P, EMERGENCY MEDICAL SERVICES AND TRAUMA RULES

Agency - Medical Care Commission

Comment Period - February 14, 2025 - April 15, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		10A NCAC 13P .0223	REQUIRED DISCLOSURE AND REPORTING INFORMATION	Eff. January 1, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0224	GROUND AMBULANCE VEHICLE MANUFACTURING STANDARDS	Amended Eff. July 1, 2024	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .0300 – SPECIALTY CARE TRANSPORT PROGRAMS	10A NCAC 13P .0301	SPECIALTY CARE TRANSPORT PROGRAM CRITERIA	Amended Eff. July 1, 2024	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0302	AIR MEDICAL SPECIALTY CARE TRANSPORT PROGRAM CRITERIA FOR LICENSED EMS PROVIDERS USING ROTARY-WING AIRCRAFT	Readopted Eff. January 1, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0305	AIR MEDICAL SPECIALTY CARE TRANSPORT PROGRAM CRITERIA FOR LICENSED EMS PROVIDERS USING FIXED-WING AIRCRAFT	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .0400 - MEDICAL OVERSIGHT	10A NCAC 13P .0401	COMPONENTS OF MEDICAL OVERSIGHT FOR EMS SYSTEMS	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0402	COMPONENTS OF MEDICAL OVERSIGHT FOR SPECIALTY CARE TRANSPORT PROGRAMS	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0403	RESPONSIBILITIES OF THE MEDICAL DIRECTOR FOR EMS SYSTEMS	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0404	RESPONSIBILITIES OF THE MEDICAL DIRECTOR FOR SPECIALTY CARE TRANSPORT PROGRAMS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0405	REQUIREMENTS FOR ADULT AND PEDIATRIC TREATMENT PROTOCOLS FOR EMS SYSTEMS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0406	REQUIREMENTS FOR ADULT AND PEDIATRIC TREATMENT PROTOCOLS FOR SPECIALTY CARE TRANSPORT PROGRAMS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0407	REQUIREMENTS FOR EMERGENCY MEDICAL DISPATCH PRIORITY REFERENCE SYSTEM	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0408	EMS PEER REVIEW COMMITTEE FOR EMS SYSTEMS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0409	EMS PEER REVIEW COMMITTEE FOR SPECIALTY CARE TRANSPORT PROGRAMS	Amended Eff. January 1, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0410	COMPONENTS OF MEDICAL OVERSIGHT FOR AIR MEDICAL PROGRAMS	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .0500 – EMS PERSONNEL	10A NCAC 13P .0501	EDUCATIONAL PROGRAMS	Amended Eff. July 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0502	INITIAL CREDENTIALING REQUIREMENTS FOR EMR, EMT, AEMT, PARAMEDIC, AND EMD	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0503	TERM OF CREDENTIALS FOR EMS PERSONNEL	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0504	RENEWAL OF CREDENTIALS FOR EMR, EMT, AEMT, PARAMEDIC, AND EMD	Amended Eff. July 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0505	SCOPE OF PRACTICE FOR EMS PERSONNEL	Amended Eff. July 1, 2018	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0506	PRACTICE SETTINGS FOR EMS PERSONNEL	Amended Eff. July 1, 2018	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0507	INITIAL CREDENTIALING REQUIREMENTS FOR LEVEL I EMS INSTRUCTORS	Amended Eff. January 1, 2022	Necessary	No		No	Necessary	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13P, EMERGENCY MEDICAL SERVICES AND TRAUMA RULES

Agency - Medical Care Commission

Comment Period - February 14, 2025 - April 15, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		10A NCAC 13P .0508	INITIAL CREDENTIALING REQUIREMENTS FOR LEVEL II EMS INSTRUCTORS	Amended Eff. January 1, 2022	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0509	CREDENTIALING OF INDIVIDUALS TO ADMINISTER LIFESAVING TREATMENT TO PERSONS SUFFERING AN ADVERSE REACTION TO AGENTS THAT MIGHT CAUSE ANAPHYLAXIS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0510	RENEWAL OF CREDENTIALS FOR LEVEL I AND LEVEL II EMS INSTRUCTORS	Amended Eff. July 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0511	CRIMINAL HISTORIES	Amended Eff. January 1, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0512	REINSTATEMENT OF LAPSED EMS CREDENTIAL	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0513	REFRESHER COURSES	Eff. January 1, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .0600 – EMS EDUCATIONAL INSTITUTIONS AND PROGRAMS	10A NCAC 13P .0601	CONTINUING EDUCATION EMS EDUCATIONAL PROGRAM REQUIREMENTS	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0602	BASIC AND ADVANCED EMS EDUCATIONAL INSTITUTION REQUIREMENTS	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0605	ACCREDITED EMS EDUCATIONAL INSTITUTION REQUIREMENTS	Eff. January 1, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .0900 - TRAUMA CENTER STANDARDS AND APPROVAL	10A NCAC 13P .0901	TRAUMA CENTER CRITERIA	Amended Eff. September 1, 2019	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0904	INITIAL DESIGNATION PROCESS	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .0905	RENEWAL DESIGNATION PROCESS	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .1000 – TRAUMA CENTER DESIGNATION ENFORCEMENT	10A NCAC 13P .1003	MISREPRESENTATION OF DESIGNATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .1100 - TRAUMA SYSTEM DESIGN	10A NCAC 13P .1101	STATE TRAUMA SYSTEM	Amended Eff. July 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1102	REGIONAL TRAUMA SYSTEM PLAN	Amended Eff. January 1, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1103	REGIONAL TRAUMA SYSTEM POLICY DEVELOPMENT	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .1400 - RECOVERY AND REHABILITATION OF CHEMICALLY DEPENDENT EMS PERSONNEL	10A NCAC 13P .1401	CHEMICAL ADDICTION OR ABUSE RECOVERY PROGRAM REQUIREMENTS	Amended Eff. July 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1402	PROVISIONS FOR PARTICIPATION IN THE CHEMICAL ADDICTION OR ABUSE RECOVERY PROGRAM	Readopted Eff. January 1, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1403	CONDITIONS FOR RESTRICTED PRACTICE WITH LIMITED PRIVILEGES	Amended Eff. July 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1404	REINSTATEMENT OF AN UNENCUMBERED EMS CREDENTIAL	Amended Eff. July 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1405	FAILURE TO COMPLETE THE CHEMICAL ADDICTION OR ABUSE RECOVERY PROGRAM	Amended Eff. July 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .1500 - DENIAL, SUSPENSION, AMENDMENT, OR REVOCATION	10A NCAC 13P .1501	ENFORCEMENT DEFINITIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13P, EMERGENCY MEDICAL SERVICES AND TRAUMA RULES

Agency - Medical Care Commission

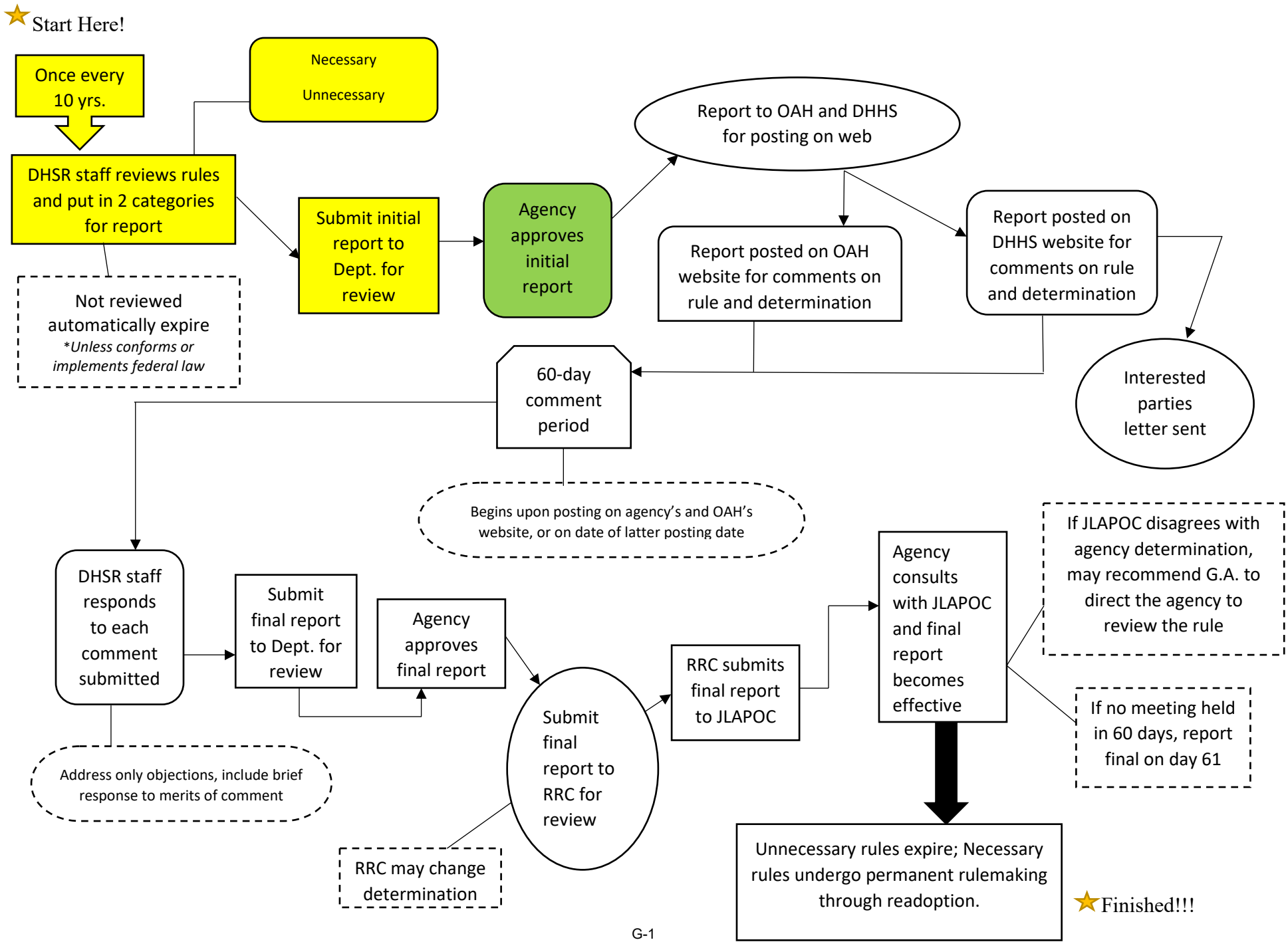
Comment Period - February 14, 2025 - April 15, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		10A NCAC 13P .1502	LICENSED EMS PROVIDERS	Amended Eff. July 1, 2018	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1503	SPECIALTY CARE TRANSPORT PROGRAMS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1504	TRAUMA CENTERS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1505	EMS EDUCATIONAL INSTITUTIONS	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1506	EMS VEHICLE PERMITS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1507	EMS PERSONNEL CREDENTIALS	Amended Eff. April 1, 2024.	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1508	SUMMARY SUSPENSION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1509	PROCEDURES FOR DENIAL, SUSPENSION, AMENDMENT, OR REVOCATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1510	PROCEDURES FOR THE VOLUNTARY SURRENDER OR MODIFICATION OF THE LEVEL OF AN EMS CREDENTIAL	Eff. January 1, 2017	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13P .1511	PROCEDURES FOR QUALIFYING FOR AN EMS CREDENTIAL FOLLOWING ENFORCEMENT ACTION	Amended Eff. July 1, 2021	Necessary	No		No	Necessary	Select One	Select One	Select One

Periodic Rules Review Process for DHSR

Exhibit G



SECTION .1900 - SUPPLEMENTAL RULES FOR THE LICENSURE OF THE SKILLED: INTERMEDIATE: ADULT CARE HOME BEDS IN A HOSPITAL

10A NCAC 13B .1901 SUPPLEMENTAL RULES

When a hospital offers nursing facility or adult care home long-term care services, the services shall be included under one hospital license as provided in Rule .0201(c). The general requirements included in this Subchapter shall apply when applicable but in addition the nursing facility care and adult care home care unit must meet the supplemental requirements of this Section.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1902 DEFINITIONS

The following definitions shall apply throughout this Section, unless text otherwise indicates to the contrary:

(1) "Accident" means something occurring by chance or without intention that has caused physical or mental harm to a patient, resident, or employee.

(2) "Administer" means as defined in G.S. 90-87.

(3) "Administrator" means the person who has authority for and is responsible to the governing board for the overall operation of a facility.

(4) "Brain injury long-term care" is defined as an interdisciplinary, intensive maintenance program for patients who have incurred brain damage caused by external physical trauma and who have completed a primary course of rehabilitative treatment and have reached a point of no gain or progress for more than three consecutive months. Services are provided through a medically supervised interdisciplinary process and are directed toward maintaining the individual at the optimal level of physical, cognitive, and behavioral functioning.

(5) "Combination Facility" means any hospital with nursing home beds that is licensed to provide more than one level of care such as a combination of intermediate care and skilled nursing care and adult care home care.

(6) "Department" means the North Carolina Department of Health and Human Services.

(7) "Director of Nursing" means the nurse who has authority and responsibility for all nursing services and nursing care.

(8) "Dispense" means as defined in G.S. 90-87.

(9) "Drug" means as defined in G.S. 90-87.

(10) "Duly Licensed" means holding a current and valid license as required under the General Statues of North Carolina.

(11) "Incident" means an intentional or unintentional action, occurrence or happening that is likely to cause or lead to physical or mental harm to a patient, resident, or employee.

(12) "Licensed Practical Nurse" means as defined in G.S. 90-171.30 or G.S. 90-171.32.

(13) "Medication" means "drug" as defined in Item (9) of this Rule.

(14) "Nurse Aide" means any individual providing nursing or nursing-related services to patients in a facility, and is not a licensed health professional, a qualified dietitian or someone who volunteers to provide such services without pay, and who is listed in a Nurse Aide Registry pursuant to G.S. 131E-255.

(15) "Nurse Aide Trainee" means an individual who has not completed an approved nurse aide training course by the Department in accordance with 10A NCAC 13O .0301, herein incorporated by reference including subsequent amendments and editions, and competency evaluation and is demonstrating knowledge, while performing tasks that they have been found proficient in by an instructor. These tasks shall be performed under the supervision of a registered nurse. The term does not apply to volunteers.

(16) "Nursing Facility" means that portion of a nursing home certified under Title XIX of the Social Security Act (Medicaid) as in compliance with federal program standards for nursing facilities. It is often used synonymous with the term "nursing home," the usual prerequisite level for state licensure for nursing facility (NF) certification and Medicare skilled nursing facility (SNF) certification.

(17) "Nurse in Charge" means the nurse to whom duties for a specified number of patients and staff for a specified period of time have been delegated, such as for Unit A on the 7-3 or 3-11 shift.

(18) "On Duty" means personnel who are awake, dressed, and responsive to patient needs and present in the facility performing assigned duties.

(19) "Patient" means any person admitted for care to a skilled nursing or intermediate care facility.

(20) "Physician" means as defined in G.S. 90-9.1 or G.S. 90-9.2.

(21) "Qualified Dietitian" means as defined in 42 CFR 483.60(a)(1), herein incorporated by reference including subsequent amendments and editions. Electronic copies of 42 CFR 483.60 can be obtained free of charge at https://www.ecfr.gov/cgi-bin/text-idx?SID=1260800a39929487f0ca55b0ab5e710b&mc=true&tpl=/ecfrbrowse/Title42/42cfrv5_02.tpl#0.

(22) "Registered Nurse" means as defined in G.S. 90, Article 9A.

(23) "Resident" means as defined in G.S.131D-2.1.

(24) "Supervisor-in-Charge" means a duly licensed nurse to whom supervisory duties have been delegated by the Director of Nursing.

(25) "Ventilator dependence" means physiological dependency by a patient on the use of a ventilator for more than eight hours a day.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. February 1, 1993; December 1, 1991; March 1, 1991;
Readopted Eff. April 1, 2020.

10A NCAC 13B .1903 INSPECTIONS

(a) Any hospital with beds licensed by the Department under Section .1900 of these Rules may be inspected by one or more authorized representatives of the Department at any time. Generally, inspections will be conducted between the hours of 8:00 a.m. and 6:00 p.m., Monday through Friday. However, complaint investigations shall be conducted at the most appropriate time for investigating allegations of the complaint.

(b) At the time of inspection, any authorized representative of the Department shall make his presence known to the administrator or other person in charge who shall cooperate with such representative and facilitate the inspection.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1904 PROCEDURE FOR APPEAL

A hospital with nursing facility or adult care home beds may appeal any decision of the Department to deny, revoke or alter a license by making such an appeal in accordance with G.S. Chapter 150B.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1905 ADMISSIONS

(a) No patient shall be admitted except under the orders of a duly licensed physician.

(b) The facility shall acquire prior to or at the time of admission orders from the attending physician for the immediate care of the patient or resident.

(c) Within 48 hours of admission, the facility shall acquire medical information which shall include current medical findings, diagnosis, rehabilitation potential, a summary of the hospital stay if the patient is being transferred from a hospital, and orders for the ongoing care of the patient.

(d) If a patient is admitted from somewhere other than a hospital, a physical examination shall be performed either within 5 days prior to admission or within 48 hours following admission.

(e) Hospitals offering nursing facility or domiciliary home care as a new service must prepare a plan of admission which, at a minimum, assures availability of staff time and plans for individual patient assessments, initiation of health care or nursing care plans, and implementation of physician and nursing treatment plans. This plan must be available for inspection during the initial licensure survey prior to issuance of a license.

(f) Only persons who are 18 years of age or older shall be admitted to adult care home beds in a facility.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1906 POLICIES AND PROCEDURES

The governing board shall assure written policies and procedures which are available to and implemented by staff. These policies and procedures shall cover at least the following areas:

(1) admissions;
(2) dietary;
(3) discharges with physician orders and patients or residents leaving against physician advice;
(4) gratuities and solicitation which at a minimum shall provide that no owner, operator, agent or employee of a facility nor any member of his family shall accept a gratuity directly or indirectly from an patient or resident in the facility or solicit for any type of contribution;
(5) housekeeping;
(6) infection control which must include, but shall not be limited to, requirements for sterile, aseptic and isolation techniques; and communicable disease screening including, at a minimum, annual tuberculosis screening for all staff and inpatients of the facility;
(7) maintenance of patient medical or health care records including charging or record keeping;
(8) orientation of all facility personnel;
(9) patient or resident care plans, treatment and other health care or nursing care, including but not limited to all policies and procedures required by rules contained in this Subchapter;
(10) patients' or residents' rights;
(11) physical evaluation for residents and patients at least annually;
(12) physician services and utilization of the individual's private physician;
(13) procurement of supplies and equipment to meet individual patient care needs;
(14) protection of patients from abuse and neglect;
(15) range of services provided;
(16) recording and reporting to the department of accidents or incidents occurring to patients in any part of the facility and maintenance of such reports or records;
(17) rehabilitation services;
(18) release of medical record information;
(19) screening and reporting communicable disease to the local health department; and
(20) transfers.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1907 GENERAL

The governing board shall assure that policies and procedures are available and implemented for assessing each patient's or resident's health care needs and planning for meeting identified health care needs. There shall be a system for evaluating the effectiveness of the assessment, planning and implementation (delivery of care processes) for each patient or resident.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1908 FREQUENCY: METHOD AND CONTENT OF ASSESSMENT: PLANNING

Each patient's and resident's condition must be assessed on a regular, periodic basis, at least quarterly, with appropriate notation and updating of the health care plan. Health care planning for each patient and resident shall be an on-going process and must include, but shall not be limited to, the following:

(1) data which is systematically and continuously collected about his or her health status; the data shall be recorded so as to be accessible and communicated to all staff involved in the patient's or resident's care;

(2) current problems or needs identified and prioritized from a completed assessment relevant to the patient's or resident's response to aging, illness and general health status; and

(3) a current plan of care developed in conjunction with the patient or resident or legal guardian that includes measurable time related goals and approaches, or measures to be employed by various disciplines in order to achieve the identified goals.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1909 IMPLEMENTATION OF HEALTH PLAN

All parts of the plan of care shall be assigned to specific disciplines or staff as indicated in the plan of care to assure that health care and rehabilitative services are performed daily and documented for those patients and residents who require such services.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1910 NURSING/HEALTH CARE ADMINISTRATION AND SUPERVISION

(a) A licensed facility shall have a director of nursing service who shall be responsible for the overall organization and management of all nursing services and shall be currently licensed to practice as a registered nurse by the North Carolina Board of Nursing in accordance with G.S. 90, Article 9A.

(b) The Director of Nursing shall not serve as administrator or assistant administrator.

(c) A licensed facility with nursing facilities shall provide a full-time director of nursing on duty at least eight hours per day, five days a week. A registered nurse shall relieve the Director of Nursing (be in charge of nursing) during the Director's absence.

(d) A licensed facility shall employ and assign registered nurses, licensed practical nurses, nurse aides and nurse aide trainees for duties in accordance with G.S. 90, Article 9A.

(e) The Director of Nursing shall cause the following to be accomplished:

(1) establishment and implementation of nursing policies and procedures which shall include, but shall not be limited to the following:
  - (A) assessment of and planning for patients' nursing care or health care needs, and implementation of nursing or health care plans;
  - (B) daily charting of any unusual occurrences or acute episodes related to patient care, and progress notes written monthly reporting each patient's performance in accordance with identified goals and objectives and each patient's progress toward rehabilitative nursing goals;
  - (C) assurance of the delivery of nursing services in accordance with physicians' orders, nursing care plans and the facility's policies and procedures;
  - (D) notification of emergency physicians or on-call physicians;
  - (E) infection control to prevent cross-infection among patients and staff;
  - (F) reporting of deaths;
  - (G) emergency reporting of fire, patient and staff accidents or incidents, or other emergency situations;
  - (H) use of protective devices or restraints to assure that each patient or resident is restrained in accordance with physician orders and the facility's policies, and that the restrained patient or resident is appropriately evaluated and released at a minimum of every two hours;
  - (I) special skin care and decubiti care;
  - (J) bowel and bladder training;
  - (K) maintenance of proper body alignment and restorative nursing care;
  - (L) supervision of and assisting patients with feeding;
  - (M) intake and output observation and reporting for those patients whose condition warrants monitoring of their fluid balance. This will include those patients on intravenous fluids or tube feedings, and patients with kidney failure and temperatures elevated to 102 degrees Fahrenheit or above;
  - (N) catheter care; and
  - (O) procedures used in caring for patients in the facility;
(2) development of written job descriptions for nursing personnel;
(3) periodic assessment of the nursing department with identification of personnel requirements as they relate to patient care needs and reporting same to the administrator;
(4) a planned orientation and continuing inservice education program for nursing employees and documentation of staff attendance and subject matter covered during inservice education programs;
(5) provision of appropriate reference materials for the nursing department, which includes a Physician's Desk Reference or comparable drug reference, policy and procedure manual, and medical dictionary for each nursing station; and
(6) establishment of operational procedures to assure that appropriate supplies and equipment are available to nursing staff as determined by individual patient care needs.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;

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10A NCAC 13B .1911 VACANT DIRECTOR OF NURSING POSITION

(a) The administrator shall notify the Department within 72 hours when the director of nursing position becomes vacant and shall provide the name and license number of the individual who is acting director or the replacement for the director of nursing.

(b) A facility shall not operate without either a director of nursing or acting director or nursing.

(c) The administrator shall employ a director of nursing within 30 days after a position becomes vacant. A vacancy which exceeds 30 days shall be reviewed by the Department for action relative to licensure status of the facility.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1912 NURSE STAFFING REQUIREMENTS

(a) A licensed facility shall provide licensed nursing personnel sufficient to accomplish the following:

(1) patient needs assessment,

(2) patient care planning, and

(3) supervisory functions in accordance with the level of patient or resident care advertised or offered by the facility.

The facility also shall provide other nursing personnel sufficient to assure that at least activities of daily living, personal grooming, restorative nursing actions and other health care needs as identified in each patient's or resident's plan of care are met.

(b) A licensed multi-storied facility (one having more than one story) shall provide at least one person on duty on each patient care floor at all times.

(c) Daily direct patient care nursing staff, licensed and unlicensed, shall equal or exceed 2.1 nursing hours per patient. (This is sometimes referred to as nursing hours per patient day or NHPPD or NH/PD.)

(1) Inclusive in these figures is the requirement that at least one licensed nurse is on duty for direct patient care at all time; and

(2) Nursing care shall include the services of a registered nurse for at least eight consecutive hours a day, seven days a week. This coverage can be spread over more than one shift if such a need exists. The Director of Nursing may be counted as meeting the requirements for both the Director of Nursing and patient and resident care staffing for facilities of a total census of 60 beds or less.

(d) Nursing support personnel including ward clerks, secretaries, nurse educators and persons in primarily administrative management positions and not actively involved in direct patient care shall not be counted toward compliance with minimum daily requirements for direct care staffing.

(e) All exceptions to meeting minimum staffing requirements shall be reported to the Department at the end of each month. Staffing waivers granted by the federal government for Medicare and Medicaid certified beds shall be accepted for licensure purposes.

(f) The ratio of male to female nurse aides will be determined by the needs of the patients, particularly the numbers of male patients requiring assistance with personal care.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (b)(4)(C);*
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Amended Eff. March 1, 1990;
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Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1915 ADULT CARE HOME PERSONNEL REQUIREMENTS

(a) The administrator shall designate a person to be in charge of the adult care home residents at all times. The nurse in charge of nursing services may also serve as supervisor-in-charge of the adult care home beds.

(b) If adult care home beds are located in a separate building or a separate level of the same building, there shall be a person on duty in the adult care home areas at all times.

(c) A licensed facility shall provide staff to assure that activities of daily living, personal grooming, and assistance with eating are provided to each resident. Medication administration as indicated by each resident's condition or physician's orders shall be carried out as identified in each resident's plan of care.

(d) Adult care home facilities licensed as a part of a combination facility shall comply with the staffing requirements in 10A NCAC 13F .0605 herein incorporated by reference including subsequent amendments and editions.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Readopted Eff. April 1, 2020.

10A NCAC 13B .1916 REHABILITATIVE NURSING AND DECUBITUS CARE

Each patient or resident shall be given care to prevent contractures, deformities, and decubiti, including but not limited to:

(1) changing positions of bedfast and chairfast patients or residents every two hours and administering simple preventive care. Documentation of such care and outcome must be included in routine summaries or progress notes;

(2) maintaining proper alignment and joint movement to prevent contractures and deformities, which must be documented in routine summaries or progress notes;

(3) implementing an individualized bowel and bladder training program except for patients or residents whose records are documented that such training is not effective. A monthly summary for patients and quarterly summaries for domiciliary residents shall be written relative to each patient's or resident's performance in the bowel and bladder training program; and

(4) such other services as necessary to meet the needs of the patient.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1917 MEDICATION ADMINISTRATION

(a) A licensed facility shall have policies and procedures governing the administration of medications which shall be enforced and implemented by administration and staff. Policies and procedures shall include, but shall not be limited to:

(1) automatic stop orders for treatment and drugs;

(2) accountability of controlled substances as defined by the North Carolina Controlled Substances Act, G.S. 90, Article 5;

(3) dispensing and administering behavior modifying drugs, such as hypnotics, sedatives, tranquilizers, antidepressants and other psychotherapeutic agents; insulin; intravenous fluids and medications; cardiovascular regulating drugs; and antibiotics.

(b) All medications or drugs and treatments shall be administered and discontinued in accordance with signed physician's orders which are recorded in the patient's or resident's medical record.

(1) Only physicians, registered nurses, licensed practical nurses or physician assistants, if in accordance with the assistant's approved practice, shall administer medications.

(2) To ensure accountability, any medication shall be administered by the same licensed personnel who prepared the dose for administration. This Rule does not apply to the dispensing of medications from a pharmacy utilizing a unit of use drug delivery system.

(3) Medications shall be administered within a half hour prior to or half hour after the prescribed time for administration unless precluded by emergency situations.

(4) The person administering medications shall identify each patient or resident in accordance with the facility's policies and procedures prior to administering any medication.

(5) Medication administered to a patient or resident shall be recorded in the patient's or resident's medication administration record immediately after administration in accordance with the facility's policies and procedures.

(6) Omission of medication and the reason for the omission shall be indicated in the patient's or resident's medical record.

(7) The person administering medications which are ordered to be given as needed (PRN) shall justify the need for the same in the patient's or resident's medical record.

(8) Medication administration records shall provide identification of the drug and strength of drug, quantity of drug administered, name of administering employee, title of employee and time of administration.

(c) Self-administration of medications shall be permitted only if prescribed by a physician and directions are printed on the container.

(d) The administration of one patient's or resident's medications to another patient or resident is prohibited except in the case of an emergency. In the event of such an emergency, steps shall be taken to assure that the borrowed medications shall be replaced promptly and so documented.

(e) Verbal orders shall be countersigned by a physician within five days of issuance.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. December 1, 1991; March 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1918 TRAINING

(a) A licensed facility shall provide patient or resident care employees a planned orientation and continuing education program emphasizing patient or resident assessment and planning, activities of daily living, personal grooming, rehabilitative nursing or restorative care, other patient or resident care policies and procedures, patients' rights, and staff performance expectations. Attendance and subject matter covered shall be documented for each session, retained in accordance with policy established by the facility, and available for licensure inspections.

(b) The administrator shall assure that employees are oriented within the first week of employment to the facility's philosophy and goals.

(c) Employees shall have specific on-the-job training as necessary to perform their individual job assignment.

(d) A nurse aide trainee may be employed to perform the duties of a nurse aide for a period of time not to exceed four months. During this period of time the nurse aide trainee shall be permitted to perform only those tasks that competence has been demonstrated and documented on the record. Nurse aide I shall meet the training and competency evaluation standards in 10A NCAC 13O .0301, incorporated herein by reference including subsequent amendments and editions. A record of nurse aide qualifications shall be maintained for each nurse aide used by a facility and shall be retained in the general personnel files of the facility in accordance with policy established by the facility.

(e) The initial orientation to the facility shall be exclusive of the Nurse Aide I training program. Competency evaluation shall be conducted in each of the following areas:

(1) Observation and documentation,
(2) Basic nursing skills,
(3) Personal care skills,
(4) Mental health and social service needs,
(5) Basic restorative services, and
(6) Residents' Rights.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (b)(5);*
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Readopted Eff. April 1, 2020.

10A NCAC 13B .1919 DENTAL CARE

(a) A dental examination shall be performed at the time of admission with the following information being placed in the patient's or resident's medical or health care record:

(1) type of diet which the patient or resident can best manage (such as normal, soft or pureed);
(2) the presence of infection of gums, teeth, or jaws;
(3) brief descriptions of any removable dental appliances and a statement of their condition; and
(4) indications for dental treatment at the time of admission.

(b) Names of dentists who have agreed to render emergency dental care shall be maintained at each nursing station and at the supervisor's station in a adult care home.

(c) Staff of the facility shall ensure that:

(1) necessary daily dental care is provided;
(2) each patient or resident possesses appropriate toothbrushes and is encouraged and, when necessary, assisted in their use; and
(3) each patient or resident having a removable denture is furnished a receptacle in which to immerse the denture in water overnight.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1920 AVAILABILITY OF PHARMACEUTICAL SERVICES

(a) A licensed facility shall provide pharmaceutical services under the supervision of a pharmacist currently licensed to practice pharmacy in North Carolina.

(b) A facility shall be responsible for obtaining drugs, therapeutic nutrients and related products prescribed or ordered by a physician for patients or residents in the facility.

(c) Services shall include documented on-site pharmaceutical reviews accomplished at least every 31 calendar days for all patients and residents.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1921 DINING FACILITIES

Patients, including wheelchair patients, shall be encouraged to eat at the tables in the dining area and shall be assisted when necessary by non-dietary staff. An overbed table shall be provided for patients who eat in bed. A sturdy tray stand shall be provided for those patients who eat out of bed but are unable to go to the dining area. An overbed table which can be lowered to chair height may substitute for the tray stand.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1922 ACTIVITIES AND RECREATION

(a) The administrator shall designate an activities and recreation director to be in charge of activities and recreation for all patients and residents. The activities and recreation director shall have training and experience in directing recreational and group activities. The designated activities and recreation director shall be under the supervision of the administrator and shall be qualified to meet the needs of the patients and residents. A qualified individual shall be anyone eligible for a N.C. license as an occupational therapist or assistant therapist under G.S. 90-270; anyone eligible for N.C. certification as a recreation therapist or assistant therapist under G.S. 90C-9; anyone with a baccalaureate degree and one year experience; anyone who has completed an approved 36-hour or longer course in activities program management; or anyone not otherwise qualified but receiving at least four hours consultation per month from one who is qualified.

(b) The facility shall maintain and make available a listing of local resources for activities and recreation to be utilized in meeting the needs and interests of all patients and residents.

(c) Restoration to self care and resumption of normal activity shall be one of the main goals of the recreation or activity program. The scope of the activity program shall include:

(1) social activities involving individual and group participation which are designed to promote group relationships;
(2) recreational activities, both indoor and outdoor;
(3) opportunity to participate in activities outside the facility;
(4) religious programs, including the right of each patient and resident to attend the church or religious program of his choice;
(5) creative and expressive activities;
(6) educational activities; and
(7) exercise.

(d) The facility shall have written policies and procedures which are available and implemented by staff that:

(1) attempt to prevent the further mental or physical deterioration for those patients or residents who cannot realistically resume normal activities;
(2) assure opportunities for patient involvement, both individual and group, in both planning and implementing the activity program;
(3) provide patients or residents the opportunity for choice among a variety of activities; and
(4) encourage participation by each patient or resident in social and recreational activities according to individual need and abilities and desires unless the patient's or resident's record contains documentation that he is unable to participate.

(e) Each patient's or resident's activity plan shall be a part of his overall plan of care and shall contain documentation of periodic assessments of the individual's activity needs and interests. A record of activities and individuals participating shall be maintained in the facility.

(f) A licensed facility shall display a monthly activities calendar which includes variety to appeal to different interest groups in the nursing care and adult care home services.

(g) A licensed facility shall provide:

(1) Space for recreational and diversional activities. In hospitals offering new nursing home services, space shall be provided separately from the main living and dining areas; however, these areas may also be used for social activities.
(2) Designated indoor and outdoor activity areas for independent and group needs of patients and residents, and which are:
    (A) accessible to wheelchair and ambulatory patients; and
    (B) of sufficient size to accommodate necessary equipment and permit unobstructed movement of wheelchair and ambulatory patients or personnel responsible for instruction and supervision.
(3) Adequate space to store equipment and supplies without blocking exists or otherwise threatening the health and safety of patients and residents.

(h) There shall be equipment and supplies sufficient to carry out planned programs for both individual and group activities.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (a);*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;

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Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1923 SOCIAL SERVICES

(a) The administrator shall designate an employee to be responsible for the provision of social services. This person shall be known as the social services director. Subsequent to the effective date of the rules contained in this Subchapter any newly designated person must be a graduate of a four year college or university with one year's experience in the health care or long-term care field or have an equivalent combination of education and experience. An equivalent combination of education and experience means the number of years of education leading to a baccalaureate or associate degree plus the number of years of long-term nursing facility experience equal to five years; or eligible for certification as a social worker pursuant to G.S. 90B-7. The social services director shall have authority to carry out provisions contained in Rule .1923(b) of this Section.

(b) Each patient's or resident's plan of care shall contain a written plan for meeting his individual social needs and involving his active participation, the plan shall provide for:

(1) needed assistance in meeting the patient's or resident's physical, social and emotional needs through consultation with the patient or resident or his legal guardian, and relative, physician or others;

(2) assisting the patient or resident in adjusting to his environment, for referral to other supporting resources, for protective services, for financial services and for assistance at the time of discharge or transfer into a new environment;

(3) the utilization of caseworkers employed by the county department of social services in the case of recipients of public assistance and for the utilization of appropriate persons with experience and training in the general area of social work in the case of those not on public assistance.

(c) Discharge planning shall be in keeping with each patient's and resident's discharge needs. These are as follows:

(1) The administrator shall assure that a medical order for discharge including any special instructions for meeting rehabilitation potential is obtained from all patients or residents except when a patient or resident leaves against a physician's order or advice; and

(2) The social services director shall coordinate discharge instructions and assure that patients and residents and their families are instructed in accordance with discharge orders.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1924 RESTRAINTS

(a) Patients and residents shall be restrained only by physician orders.

(b) The nurse in charge shall be responsible for making the decision relative to necessity for, type and duration of restraint in emergency situations requiring restraints while contacting the physician. The nurse also shall be responsible for documenting same in the patient's or resident's record.

(c) The type of restraint used and the time of application and removal shall be recorded by a licensed nurse in the patient's or resident's record.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1925 REQUIRED SPACES

(a) A combination or nursing facility shall meet the following requirements for bedrooms, dining, recreation, and common use areas:

(1) single bedrooms shall be provided with not less than 100 square feet of floor area;

(2) bedrooms with more than one bed shall be provided with not less than 80 square feet of floor area per bed;

(3) dining, recreation, and common use areas shall:

(A) total not less than 25 square feet of floor area per bed for skilled nursing and intermediate care beds;

(B) total not less than 30 square feet of floor area per bed for adult care home beds; and

(C) be contiguous to patient and resident bedrooms.

(b) Floor space for the following rooms, areas, and furniture shall not be included in the floor areas required by Paragraph (a) of this Rule:

(1) toilet rooms;

(2) vestibules;

(3) bath areas;

(4) closets;

(5) lockers;

(6) built-in furniture;

(7) movable wardrobes;

(6) corridors; and

(7) areas for physical and occupational therapy.

History Note: *Authority G.S. 131E-79;*
Eff. February 1, 1986;
Readopted Eff. April 1, 2020.

10A NCAC 13B .1926 NURSING HOME PATIENT OR RESIDENT RIGHTS

(a) Written policies and procedures shall be developed and enforced to implement requirements in G.S. 131E-115 et seq. (Nursing Home Patients' Bill of Rights) concerning the rights of patients and residents. The administrator shall make these policies and procedures known to the staff, patients and residents, and families of patients and residents and shall ensure their availability to the public by placing them in a conspicuous place.

(b) Any violation of patient rights contained in G.S. 131E-117 shall be determined by representatives of the Department by investigation or survey.

(c) If a licensed facility is found to be in violation of any of the rights contained in G.S. 131E-117, the Department shall impose penalties for each violation as provided by G.S. 131E-129.

(d) When the Department has been notified that corrective action has been taken for each violation, verification of same shall be made by a representative of the Department.

(e) The Department shall calculate a total of all fines levied against a facility based on the number of violations and the number of days and patients or residents involved in each violation.

(f) The Department shall mail a statement to the facility showing a total fine for each violation and a total of fines due to be paid for all violations. The facility shall pay the penalty within 60 days unless a hearing is requested under G.S. Chapter 150B.

(g) When it is found that a violation of G.S. 131E-117 has occurred but corrective action was taken prior to the date of discovery, fines shall be calculated and assessed in accordance with (e) and (f) of this Rule.

(h) In matters of patient abuse, neglect or misappropriation the definitions shall have the meanings defined for abuse, neglect and exploitation respectively as contained in the North Carolina PROTECTION OF THE ABUSED, NEGLECTED OR EXPLOITED DISABLED ADULT ACT, G.S. 108A-99 et seq.

History Note: *Authority G.S. 131E-79; 42 U.S.C. 1396 r (e)(2)(B);*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Amended Eff. March 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1927 BRAIN INJURY LONG-TERM CARE PHYSICIAN SERVICES

(a) For nursing facility patients located in designated brain injury long-term care units, there shall be an attending physician who is responsible for the patient's specialized care program. The intensity of the program requires that there shall be direct patient contact by a physician at least once per week and more often as the patient's condition warrants. Each patient's interdisciplinary, long-term care program shall be developed and implemented under the supervision of a physiatrist (a physician trained in Physical Medicine and Rehabilitation) or a physician of equivalent training and experience.

(b) If a physiatrist or physician of equivalent training or experience, is not available on a weekly basis to the facility, the facility shall provide for weekly medical management of the patient, by another physician. In addition, oversight for the patient's interdisciplinary, long-term care program shall be provided by a qualified consultant physician who visits patients monthly, makes recommendations for and approves the interdisciplinary care plan, and provides consultation as requested to the physician who is managing the patient on a weekly basis.

(c) The attending physician shall actively participate in individual case conferences or care planning sessions and shall review and sign discharge summaries and records within 15 days of patient discharge. When patients are to be discharged to either another health care facility or a residential setting the attending physician shall assure that the patient has been provided with a discharge plan which incorporates optimum utilization of community resources and post discharge continuity of care and services.

History Note: *Authority G.S. 131E-79;*
Eff. December 1, 1991;
Amended Eff. February 1, 1993;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1929 SPECIAL NURSING REQUIREMENTS FOR BRAIN INJURY LONG-TERM CARE

Direct care nursing personnel staffing ratio (NH/PD) established in Rule .1912 of this Section shall not be applied to nursing services for patients who require brain injury long-term care, due to their more intensive maintenance and nursing needs. The minimum direct care nursing staff shall be 5.5 hrs. per patient day allocated on a per shift basis as the facility chooses to appropriately meet the patient's needs. It is also required that regardless of how low the patient census the direct care nursing staff shall not fall below a registered nurse and a nurse aide I at any time during a 24-hour period.

History Note: *Authority G.S. 131E-79;*
Eff. December 1, 1991;
Amended Eff. February 1, 1993;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1930 VENTILATOR DEPENDENCE

The general requirements in this Subchapter shall apply when applicable. In addition, facilities having patients requiring the use of ventilators for more than eight hours a day must meet the following requirements:

(1) Respiratory therapy shall be provided and supervised by a respiratory therapist currently registered by the National Board for Respiratory Care. The respiratory therapist shall:
   (a) make, as a minimum, weekly on-site assessments of each patient receiving ventilator support with corresponding progress notes;
   (b) be on-call 24 hours daily; and
   (c) assist the pulmonologist and nursing staff in establishing ventilator policies and procedures, including emergency policies and procedures.

(2) Direct nursing care staffing shall be in accordance with Rule .1912 of this Section.

History Note: *Authority G.S. 131E-79;*
Eff. December 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1931 PHYSICIAN SERVICES FOR VENTILATOR DEPENDENT PATIENTS

Hospitals with nursing facility beds with ventilator dependent care patients shall contract with a physician who is licensed to practice in North Carolina with Board Certification and who has specialized training in pulmonary medicine. This physician shall be responsible for respiratory services and shall:

(1) establish, with the respiratory therapist and nursing staff, appropriate ventilator policies and procedures, including emergency procedures;
(2) assess each ventilator patient's status at least monthly with corresponding progress notes;
(3) be available on an emergency basis; and
(4) participate in individual patient case planning.

History Note: *Authority G.S. 131E-79;*
Eff. December 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .1932 EMERGENCY ELECTRICAL SERVICE

(a) A minimum of one dedicated emergency branch circuit per bed is required for ventilator dependent patients in addition to the normal system receptacle at each bed location required by the National Electrical Code. This emergency circuit shall be provided with a minimum of two duplex receptacles identified for emergency use. Additional emergency branch circuits/receptacles shall be provided where the electrical life support needs of the patient exceed the minimum requirements stated in this Paragraph. Each emergency circuit serving ventilator dependent patients shall be fed from the automatically transferred critical branch of the essential electrical system. This Paragraph shall apply to both new and existing facilities.

(b) Heating equipment provided for ventilator dependent patient bedrooms shall be connected to the critical branch of the essential electrical system and arranged for delayed automatic or manual connection to the emergency power source if the heating equipment depends upon electricity for proper operation. This Paragraph shall apply to both new and existing facilities.

(c) Task lighting connected to the automatically transferred critical branch of the essential electrical system shall be provided for each ventilator dependent patient bedroom. This Paragraph shall apply to both new and existing facilities.

History Note: *Authority G.S. 131E-79;*
Eff. December 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .2020 DEFINITIONS

The following definitions shall apply to inpatient rehabilitation facilities or units only:

(1) "Case management" means the coordination of services, for a given patient, between disciplines so that the patient may reach optimal rehabilitation through the judicious use of resources.

(2) "Comprehensive, inpatient rehabilitation program" means a program for the treatment of persons with functional limitations or chronic disabling conditions who have the potential to achieve a significant improvement in activities of daily living. A comprehensive, rehabilitation program utilizes a coordinated and integrated, interdisciplinary approach, directed by a physician, to assess patient needs and to provide treatment and evaluation of physical, psycho-social and cognitive deficits.

(3) "Inpatient rehabilitation facility or unit" means a free-standing facility or a unit (unit pertains to contiguous dedicated beds and spaces) within an existing licensed health service facility approved in accordance with G.S. 131E, Article 9 to establish inpatient, rehabilitation beds and to provide a comprehensive, inpatient rehabilitation program.

(4) "Medical consultations" means consultations which the rehabilitation physician or the attending physician determine are necessary to meet the acute medical needs of the patient and do not include routine medical needs.

(5) "Occupational therapist" means any individual licensed in the State of North Carolina as an occupational therapist in accordance with the provisions of G.S. 90, Article 18D.

(6) "Occupational therapist assistant" means any individual licensed in the State of North Carolina as an occupational therapist assistant in accordance with the provisions of G.S. 90, Article 18D.

(7) "Psychologist" means a person licensed as a practicing psychologist in accordance with G.S. 90, Article 18A.

(8) "Physiatrist" means a licensed physician who has completed a physical medicine and rehabilitation residency training program approved by the Accreditation Council of Graduate Medical Education or the American Osteopathic Association.

(9) "Physical therapist" means any person licensed in the State of North Carolina as a physical therapist in accordance with the provisions of G.S. 90, Article 18B.

(10) "Physical therapist assistant" means any person duly licensed in the State of North Carolina as a physical therapist assistant in accordance with the provisions of G.S. 90-270.24, Article 18B.

(11) "Recreational therapist" means a person certified by the State of North Carolina Therapeutic Recreational Certification Board.

(12) "Rehabilitation nurse" means a registered nurse licensed in North Carolina, with training, either academic or on-the-job, in physical rehabilitation nursing and at least one year experience in physical rehabilitation nursing.

(13) "Rehabilitation aide" means an unlicensed assistant who works under the supervision of a registered nurse, licensed physical therapist or occupational therapist in accordance with the appropriate occupational licensure laws governing his or her supervisor and consistent with staffing requirements as set forth in Rule .2027 of this Section. The rehabilitation aide shall be listed on the North Carolina Nurse Aide Registry and have received additional staff training as listed in Rule .2028 of this Section.

(14) "Rehabilitation physician" means a physiatrist or a physician who is qualified, based on education, training and experience regardless of specialty, of providing medical care to rehabilitation patients.

(15) "Social worker" means a person certified by the North Carolina Social Work Certification and Licensure Board in accordance with G.S. 90B-3.

(16) "Speech and language pathologist" means any person licensed in the State of North Carolina as a speech and language pathologist in accordance with the provisions of G.S. 90, Article 22.

History Note: *Authority G.S. 131E-79; 143B-165;*
Eff. May 1, 1993;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .2033 DEEMED STATUS FOR INPATIENT REHABILITATION FACILITIES OR UNITS

(a) If an inpatient rehabilitation facility or unit with a comprehensive inpatient rehabilitation program is surveyed and accredited by the Joint Commission for the Accreditation of Health Care Organizations (JCAHO) or the Commission on Accreditation of Rehabilitation Facilities (CARF) and has been approved by the Department in accordance with Article 9 Chapter 131E of the North Carolina General Statutes, the Department deems the facility to be in compliance with Rules .2020 through .2030 and .2033 of this Section.

(b) Deemed status shall be provided only if the inpatient rehabilitation facility or unit provides copies of survey reports to the Division. The JCAHO report shall show that the facility or unit was surveyed for rehabilitation services. The CARF report shall show that the facility or unit was surveyed for comprehensive rehabilitation services. The facility or unit shall sign an agreement (Memorandum of Understanding) specifying these terms.

(c) The inpatient rehabilitation facility or unit shall be subject to inspections or complaint investigations by representatives of the Department at any time. If the facility or unit is found not to be in compliance with the rules listed in Paragraph (a) of this Rule, the facility shall submit a plan of correction and be subject to a follow-up visit to assure compliance.

(d) If the inpatient rehabilitation facility or unit loses or does not renew its accreditation, the facility or unit shall notify the Division in writing within 30 days.

History Note: *Authority G.S. 131E-79;*
Eff. May 1, 1993;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .2102 REPORTING REQUIREMENTS

(a) The Department shall establish the lists of the statewide 100 most frequently reported DRGs, 20 most common outpatient imaging procedures, and 20 most common outpatient surgical procedures performed in the hospital setting to be used for reporting the data required in Paragraphs (c) through (e) of this Rule. The lists shall be determined annually based upon data provided by the certified statewide data processor. The Department shall make the lists available on its website. The methodology to be used by the certified statewide data processor for determining the lists shall be based on the data collected from all licensed facilities in the State in accordance with G.S. 131E-214.2 as follows:

(1) the 100 most frequently reported DRGs shall be based upon all hospital's discharge data that has been assigned a DRG based on the Centers for Medicare & Medicaid Services grouper for each patient record, then selecting the top 100 to be provided to the Department;

(2) the 20 most common imaging procedures shall be based upon all outpatient data for both hospitals and ambulatory surgical facilities and represent all occurrences of the diagnostic radiology imaging codes section of the CPT codes, then selecting the top 20 to be provided to the Department; and

(3) the 20 most common outpatient surgical procedures shall be based upon the primary procedure code from the ambulatory surgical facilities and represent all occurrences of the surgical codes section of the CPT codes, then selecting the top 20 to be provided to the Department.

(b) Information required or reported in Paragraphs (a), (c), (d), and (i) of this Rule shall be posted on the Department's website at: http://www.ncdhhs.gov/dhsr/ahc and may be accessed at no cost.

(c) In accordance with G.S. 131E-214.13, all licensed hospitals shall report the data required in Paragraph (e) of this Rule related to the statewide 100 most frequently reported DRGs to the certified statewide data processor in a format provided by the certified statewide processor. Commencing with the reporting period ending September 30, 2015, an annual data report shall be submitted that includes all sites operated by the licensed hospital. Each annual report shall be submitted by the due date of January 1.

(d) In accordance with G.S. 131E-214.13, all licensed hospitals shall report the data required in Paragraph (e) of this Rule related to the statewide 20 most common outpatient imaging procedures and the statewide 20 most common outpatient surgical procedures to the certified statewide data processor in a format provided by the certified statewide processor. This report shall include the related primary CPT and HCPCS codes. Commencing with the reporting period ending September 30, 2015, an annual data report shall be submitted that includes all sites operated by the licensed hospital. Each annual report shall be submitted by January 1.

(e) The reports as described in Paragraphs (c) and (d) of this Rule shall be specific to each reporting hospital and shall include:

(1) the average gross charge for each DRG, CPT code, or procedure without a public or private third party payer source;

(2) the average negotiated settlement on the amount that will be charged for each DRG, CPT code, or procedure as required for patients defined in Subparagraph (e)(1) of this Rule. The average negotiated settlement shall be calculated using the average amount charged all patients eligible for the hospital's financial assistance policy, including self-pay patients;

(3) the amount of Medicaid reimbursement for each DRG, CPT code, or procedure, including all supplemental payments to and from the hospital;

(4) the amount of Medicare reimbursement for each DRG, CPT code, or procedure; and

(5) on behalf of patients who are covered by a Department of Insurance licensed third-party and teachers and State employees, the lowest, average, and highest amount of payments made for each DRG, CPT code, or procedure by each of the hospital's top five largest health insurers.

(A) each hospital shall determine its five largest health insurers based on the dollar volume of payments received from those insurers;

(B) the lowest amount of payment shall be reported as the lowest payment from each of the five insurers on the DRG, CPT code, or procedure;

(C) the average amount of payment shall be reported as the arithmetic average of each of the five health insurers payment amounts;

(D) the highest amount of payment shall be reported as the highest payment from each of the five insurers on the DRG, CPT code, or procedure; and

(E) the identity of the top five largest health insurers shall be redacted prior to submission.

(f) The data reported, as defined in Paragraphs (c) through (e) of this Rule, shall reflect the payments received from patients and health insurers for all closed accounts. For the purpose of this Rule, "closed accounts" are patient accounts with a zero balance at the end of the data reporting period.
(g) A minimum of three data elements shall be required for reporting under Paragraphs (c) and (d) of this Rule.
(h) The information submitted in the report shall be in compliance with the federal Health Insurance Portability and Accountability Act of 1996, 45 CFR Part 164.
(i) The Department shall provide the location of each licensed hospital and all specific hospital data reported pursuant to this Rule on its website. Hospitals shall be grouped by category on the website. On each quarterly report, hospitals shall determine one category that most accurately describes the type of facility. The categories are:

(1) "Academic Medical Center Teaching Hospital," means a hospital as defined in Policy AC-3 of the N.C. State Medical Facilities Plan. The N.C. State Medical Facilities Plan may be accessed at: http://www.ncdhhs.gov/dhsr/ncsmfp at no cost.

(2) "Teaching Hospital," means a hospital that provides medical training to individuals, provided that such educational programs are accredited by the Accreditation Council for Graduated Medical Education to receive graduate medical education funds from the Centers for Medicare & Medicaid Services.

(3) "Community Hospital," means a general acute hospital that provides diagnostic and medical treatment, either surgical or nonsurgical, to inpatients with a variety of medical conditions, and that may provide outpatient services, anatomical pathology services, diagnostic imaging services, clinical laboratory services, operating room services, and pharmacy services, that is not defined by the categories listed in this Subparagraph and Subparagraphs (i)(1), (2), or (5) of this Rule.

(4) "Critical Access Hospital," means a hospital defined in the Centers for Medicare & Medicaid Services' State Operations Manual, Chapter 2 – The Certification Process, 2254D – Requirements for Critical Access Hospitals (Rev. 1, 05-21-04), including all subsequent updates and revisions. The manual may be accessed at the website: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf at no cost.

(5) "Mental Health Hospital," means a hospital providing psychiatric services pursuant to G.S. 131E-176(21).

History Note: *Authority G.S. 131E-214.4; 131E-214.13;*
Temporary Adoption Eff. December 31, 2014;
Eff. September 30, 2015;
Temporary Amendment Eff. March 31, 2016;
Amended Eff. January 31, 2017.

SECTION .2100 – TRANSPARENCY IN HEALTH CARE COSTS

10A NCAC 13B .2101 DEFINITIONS

In addition to the terms defined in G.S. 131E-214.13, the following terms shall apply throughout this Section, unless text indicates to the contrary:

(1) "Current Procedural Terminology (CPT)" means a medical code set developed by the American Medical Association.

(2) "Diagnostic related group (DRG)" means a system to classify hospital cases assigned by a grouper program based on ICD (International Classification of Diseases) diagnoses, procedures, patient's age, sex, discharge status, and the presence of complications or co-morbidities.

(3) "Department" means the North Carolina Department of Health and Human Services.

(4) "Financial assistance" means a policy, including charity care, describing how the organization will provide assistance at its hospital(s) and any other facilities. Financial assistance includes free or discounted health services provided to persons who meet the organization's criteria for financial assistance and are unable to pay for all or a portion of the services. Financial assistance does not include:

(a) bad debt;

(b) uncollectable charges that the organization recorded as revenue but wrote off due to a patient's failure to pay;

(c) the cost of providing such care to the patients in Sub-Item (4)(b) of this Rule; or

(d) the difference between the cost of care provided under Medicare or other government programs, and the revenue derived therefrom.

(5) "Healthcare Common Procedure Coding System (HCPCS)" means a three-tiered medical code set consisting of Level I, II and III services and contains the CPT code set in Level I.

History Note: *Authority G.S. 131E-214.13;*
Temporary Adoption Eff. December 31, 2014;
Eff. September 30, 2015.

SECTION .3000 - GENERAL INFORMATION

10A NCAC 13B .3001 DEFINITIONS

Notwithstanding Section .1900 of this Subchapter, the following definitions shall apply throughout this Subchapter unless the context indicates to the contrary:

(1) "Appropriate" means suitable or fitting, or conforming to standards of care as established by professional organizations, including Association of Professionals in Infection Control and Epidemiology (APIC), American Medical Association (AMA) and American Nurses Association (ANA).

(2) "Authority having jurisdiction" means the Division of Health Service Regulation.

(3) "Certified Dietary Manager" or "CDM" means an individual who is certified by the Certifying Board of the Dietary Managers and meets the standards and qualification as referenced in the "Dietary Manager Training Program Requirements." These standards include any subsequent amendments and editions of the referenced manual. Copies of the "Dietary Manager Training Program Requirements" may be obtained free of charge at https://www.cbdmonline.org/.

(4) "Competence" means the state or quality of being able to perform specific functions well; skill; and ability.

(5) "Construction documents" means final building plans and specifications for the construction of a facility that a governing body submits to the Construction Section for approval as specified in Rule .3102 of this Subchapter.

(6) "Construction Section" means the Construction Section of the Division of Health Service Regulation.

(7) "Continuous" means ongoing or uninterrupted, 24 hours per day.

(8) "CRNA" means a Certified Registered Nurse Anesthetist who meets the criteria set forth in G.S. 90-171.21(d)(4).

(9) "Credentialed" means that the individual having a given title or position has been credited with the right to exercise official responsibilities to provide specific patient care and treatment services, within defined limits, based upon the individual's license, education, training, experience, competence, and judgment.

(10) "Department" means the Department of Health and Human Services.

(11) "Dietetics" means as defined in G.S. 90-352.

(12) "Dietitian" means a person who meets the criteria set forth in G.S. 90, Article 25.

(13) "Direct Supervision" means the state of being under the control of a supervisor, manager, or other person of authority.

(14) "Division" means the Division of Health Service Regulation.

(15) "Facility" means a hospital as defined in G.S. 131E-76.

(16) "Full-time equivalent" means a unit of measure of employee work time that is equal to the number of hours that one full-time employee would work during one calendar year if the employee worked eight hours a day, five days a week, and 52 weeks a year; i.e. 2,080 hours per year.

(17) "Governing body" means the authority as defined in G.S. 131E-76.

(18) "Imaging" means a reproduction or representation of a body or body part for diagnostic purposes by radiologic intervention that may include conventional fluoroscopic exam, magnetic resonance, nuclear or radio-isotope scan.

(19) "Invasive procedure" means a procedure involving puncture or incision of the skin, insertion of an instrument or foreign material into the body (excluding venipuncture and intravenous therapy).

(20) "License" means formal permission to provide services as granted by the State.

(21) "Medical staff" means the formal organization that is comprised of individuals who have sought and obtained clinical privileges in a facility. As defined by the facility's medical staff bylaws, rules and regulations, those members of the medical staff who regularly and routinely admit patients to a facility constitute the active medical staff.

(22) "Mission statement" means a written statement of the philosophy and beliefs of the organization or hospital as approved by the governing body.

(23) "Neonate" means the newborn from birth to one month.

(24) "Nurse executive" means a registered nurse who is the director of nursing services or a representative of decentralized nursing management staff.

(25) "Nurse midwife" means a person who meets the criteria as set forth in G.S. 90-171.21(d)(4).

(26) "Nursing facility" means as defined in G.S. 131E-116(2).
(27) "Nursing staff" means the registered nurses, licensed practical nurses, nurse aides, and others under nurse supervision, who provide patient care. The term also includes clerical personnel who work in clinical areas under nurse supervision.
(28) "Nutrition and Dietetic Technician Registered" means as defined by the Academy of Nutrition and Dietetics. A copy of the requirements can be obtained at https://www.eatrightpro.org/about-us/what-is-an-rdn-and-dtr/what-is-a-nutrition-and-dietetics-technician-registered at no cost.
(29) "Nutrition therapy" ranges from intervention and counseling on diet modification to administration of specialized nutrition therapies as determined necessary to manage a condition or treat illness or injury. Specialized nutrition therapies include supplementation with medical foods, enteral and parenteral nutrition. Nutrition therapy integrates information from the nutrition assessment with information on food and other sources of nutrients and meal preparation consistent with cultural background and socioeconomic status.
(30) "Observation bed" means a bed used for no more than 24-hours, to evaluate and determine the condition and disposition of a patient and is not considered a part of the hospital's licensed bed capacity.
(31) "Patient" means any person receiving diagnostic or medical services at a hospital.
(32) "Pharmacist" means as defined in G.S. 90-85.3.
(33) "Physical Rehabilitation Services" means any combination of physical therapy, occupational therapy, speech therapy, or vocational rehabilitation.
(34) "Physician" means a person who meets the criteria set forth in G.S.90-9.1 or G.S. 90-9.2.
(35) "Provisional license" means a hospital license recognizing less than full compliance with the licensure rules.
(36) "Qualified" means having complied with the specific conditions for employment or the performance of a function.
(37) "Reference" means to use in consultation to obtain information.
(38) "Special Care Unit" means a unit or area of a hospital that includes a critical care unit, an intermediate care unit, or a pediatric care unit.
(39) "Unit" means a designated area of the hospital for the delivery of patient care services.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of Statutory Authority Eff. July 13, 1995;
Eff. January 1, 1996;
Readopted Eff. April 1, 2020.

SECTION .3100 - PROCEDURE

10A NCAC 13B .3101 GENERAL REQUIREMENTS

(a) An application for licensure shall be submitted to the Division prior to a license being issued or patients admitted.

(b) An existing facility shall not sell, lease, or subdivide a portion of its bed capacity without the approval of the Division.

(c) Application forms may be obtained by contacting the Division.

(d) The Division shall be notified in writing 30 days prior to the occurrence of any of the following:

(1) addition or deletion of a licensable service;
(2) increase or decrease in bed capacity;
(3) change of chief executive officer;
(4) change of mailing address;
(5) ownership change; or
(6) name change.

(e) Each application shall contain the following information:

(1) legal identity of applicant;
(2) name or names used to present the hospital or services to the public;
(3) name of the chief executive officer;
(4) ownership disclosure;
(5) bed complement;
(6) bed utilization data;
(7) accreditation data;
(8) physical plant inspection data; and
(9) service data.

(f) A license shall include only facilities or premises within a single county.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended Eff. April 1, 2003;
Readopted Eff. April 1, 2020.

10A NCAC 13B .3102 PLAN APPROVAL

(a) For the purposes of this Rule, the Guidelines for the Design and Construction of Hospitals and Outpatient Facilities that is incorporated by reference in Rule .6105 of this Subchapter shall be referred to as the "FGI Guidelines."

(b) The definitions as set forth in Rule .6003 of this Subchapter shall apply to this Rule.

(c) The facility design and construction shall be in accordance with this Rule and the standards set forth in Sections .6000 through .6200 of this Subchapter.

(d) The site where the facility is located shall:

(1) be approved by the Construction Section prior to the construction of a new facility or the construction of an addition to an existing facility;

(2) be free from noise from railroads, freight yards, main traffic arteries, and schools and children's playgrounds; and

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

(e) Prior to the construction of a new facility or the construction of an addition or alteration to an existing facility, the governing body shall submit paper copies of the following to the Construction Section for review and approval:

(1) one set of schematic design drawings;

(2) one set of design development drawings; and

(3) one set of construction documents and specifications.

(f) If the North Carolina State Building Code Administrative Code and Policies requires the North Carolina Department of Insurance to review and approve the construction documents and specifications, the governing body shall submit a copy of the construction documents and specifications to the North Carolina Department of Insurance.

(g) The governing body shall submit a functional program that complies with Section 1.2-2 Functional Program of the FGI Guidelines with each submittal cited in Paragraph (e) of this Rule.

(h) The governing body shall:

(1) prepare any component of the safety risk assessment required by Section 1.2-3 Safety Risk Assessment of the FGI Guidelines; and

(2) submit any component of the safety risk assessment prepared to the Construction Section with each submittal cited in Paragraph (e) of this Rule.

(i) In order to maintain compliance with the standards established in this Rule and Sections .6000 through .6200 of this Subchapter, the governing body shall obtain written approval from the Construction Section for any changes made during the construction of the facility in the same manner as set forth in Paragraph (e) of this Rule.

(j) Two weeks prior to the anticipated construction completion date, the governing body shall notify the Construction Section of the anticipated construction completion date in writing either by U.S. Mail at the Division of Health Service Regulation, Construction Section, 2705 Mail Service Center, Raleigh, NC, 27699-2705 or by e-mail at DHSR.Construction.Admin@dhhs.nc.gov.

(k) Construction documents and building construction, including the operation of all building systems, shall be approved in writing by the Construction Section prior to licensure or patient occupancy.

(l) When the Construction Section approves the construction documents and specifications, they shall provide the governing body with an approval letter. The Construction Section's approval of the construction documents and specifications shall expire 12 months after the issuance of the approval letter, unless the governing body has obtained a building permit for construction. If the Construction Section's approval has expired, the governing body may obtain a renewed approval of the construction documents and specifications from the Construction Section as follows:

(1) If the standards established in this Rule and Sections .6000 through .6200 of this Subchapter have not changed, the governing body shall request a renewed approval of the construction documents and specifications from the Construction Section.

(2) If the standards established in this Rule and Sections .6000 through .6200 of this Subchapter have changed, the governing body shall:

(A) submit revised construction documents and specifications meeting the current standards established in this Rule and Sections .6000 through .6200 of this Subchapter to the Construction Section; and

(B) obtain written approval of the revised construction documents and specifications from the Construction Section.

(m) Bassinets in a Neonatal Level I nursery as specified in Rule .6228 of this Subchapter shall not be included in a facility's bed capacity; however, no more bassinets shall be placed in service than the number allowed by the

requirements set forth in Rule .6228 of this Subchapter. Beds in Neonatal Level II, III, and IV nurseries as specified in Rule .6228 of this Subchapter shall be included in a facility's bed capacity.

History Note: *Authority G.S. 131E-77; 131E-79;*
Eff. January 1, 1996;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, 2003;
Readopted Eff. April 1, 2019.

10A NCAC 13B .3103 CLASSIFICATION OF MEDICAL FACILITIES

(a) For purpose of this Subchapter the classification of "hospital" shall be restricted to facilities that provide as their functions diagnostic services and medical and nursing care in the treatment of acute stages of illness. On the basis of specialized facilities and services available, the Division shall license each such hospital according to the following medical types:

(1) general acute care hospital;
(2) rehabilitation hospital;
(3) critical access hospital; or
(4) long term acute care hospital which is a hospital which has been classified and certified as a long term care hospital pursuant to 42 CFR Part 412.

(b) All other inpatient medical facilities accepting patients requiring skilled nursing services but which are not operated as a part of any hospital within the above meaning shall be considered to be operating as a nursing home and, therefore, are not subject to licensure pursuant to this Subchapter.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended Eff. June 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3104 LENGTH OF LICENSE

Licenses shall remain in effect until one of the following occurs:

(1) Division imposes an administrative sanction which specifies license expiration;
(2) change of ownership;
(3) closure;
(4) change of site;
(5) failure to comply with Rule .3105 of this Section.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3105 STATISTICAL INFORMATION

Utilization data shall be submitted annually upon request by the Division. Forms for collection of this data will be forward to each facility by the Division.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3106 LICENSURE SURVEYS

(a) Prior to the initial issuance of a license to operate a facility, the Division shall conduct a survey to determine compliance with rules promulgated pursuant to G.S. 131E-79.

(b) The Division may conduct an investigation of a complaint in any facility.

(c) Facilities that are accredited through an accrediting body approved pursuant to section 1865(a) of the Social Security Act shall not be subject to routine inspections.

(d) The Division shall survey non-accredited facilities at least once every three years.

History Note: *Authority G.S. 131E-79; 131E-80;*
Eff. January 1, 1996;
Amended Eff. October 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3108 SUSPENSION OF ADMISSIONS

(a) The Department may amend a license, pursuant to G.S. 131E-78, by suspending the admission of any new patients to any facility when the conditions in the facility are detrimental to the health or safety of the patients in the facility.

(b) The Department shall notify the facility by registered or certified mail or by personal service of the decision to suspend admissions. Such notice will include:

(1) the period of the suspension;
(2) factual allegations;
(3) citation of statutes and rules alleged to be violated; and
(4) notice of the facility's right to a contested case hearing.

(c) The suspension shall be effective when the notice is served or on the date specified in the notice of suspension, whichever is later. The suspension shall remain effective for the period specified in the notice or until the facility demonstrates to the Department that conditions are no longer detrimental to the health and safety of the patient.

(d) The facility shall not admit new patients during the effective period of the suspension.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3107 DENIAL, AMENDMENT OR REVOCATION OF LICENSE

(a) The Department may deny any licensure application upon becoming aware that the applicant is not in compliance with any applicable provision of the Certificate of Need law located in G.S. 131E, Article 9 and the rules adopted under that law.

(b) The Department may amend a license by reducing it from a full license to a provisional license whenever the Department finds that:

(1) the licensee has failed to comply with the provisions of G.S. 131E, Article 5 and the rules promulgated under that article;

(2) there is a probability that the licensee can remedy the licensure deficiencies within a length of time not to exceed the expiration date on the license; and

(3) there is a probability that the licensee will be able thereafter to remain in compliance with the hospital licensure rules for the foreseeable future.

(c) The Department shall also amend a license to provisional status by specifically prohibiting a licensee from providing certain services, for which it has been found to be out of compliance with G.S. 131E, Articles 5 or 9. In all cases the Department shall give the licensee written notice of the amendment of the license. This notice shall be given by registered or certified mail or by personal service and shall set forth:

(1) the length of the provisional license;

(2) the factual allegations;

(3) the statutes and rules alleged to be violated; and

(4) notice of the facility's right to a contested case hearing on the amendment of the license.

(d) The provisional license shall be effective immediately upon its receipt by the licensee and shall be posted in a prominent location, accessible to public view, within the licensed premises in lieu of the full license. The provisional license shall remain in effect until:

(1) the Department restores the licensee to full licensure status;

(2) the Department revokes the licensee's license; or

(3) the end of the licensee's licensure period. If a licensee has a provisional license at the time that the licensee submits a renewal application, the license, if renewed, shall also be a provisional license unless the Department determines that the licensee can be returned to full licensure status. A decision to issue a provisional license is stayed during the pendency of an administrative appeal and the licensee may continue to display its full license during the appeal.

(e) The Department shall revoke a license whenever:

(1) The Department finds that:

(A) the licensee has failed to comply with the provisions of G.S. 131E, Article 5 and the rules promulgated under that article; and

(B) it is not probable that the licensee can remedy the licensure deficiencies within a length of time acceptable to the Department; or

(2) The Department finds that:

(A) The licensee has failed to comply with the provisions of G.S. 131E, Article 5; and

(B) although the licensee may be able to remedy the deficiencies within a reasonable time, it is not probable that the licensee will be able to remain in compliance with hospital licensure rules for the foreseeable future; or

(3) The Department finds that the licensee has failed to comply with any of the provisions of G.S. 131E, Article 5 and the rules promulgated thereunder that endangers the health, safety or welfare of the patients in the facility.

The issuance of a provisional license is not a procedural prerequisite to the revocation of a license pursuant to Subparagraphs (e)(1), (2) or (3) of this Rule.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3109 PROCEDURE FOR APPEAL

A facility may appeal any decision of the Department to deny, revoke or amend a license or any decision to suspend admissions by making such an appeal in accordance with G.S. 150B.

History Note: *Authority G.S. 131E-78; 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3110 ITEMIZED CHARGES

(a) The facility shall provide an itemized list of charges to discharged patients or the facility shall include on patients' bills that are not itemized, notification of the right to request an itemized bill within three years of receipt of the non-itemized bill or so long as the hospital, a collections agency, or other assignee asserts the patient has an obligation to pay the bill.

(b) If requested, the facility shall provide an itemized list of charges to the patient or the patient's representative. This list shall detail in language comprehensible to an ordinary layperson the specific nature of the charges or expenses incurred by the patient.

(c) The itemized listing shall include each specific chargeable item or service in the following service areas:

(1) room rate;
(2) laboratory;
(3) radiology and nuclear medicine;
(4) surgery;
(5) anesthesiology;
(6) pharmacy;
(7) emergency services;
(8) outpatient services;
(9) specialized care;
(10) extended care;
(11) prosthetic and orthopedic appliances; and
(12) professional services provided by the facility.

History Note: *Authority G.S. 131E-79; 131E-91;*
Eff. January 1, 1996;
Temporary Amendment Eff. May 1, 2014;
Amended Eff. November 1, 2014;
Readopted Eff. April 1, 2020.

10A NCAC 13B .3111 TEMPORARY CHANGE IN BED CAPACITY

(a) A hospital may temporarily increase its bed capacity by up to 10 percent over its licensed bed capacity, as determined by the administrator, by utilizing observational beds for inpatients for a period of no more than 60 consecutive days following approval by the Division of Health Service Regulation.

(b) To qualify for a temporary change in licensed capacity, the hospital census shall be at least 90 percent of its licensed bed capacity, excluding beds that are under renovation or construction, and the hospital must demonstrate conditions requiring the temporary increase that may include but are not limited to the following:

(1) natural disaster;
(2) catastrophic event; or
(3) disease epidemic.

(c) The Division may approve a temporary increase in licensed beds only if:

(1) It is determined that the request has met the requirements of Paragraphs (a) and (b) of this Rule; and
(2) The hospital administrator certifies that the physical facilities to be used are adequate to safeguard the health and safety of patients. However this approval shall be revoked if the Division determines, as a result of a physical site visit, that these safeguards are not adequate to safeguard the health and safety of patients.

History Note: *Authority G.S. 131E-79;*
Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .3200 - GENERAL HOSPITAL REQUIREMENTS

10A NCAC 13B .3201 HOSPITAL REQUIREMENTS

A facility shall have all of the following:

(1) an organized governing body;
(2) a chief executive officer;
(3) an organized medical staff;
(4) an organized nursing staff;
(5) continuous medical services;
(6) continuous nursing services;
(7) permanent on-site facilities for the care of patients 24 hours a day;
(8) a hospital-wide infection control program;
(9) minimum on-site clinical provisions as follows:
    (a) appropriately equipped inpatient care areas;
    (b) nursing care units;
    (c) diagnostic and treatment areas to include on-site laboratory and imaging facilities with the capacity to provide immediate response to patient emergencies;
    (d) pharmaceutical services in compliance with the Pharmacy Laws of North Carolina;
    (e) facilities to assure the sterilization of equipment and supplies;
    (f) medical records services;
    (g) provision for social work services;
    (h) current reference sources to meet staff needs; and
    (i) nutrition services.
(10) minimum supportive capabilities or facilities as follows:
    (a) nutrition and dietetic services;
    (b) scheduled general and preventive maintenance services for building, services and biomedical equipment;
    (c) capability for obtaining police and fire protection, emergency transportation, grounds-keeping, and snow removal;
    (d) personnel recruitment, training and continuing education;
    (e) business management capability;
    (f) short and long-range planning capability;
    (g) financial plan to provide continuity of operation under both normal and emergency conditions;
    (h) provision for patient, employee, and visitor safety; and
    (i) policies for preventive and corrective maintenance including procedures to be followed in the event of a breakdown of essential equipment.
(11) facilities must comply with construction rules in Sections .6000 - .6200 of this Subchapter.
(12) a risk management program as follows:
    (a) a specific staff member shall be assigned responsibility for development and administration of the program;
    (b) a written policy statement evidencing a current commitment to the risk management program together with written procedures, policies and educational programs applicable to a risk management program which are reviewed at least every three years and updated as necessary;
    (c) established lines of communication between the risk management program and other functions relating to quality of patient care, safety, and professional staff performance; and
    (d) a written report of the activities of the risk management program shall be annually submitted to the governing body.
(13) a quality assessment and improvement program which provides:
    (a) continuous assessment and evaluation of patient care and related services in all services and departments;
    (b) a designated individual to coordinate the quality assessment and improvement program who will assist in the establishment of quality assessment and improvement plans and reporting methods for each service and department;

(c) a committee made up of representatives of the medical and nursing staff, administration, and other services or departments as defined by the hospital to coordinate the program, meet at least quarterly and maintain minutes of the meetings and committee activities; and

(d) for each service and department as defined by the hospital to be involved in the continuous assessment, monitoring and evaluation of patient care and related services.

History Note: *Authority G.S. 131E-75; 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3202 ADMISSION AND DISCHARGE

(a) The facility shall provide written admission and discharge, and referral policies.

(b) There shall be on the premises at all times an employee authorized to receive patients and to make arrangements for their disposition.

(c) A patient shall be admitted only under the care of a member of the medical staff meeting the provisions of Section .3700 of this Subchapter.

(d) The facility shall take appropriate precautions to protect the safety and legal rights of patients and employees.

(e) The facility shall maintain a complete and permanent record of all outpatients and inpatients including the date and time of admission and discharge. Effort shall be made to verify the full and true name, address, date of birth, nearest of kin, provisional diagnosis, condition on admission and discharge, referring physicians, attending physician or service.

(f) Facility staff shall provide at the time of admission an identification bracelet, band, or other suitable device for positive identification of each patient.

(g) No mentally competent adult shall be detained by the facility against his will, except as authorized by law.

History Note: *Authority G.S. 131E-75; 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3203 DISCHARGE PLANNING

(a) Discharge planning shall be an integral part of in-patient hospitalization.

(b) The facility shall have written policies and procedures governing discharge planning. These shall include but need not be limited to the following:

(1) appropriate screening to determine the need for discharge planning;

(2) methods to facilitate the provision of follow-up care;

(3) information to be given to the patient or his family or other persons involved in caring for the patient on matters such as the patient's condition; his health care needs; the amount of activity he should engage in; any necessary medical regimens including drugs, nutrition therapy, appointments or other forms of therapy; sources of additional help from other agencies; and procedures to follow in case of complications; and

(4) procedures for assisting the patient and his family in gaining information regarding financial assistance in paying bills incurred as a result of the hospitalization, including how to receive assistance from the various federal and State government programs.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3204 TRANSFER AGREEMENT

(a) Any facility that does not provide hospital based nursing facility service shall maintain written agreements with institutions offering this kind of care. Such agreements shall provide for the transfer and admission of patients who no longer require the services of the hospital but do require nursing facility services.

(b) A patient shall not be transferred to another medical care facility unless prior arrangements for admission have been made. Clinical records to provide continuity of care shall accompany the patient.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. April 1, 2020.

10A NCAC 13B .3205 DISCHARGE OF MINOR OR INCOMPETENT

Individuals who cannot legally consent to his or her own care shall be discharged to the custody of parents, legal guardian, person standing in loco parentis, or patient representative pursuant to 42 CFR 483.12(a)(1) herein incorporated by reference with subsequent amendments and editions, unless otherwise directed by the parent or guardian, or court of competent jurisdiction. This regulation may be accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals at no cost. If the parent or guardian directs that discharge be made otherwise, he or she shall so state in writing, and the statement shall become a part of the permanent medical record of the patient.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. April 1, 2020.

SECTION .3300 - PATIENT'S BILL OF RIGHTS

10A NCAC 13B .3301 PRINCIPLE

It is the purpose of these requirements to promote the interests and well-being of the patients in facilities subject to this Subchapter even in those instances where the interests of the patients may be in opposition to the interests of the facility. The facility has the right to expect the patient to fulfill patient responsibilities as may be stated in the facilities' policies affecting patient care and conduct.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3302 MINIMUM PROVISIONS OF PATIENT'S BILL OF RIGHTS

This Rule does not apply to patients in licensed nursing facility beds since these individuals are granted rights pursuant to G.S. 131E-117. A patient in a hospital facility subject to this Rule has the following rights pursuant to 42 CFR 482.13, which is hereby incorporated by reference including subsequent amendments and editions. This regulation can be accessed at https://www.ecfr.gov/cgi-bin/text-idx?SID=e867c7c6cbfeb689406afea7d88e8a80&mc=true&node=pt42.5.482&rgn=div5#se42.5.482_113 at no cost:

(1) A patient has the right to respect, dignity, and comfort.

(2) A patient has the right, upon request, to be given the name of his or her attending physician, the names of all other physicians participating in his or her care, and the names and functions of other health care persons having contact with the patient.

(3) A patient has the right to privacy concerning his or her own medical care program. Case discussion, consultation, examination, and treatment are considered confidential and shall be conducted privately pursuant to 42 CFR 482.13(c)(1):

(4) A patient has the right to know what facility rules and regulations apply to his or her conduct as a patient.

(5) A patient has the right to expect emergency procedures to be implemented without delay.

(6) A patient has the right to quality care and professional standards that are maintained and reviewed.

(7) A patient has the right to information in laymen's terms, concerning his or her diagnosis, treatment and prognosis, including information about alternative treatments and possible complications. When it is not possible or medically advisable to give such information to the patient, the information shall be given on his or her behalf to the patient's designee.

(8) Except for emergencies, a physician must obtain informed consent prior to the start of any procedure or treatment.

(9) A patient has the right to be advised when a physician is considering the patient as a part of a medical care research program or donor program. Informed consent shall be obtained prior to participation in such a program. The patient or legally responsible party may refuse to continue in any program that he or she has previously given informed consent. An Institutional Review Board (IRB) may waive or alter the informed consent requirement if it reviews and approves a research study in accordance with federal regulations for the protection of human research subjects including U.S. Department of Health and Human Services (HHS) regulations under 45 CFR Part 46 and U.S. Food and Drug Administration (FDA) regulations under 21 CFR Parts 50 and 56. 45 CFR Part 46 and 21 CFR Parts 50 and 56 are incorporated by reference, including subsequent amendments and editions. These regulations may be accessed at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html at no cost. For any research study proposed for conduct under an FDA "Exception from Informed Consent Requirements for Emergency Research" or an HHS "Emergency Research Consent Waiver" that waives informed consent but community consultation and public disclosure about the research are required, any facility proposing to be engaged in the research study shall also verify that the proposed research study has been registered with the North Carolina Medical Care Commission. When the IRB has authorized the start of the community consultation process required for emergency research, but before the beginning of that process, notice of the proposed research study shall be provided to the North Carolina Medical Care Commission. The notice shall include:

(a) the title of the research study;

(b) a description of the research study, including a description of the population to be enrolled;

(c) a description of the planned community consultation process, including proposed meeting dates and times;

(d) instructions for opting out of the research study; and

(e) contact information including mailing address and phone number for the IRB and the principal investigator.

The Medical Care Commission may publish all or part of the above information in the North Carolina Register, in accordance with 26 NCAC 02C .0307, and may require the institution proposing to conduct the research study to attend a public meeting convened by a Medical Care Commission member in the community where the proposed research study is to take place to present and discuss the study or the community consultation process proposed.

(10) A patient has the right to refuse any drugs, treatment or procedure offered by the facility, and a physician shall inform the patient of his or her right to refuse any drugs, treatment or procedures and of the medical consequences of the patient's refusal of any drugs, treatment or procedure.

(11) A patient has the right to assistance in obtaining consultation with another physician at the patient's request and expense.

(12) A patient has the right to medical and nursing services without discrimination based upon race, color, religion, sex, sexual orientation, gender identity, national origin or source of payment.

(13) A patient who does not speak English shall have access to an interpreter.

(14) A patient or his or her designee has the right to have all records pertaining to his or her medical care treated as confidential except as otherwise provided by law or third party contractual arrangements. A patient's access to medical records may be restricted by the patient's attending physician. If the physician restricts the patient's access to information in the patient's medical record, the physician shall record the reasons on the patient's medical record. Access shall be restricted only for medical reason. A patient's designee shall have access to the information in the patient's medical records even if the attending physician restricts the patient's access to those records.

(15) A patient has the right not to be awakened by hospital staff unless it is medically necessary.

(16) The patient has the right to be free from duplication of medical and nursing procedures as determined by the attending physician.

(17) The patient has the right to medical and nursing treatment that avoids unnecessary physical and mental discomfort.

(18) When medically permissible, a patient may be transferred to another facility only after he or his next of kin or other legally responsible representative has received complete information and an explanation concerning the needs for and alternatives to such a transfer. The facility that the patient is to be transferred must first have accepted the patient for transfer.

(19) The patient has the right to examine and receive a detailed explanation of his bill.

(20) The patient has a right to information and counseling on the availability of known financial resources for his health care.

(21) A patient has the right to be informed upon discharge of his or her continuing health care requirements following discharge and the means for meeting them.

(22) A patient shall not be denied the right of access to an individual or agency who is authorized to act on his or her behalf to assert or protect the rights set out in this Section.

(23) A patient has the right to be informed of his rights at the earliest possible time in the course of his or her hospitalization.

(24) A patient has the right to designate visitors who shall receive the same visitation privileges as the patient's immediate family members, regardless of whether the visitors are legally related to the patient.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
RRC Objection due to ambiguity Eff. July 13, 1995;
Eff. January 1, 1996;
Temporary Amendment Eff. April 1, 2005;
Amended Eff. January 1, 2011; May 1, 2008; November 1, 2005;
Readopted Eff. April 1, 2020.

10A NCAC 13B .3303 PROCEDURE

(a) The facility shall develop and implement procedures to inform patients of his or her rights. Copies of the facilities' Patient's Bill of Rights shall be made available through one of the following ways:

(1) locations posted in a public place in the facility in addition to copies available upon request; or

(2) provided a copy to each patient or responsible party upon admission or as soon after admission as is feasible.

(b) The address and telephone number of the Acute and Home Care Licensure and Certification Section in the Department responsible for the enforcement of the provisions of this Rule shall be posted.

(c) The facility shall adopt procedures to ensure a comprehensive investigation of violations of patients' rights and to ensure their enforcement pursuant to 42 CFR 483.12(a)(2) herein incorporated by reference including subsequent amendments and editions. This regulation may be accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals at no cost. These procedures shall ensure that:

(1) a system is established to identify formal written complaints;

(2) written complaints are recorded and investigated;

(3) investigation and resolution of complaints shall be conducted; and

(4) disciplinary and education procedures shall be developed for members of the hospital and medical staff who are noncompliant with facility policies.

(d) The Division shall investigate or refer to other State agencies all complaints within the jurisdiction of the rules in this Subchapter.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. April 1, 2020.

SECTION .3400 - SUPPLEMENTAL RULES FOR THE LICENSURE OF CRITICAL ACCESS HOSPITALS

10A NCAC 13B .3401 SUPPLEMENTAL RULES

The rules of this Section pertain only to designated Critical Access Hospitals in accordance with 42 CFR 485 Subpart F. The general requirements of this Subchapter shall apply to such facilities except where they are specifically waived or modified by the rules of this Section.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended Eff. November 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3402 DEFINITIONS

The following definitions shall apply throughout this Section, unless context otherwise clearly indicates to the contrary:

(1) "Available" means provided directly by the facility or by written agreement with a qualified provider of the service within one hour driving time.

(2) "Critical Access Hospital" means a facility designated by the North Carolina Office of Rural Health in accordance with 42 CFR 485 Subpart F.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended Eff. November 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

10A NCAC 13B .3405 DESIGNATED CRITICAL ACCESS HOSPITALS

The requirements of 10A NCAC 13B shall apply to Critical Access Hospitals with the following modifications:

(1) Autopsy facilities required in Rule .4907 of this Subchapter are not required provided that the facility has in effect a written agreement with another facility meeting Rule .4907 of this Subchapter for providing autopsy services.

(2) Radiological services required in Section .4800 and Rule .6210 of this Subchapter are not required provided that the facility has a written agreement with another licensed facility meeting the requirements of Section .4800 and Rule .6210 of this Subchapter which makes radiological service available.

(3) Emergency services required in Rules .4102-.4110 of this Subchapter are not required. Emergency response capability set forth in Rule .4101 of this Subchapter shall be provided. Medical staff shall require that facility personnel are capable of initiating life-saving measures at a first-aid level of response for any patient or person in need of such services. This shall include:
   (a) Establishing protocols or agreements with any facility providing emergency services;
   (b) Initiating basic cardio-pulmonary resuscitation according to the American Red Cross or American Heart Association standards;
   (c) Availability of intravenous fluids and supplies required to establish intravenous access; and
   (d) Availability of first-line emergency drugs as specified by the medical staff.

(4) Anesthesia services required in Section .4600 of this Subchapter are not required in hospitals not offering outpatient surgery services.

(5) Food services required in Section .4700 of this Subchapter shall be provided for inpatients directly or made available through contractual arrangements.

(6) "Observation bed" as defined in Rule .3001(32) of this Subchapter does not apply. For purposes of this Section, "Observation bed" means a bed used for no more than 48-hours, to evaluate and determine the condition and disposition of a patient and is not considered a part of the hospital's licensed bed capacity.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended Eff. November 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .3500 - GOVERNANCE AND MANAGEMENT

10A NCAC 13B .3501 GOVERNING BODY

(a) The governing body, owner, or the person or persons designated by the owner as the governing body shall be responsible for ensuring that the objectives specified in the facility's governing documents, such as the charter or resolution, are attained.

(b) The governing body shall be the final authority for decisions for which the facility administration, the medical staff, and the facility personnel are directly or indirectly responsible within the facility.

(c) A local advisory board shall be established to provide non-binding advice to the governing body regarding the health, safety, and welfare of the community, if the facility is owned by an organization or persons outside of North Carolina. A local advisory board shall include members from the county where the facility is located.

History Note: *Authority G.S. 131E-75; 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. July 1, 2020.

10A NCAC 13B .3502 REQUIRED FACILITY BYLAWS, POLICIES, RULES, AND REGULATIONS

(a) The governing body shall adopt written bylaws, policies, rules, and regulations in accordance with all requirements contained in this Subchapter and in accordance with the community responsibility of the facility. The written bylaws, policies, rules, and regulations shall:

(1) state the objectives;
(2) describe the powers and duties of the governing body officers and committees and the responsibilities of the chief executive officer;
(3) state the qualifications for governing body membership, the procedures for selecting members, and the terms of service for members, officers and committee chairmen;
(4) describe the authority delegated to the chief executive officer and to the medical staff. No assignment, referral, or delegation of authority by the governing body shall relieve the governing body of its responsibility for the conduct of the facility. The governing body shall retain the right to rescind any such delegation;
(5) require governing body approval of the bylaws of any auxiliary organizations established by the facility;
(6) require the governing body to review and approve the bylaws of the medical staff;
(7) establish procedures for processing and evaluating the applications for medical staff membership and for the granting of clinical privileges;
(8) establish a procedure for implementing, disseminating, and enforcing a Patient's Bill of Rights as set forth in Rule .3302 of this Subchapter and in compliance with G.S. 131E-117; and
(9) require the governing body to institute procedures to provide for:
    (A) orientation of newly elected governing body members to board functions and procedures;
    (B) the development of procedures for periodic reexamination of the relationship of the governing body to the total facility community; and
    (C) the recording of minutes of all governing body and executive committee meetings and the dissemination of those minutes, or summaries thereof, after the governing body and executive committee meetings to all members of the governing body.

(b) The governing body shall provide written policies and procedures to assure billing and collection practices in accordance with G.S. 131E-91. These policies and procedures shall include:

(1) a financial assistance policy as defined in G.S. 131E-214.14(b)(3);
(2) how a patient may obtain an estimate of the charges for the statewide 100 most frequently reported Diagnostic Related Groups (DRGs), where applicable, 20 most common outpatient imaging procedures, and 20 most common outpatient surgical procedures. The policy shall require that the information be provided to the patient in writing, either electronically or by mail, within three business days;
(3) how a patient or patient's representative may dispute a bill;
(4) issuance of a refund within 45 days of the patient receiving notice of the overpayment when a patient has overpaid the amount due to the facility;
(5) providing written notification to the patient or patient's representative at least 30 days prior to submitting a delinquent bill to a collections agency;
(6) providing the patient or patient's representative with the facility's charity care and financial assistance policies, if the facility is required to file a Schedule H, federal form 990;
(7) the requirement that a collections agency, entity, or other assignee obtain written consent from the facility prior to initiating litigation against the patient or patient's representative;
(8) a policy for handling debts arising from the provision of care by the facility involving the doctrine of necessaries, in accordance with G.S. 131E-91(d)(5); and
(9) a policy for handling debts arising from the provision of care by the facility to a minor, in accordance with G.S. 131E-91(d)(6).

(c) The governing body shall ensure that the bylaws, rules, and regulations of the medical staff and the bylaws, rules, policies, and regulations of the facility shall not be in conflict.

(d) The written policies, rules, and regulations shall be reviewed every three years, revised as necessary, and dated to indicate when last reviewed or revised.

(e) To qualify for licensure or license renewal, each facility must provide to the Division, upon application, an attestation statement in a form provided by the Division verifying compliance with the requirements of this Rule.

(f) On an annual basis, on the license renewal application provided by the Division, the facility shall provide to the Division the direct website address to the facility's financial assistance policy. This Paragraph applies only to facilities required to file a Schedule H, federal form 990.

History Note: *Authority G.S. 131E-79; 131E-91; 131E-214.8; 131E-214.13(f); 131E-214.14;*
Eff. January 1, 1996;
Temporary Amendment Eff. May 1, 2014;
Amended Eff. November 1, 2014;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3503 FUNCTIONS

(a) The governing body shall:

(1) provide management, physical resources, and personnel determined by the governing body to be required to meet the needs of patients for treatment as authorized by the facility's license;

(2) require facility administration to establish a quality control mechanism that includes a risk management component and an infection control program;

(3) formulate short-range and long-range plans as defined in the facility bylaws, policies, rules, and regulations;

(4) conform to all applicable State and federal laws, rules, and regulations, and applicable local ordinances;

(5) provide for the control and use of the physical and financial resources of the facility;

(6) review the annual audit, budget, and periodic reports of the financial operations of the facility;

(7) consider the recommendation of the medical staff in granting and defining the scope of clinical privileges to individuals in accordance with medical staff bylaws requirements for making such recommendations and the facility bylaws established by the governing body for the review and final determination of such recommendations;

(8) require that applicants be informed of the disposition of their application for medical staff membership or clinical privileges in accordance with the facility bylaws established by the governing body, after an application has been submitted;

(9) review and approve the medical staff bylaws, rules, and regulations;

(10) delegate to the medical staff the authority to:

(A) evaluate the professional competence of medical staff members and applicants for medical staff membership and clinical privileges; and

(B) recommend to the governing body initial medical staff appointments, reappointments, and assignments or curtailments of privileges;

(11) require that resources be made available to address the emotional and spiritual needs of patients either directly or through referral or arrangement with community agencies;

(12) maintain communication with the medical staff which may be established through:

(A) meetings with the executive committee of the medical staff;

(B) service by the president of the medical staff as a member of the governing body with or without a vote;

(C) appointment of individual medical staff members to the medical review committee; or

(D) a joint conference committee that will be a committee of the governing body and the medical staff composed of equal representatives of each of the governing body, the chairman of the board or designee, the medical staff, and the chief of the medical staff or designee, respectively;

(13) require the medical staff to establish controls that are designed to provide that standards of ethical professional practices are met;

(14) provide administrative staff support to facilitate utilization review and infection control within the facility, to support quality control and any other medical staff functions required by this Subchapter or by the facility bylaws;

(15) meet the following disclosure requirements:

(A) provide data required by the Division;

(B) disclose the facility's average daily inpatient charge upon request of the Division; and

(C) disclose the identity of persons owning five percent or more of the facility as well as the facility's officers and members of the governing body upon request;

(16) establish a procedure for reporting the occurrence and disposition of allegations of abuse or neglect of patients and incidents involving quality of care or physical environment at the facility. These procedures shall require that:

(A) incident reports are analyzed and summarized by a designated party; and

(B) corrective action is taken based upon the analysis of incident reports;

(17) in a facility with one or more units, or portions of units, however described, utilized for psychiatric or substance abuse treatment, adopt policies implementing the provisions of G.S. 122C, Article 3, and Article 5, Parts, 2, 3, 4, 5, 7, and 8;

(18) develop arrangements for the provision of extended care and other long-term healthcare services. Such services shall be provided in the facility or by outside resources through a transfer agreement or referrals;

(19) provide and implement a written plan for the care or for the referral, or both, of patients who require mental health or substance abuse services while in the facility;

(20) develop a conflict of interest policy which shall apply to all governing body members and facility administration. All governing body members shall execute a conflict of interest statement; and

(21) conduct direct consultations with the medical staff at least twice during the year.

(b) For the purposes of this Rule, "direct consultations" means the governing body, or a subcommittee of the governing body, meets with the leader(s) of the medical staff(s), or his or her designee(s) either face-to-face or via a telecommunications system permitting immediate, synchronous communication.

(c) The direct consultations shall consist of discussions of matters related to the quality of medical care provided to the hospital's patients, including quality matters arising out of the following:

(1) the scope and complexity of services offered by the facility;

(2) specific clinical populations served by the facility;

(3) limitations on medical staff membership other than peer review or corrective action in individual cases;

(4) circumstances relating to medical staff access to a facility resource; or

(5) any issues of patient safety and quality of care that a hospital's quality assessment and performance improvement program might identify as needing the attention of the governing body in consultation with the medical staff.

(d) For the purposes of this Rule, "specific clinical populations" includes those individuals who may be treated at the facility by the medical staff in place at the time of the consultation.

History Note: *Authority G.S. 131E-14.2; 131E-79; 42 CFR 482.12; 42 CFR 482.22;*
Eff. January 1, 1996;
Readopted Eff. July 1, 2020.

SECTION .3600 - MANAGEMENT AND ADMINISTRATION OF OPERATIONS

10A NCAC 13B .3601 CHIEF EXECUTIVE OFFICER

(a) The governing body shall designate a chief executive officer whose qualifications, authority, responsibilities and duties shall be defined in a written statement adopted by the governing body.

(b) The chief executive officer shall be the designated representative of the governing body and may be given any one or more or all of the responsibilities set out in Rule .3602 of this Section.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3602 RESPONSIBILITIES

The governing body shall adopt written policies, rules, and regulations that specify the officer or officers that shall:

(1) act for the chief executive officer in his absence;
(2) manage the facility consonant with its expressed aims and policies;
(3) attend meetings of the governing body and appropriate meetings of the medical staff;
(4) implement policies adopted by the governing body for the operation of the facility;
(5) organize the administrative functions of the facility, delegate duties and establish formal means of accountability on the part of subordinates;
(6) establish such facility departments as are indicated, provide for departmental and interdepartmental meetings and attend or be represented at such meetings, and appoint hospital departmental representatives to medical staff committees where appropriate or when requested to do so by the medical staff;
(7) appoint the heads of administrative departments;
(8) report to the governing body and to the medical staff on the overall activities of the facility as well as on appropriate federal, State and local developments that affect health care in the facility;
(9) review the annual audit of the financial operations of the facility and acting upon recommendations therein;
(10) provide fiscal planning and financial management of the facility including the provision of annual budgets and periodic financial status reports to the governing board;
(11) develop in cooperation with the departmental heads and other appropriate staff, an overall organizational plan for the facility which will coordinate the functions, services and departments of the facility, when possible; and
(12) require that the agreements with service providers, such as laundry, laboratory and imaging, specifically indicate that compliance will be maintained with applicable State rules as would apply to the same services if provided directly by the facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3603 PERSONNEL POLICIES AND PRACTICES

The facility shall develop, establish and maintain personnel policies and practices which support sound patient care. The policies shall be in writing and made available to all employees, and they shall be reviewed periodically but no less often than once every three years. The date of the most recent review shall be indicated on the written policies. A procedure shall be established for notifying employees of changes in the established personnel policies.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3604 JOB DESCRIPTIONS

The facility shall develop and make available to the employee a written job description for each type of job in the facility, including the chief executive officer and heads of departments. Each job description shall include a written description of the education, experience, license, certification, or other qualifications required for the position.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3605 PERSONNEL RECORDS

(a) The facility shall maintain accurate and complete personnel records for each facility employee during the term of employment and for two years thereafter. The chief executive officer may designate an individual to carry out this assignment.

(b) Personnel records shall be maintained under such conditions as may be required by state or federal law and shall contain at least the following:

(1) information regarding the employee's education, training and experience and clinical competence, including, if applicable, professional licensure status and license number, sufficient to verify the employee's qualifications for the job for which he is employed. Such information shall be kept current. Applicants for positions requiring a licensed person shall be hired only after obtaining verification of their licenses from the appropriate board;

(2) current information relative to periodic work performance evaluations;

(3) records of such pre-employment health examinations and of subsequent health services rendered to the employees as are necessary to determine that all facility employees are physically able to perform the essential duties of their positions.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3606 EDUCATION PROGRAMS

The facility shall provide new employee orientation and continuing education programs for all employees to maintain the skills necessary for the performance of their duties and learn new developments in health care. Records shall be maintained of all orientation and educational programs, and of the participants.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3607 PERSONNEL HEALTH REQUIREMENTS

Employees shall have pre-employment medical examinations and interim examinations in accordance with medical criteria established by the facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3608 INSURANCE

The governing board shall have in place an insurance program which provides for the protection of the physical and financial resources of the facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3609 AUDIT OF FINANCIAL OPERATIONS

An audit of the financial operations of the facility shall be performed by a public accountant at least once a year.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .3700 - MEDICAL STAFF

10A NCAC 13B .3701 GENERAL PROVISIONS

(a) The facility shall have a self-governed medical staff that shall be accountable to the governing body for the quality of care provided by individuals with medical staff membership and clinical privileges to provide medical services in the facility. Facility policy shall provide that individuals with clinical privileges shall perform only services within the scope of individual privileges granted.

(b) Minutes required by the rules of this Section shall reflect all transactions, conclusions, and recommendations of meetings. Minutes shall be prepared and retained in accordance with a policy established by the facility and medical staff, and available for inspection by members of the medical staff and governing body, respectively, unless such minutes include confidential peer review information that is not accessible to others in accordance with any law protecting the confidentiality.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3703 APPOINTMENT

(a) The governing body may grant, deny, renew, modify, suspend, or terminate medical staff membership and clinical privileges after consideration of the recommendation made by the medical staff in accordance with the bylaws established by the medical staff and approved by the governing body for making such recommendations, and the facility bylaws established by the governing body for review and final determination of such recommendations.

(b) Review of an applicant for medical staff membership and the granting of clinical privileges shall follow procedures set forth in the bylaws, rules, and regulations of the medical staff. These procedures shall require the following:

(1) a signed application for medical staff membership, specifying date of birth, year and school of graduation, date of licensure, statement of postgraduate or special training and experience, and a statement of the scope of the clinical privileges sought by the applicant;

(2) verification by the facility of the applicant's qualifications as stated in the application, including any required continuing education; and

(3) written notice to the applicant from the governing body regarding appointment or reappointment, which specifies the approval or denial of clinical privileges and the scope of the privileges if granted.

(c) Members of the medical staff and others granted clinical privileges in the facility shall hold current licenses to practice in North Carolina.

(d) Medical staff appointments shall be reviewed at least once every two years by the medical staff in accordance with the bylaws established by the medical staff and approved by the governing body, and shall be followed with recommendations made to the governing body for review and a final determination.

(e) The facility shall maintain a file containing performance information for each medical staff member. Representatives of the Division shall have access to these files in accordance with, and subject to the limitations and restrictions set forth in, G.S. 131E-80; however, to the extent that the same includes confidential medical review information, such information shall be reviewable and confidential in accordance with G.S. 131E-80(d) and other applicable law.

(f) Minutes shall be taken and maintained of all meetings of the medical staff and governing body that concern the granting, denying, renewing, modifying, suspending or terminating of clinical privileges.

History Note: *Authority G.S. 131E-79; 42 CFR 482.12(a)(10); 42 CFR 482.22(a)(1);*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. July 1, 2020.

10A NCAC 13B .3704 ESTABLISHMENT AND CATEGORIES OF MEDICAL STAFF MEMBERSHIP

(a) The medical staff shall be established in accordance with the bylaws of the facility and organized in accordance with the bylaws, rules, and regulations of the medical staff. After considering the recommendations of the medical staff, the governing body of the facility may, in accordance with G.S. 131E-85, grant medical staff membership and clinical privileges to qualified, licensed practitioners in accordance with their training, experience, and demonstrated competence and judgment in accordance with the medical staff bylaws, rules, and regulations.

(b) Every facility shall have an active medical staff, as defined by the medical staff bylaws, rules, and regulations, to deliver medical services within the facility and to administer medical staff functions. The members of the active medical staff shall be eligible to vote at medical staff meetings and to hold medical staff office positions as determined by the medical staff bylaws, rules, and regulations and shall be responsible for recommendations made to the governing body regarding the organization and administration of the medical staff. Medical staff office positions shall be determined in the medical staff bylaws, rules, and regulations.

(c) The active medical staff may establish other categories for membership in the medical staff. These categories for membership shall be identified and defined in the medical staff bylaws. Examples of membership categories include:

(1) active medical staff;
(2) associate medical staff;
(3) courtesy medical staff;
(4) temporary medical staff;
(5) consulting medical staff;
(6) honorary medical staff; or
(7) other staff classifications.

The medical staff bylaws shall describe the authority, duties, privileges, and voting rights for each membership category consistent with applicable law, rules, and regulations and requirements of facility accrediting bodies.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3705 MEDICAL STAFF BYLAWS, RULES, AND REGULATIONS

(a) The active medical staff shall develop and adopt, subject to the approval of the governing body, a set of bylaws, rules, and regulations to establish a framework for self-governance of medical staff activities and accountability to the governing body.

(b) The medical staff bylaws, rules, and regulations shall provide for the following:

(1) organizational structure;
(2) qualifications for medical staff membership;
(3) procedures for granting or renewing, denying, modifying, suspending, and revoking clinical privileges;
(4) procedures for disciplinary or corrective actions;
(5) procedures for fair hearing and appellate review mechanisms for denying, modifying, suspending, and revoking clinical privileges;
(6) composition, functions and attendance of standing committees;
(7) policies for completion of medical records;
(8) formal liaison between the medical staff and the governing body;
(9) methods developed to formally verify that each medical staff member on appointment or reappointment agrees to abide by current medical staff bylaws, rules, and regulations, and the facility bylaws, rules, policies, and regulations;
(10) procedures for participation in quality assurance functions by medical staff members;
(11) the process for the selection and election and removal of medical staff officers; and
(12) procedures for the proposal, adoption, and amendment, and approval of medical staff bylaws, rules, and regulations.

(c) Neither the medical staff, the governing body, nor the facility administration may unilaterally amend the medical staff bylaws, rules, and regulations.

(d) Neither the medical staff, the governing body, nor the facility administration may waive any provision of the medical staff bylaws, rules, and regulations, except in an emergency circumstance. For purposes of this Rule, an "emergency circumstance" means a situation of urgency that justifies immediate action and when there is not sufficient time to follow the applicable provisions and procedures of the medical staff bylaws. Examples of an emergency circumstance include an immediate threat to the life or health of an individual or the public, a natural disaster, or a judicial or regulatory order. The duration of a waiver permitted by this Rule will be only so long as the emergency circumstance exists.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3706 ORGANIZATION AND RESPONSIBILITIES OF THE MEDICAL STAFF

(a) The medical staff shall be organized to accomplish its required functions as established by the governing body and medical staff bylaws, rules, and regulations and provide for the election or appointment of its own officers.

(b) There shall be an executive committee, or its equivalent, which represents the medical staff, that has responsibility for the effectiveness of all medical activities of the staff, and that acts for the medical staff.

(c) The following functions shall be performed by the medical staff:

(1) credentialing review;
(2) medical records review;
(3) drug utilization review;
(4) radiation safety review;
(5) blood usage review;
(6) bylaws review;
(7) medical review;
(8) peer review; and
(9) recommendations for discipline or corrective action of medical staff members.

(d) The medical staff shall ensure that minutes are prepared for each medical staff, departmental, and committee meeting.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3707 MEDICAL ORDERS

(a) No medication or treatment shall be administered or discontinued except in response to the order of a member of the medical staff in accordance with policies, rules, and regulations established by the facility and medical staff and as provided in Paragraph (f) of this Rule.

(b) Such orders shall be dated and recorded directly in the patient medical record. A method shall be established to safeguard against fraudulent recordings.

(c) All orders for medication or treatment shall be authenticated according to medical staff and facility policies, rules, or regulations. The order shall be taken by personnel qualified by medical staff bylaws, rules, and regulations, and shall include the date, time, and name of persons who gave the order, and the full signature of the person taking the order.

(d) The names of drugs shall be recorded in full and not abbreviated except where approved by the active medical staff.

(e) The active medical staff shall establish a written policy in conjunction with the pharmacy committee or its equivalent for all medications not specifically prescribed as to time or number of doses to be automatically stopped after a reasonable time limit, but no more than 14 days. The prescriber shall be notified according to established policies and procedures at least 24 hours before an order is automatically stopped.

(f) For patients who are under the continuing care of an out-of-state physician but are temporarily located in North Carolina, a facility may process the out-of-state physician's prescriptions or orders for diagnostic or therapeutic studies which maintain and support the patient's continued program of care, where the authenticity and currency of the prescriptions or orders can be verified by the physician who prescribed or ordered the treatment requested by the patient, and where the facility verifies that the out-of-state physician is licensed to prescribe or order the treatment.

History Note: *Authority G.S. 131E-75; 131E-79;*
Eff. January 1, 1996;
Amended Eff. April 1, 2005; August 1, 1998;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3708 MEDICAL STAFF RESPONSIBILITIES FOR QUALITY IMPROVEMENT REVIEW

(a) The medical staff shall have in effect a system to review care provided at the facility by members of the medical staff, to assess quality, to provide a process for quality improvement, and to monitor the outcome of quality improvement activities.

(b) The medical staff shall establish criteria for the evaluation of the quality of care.

(c) The facility shall have a written plan that generates reports to permit identification of patient care problems and that establishes a system to use this data to document and identify interventions. The plan shall be approved by the medical staff, facility administration, and the governing body.

(d) The medical staff shall establish a policy to maintain a review process of the care provided by members of the medical staff to all patients in every medical department of the facility. The medical staff shall have a policy to schedule meetings to examine the review process and results. The review process shall include both practitioners and allied health professionals from the medical staff.

(e) Minutes shall be prepared for all meetings reviewing quality improvement and shall reflect all of the transactions, conclusions, and recommendations of the meeting.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. July 1, 2020.

SECTION .3800 - NURSING SERVICES

10A NCAC 13B .3801 NURSE EXECUTIVE

(a) Whether the facility utilizes a centralized or decentralized organizational structure, a nurse executive shall be responsible for the coordination of nursing organizational functions.

(b) A nurse executive shall develop facility wide patient care programs, policies, and procedures that describe how the nursing care needs of patients are assessed, met, and evaluated.

(c) The nurse executive shall develop and adopt, subject to the approval of the facility, a set of administrative policies and procedures to establish a framework to accomplish required functions as required in Paragraph (e) of this Rule.

(d) There shall be scheduled meetings every 60 days of the members of the nursing staff to evaluate the quality and efficiency of nursing services. Minutes of these meetings shall be maintained.

(e) The nurse executive shall be responsible for:

(1) the development of a written organizational plan which describes the levels of accountability and responsibility within the nursing organization;
(2) planning for and the evaluation of the delivery of nursing care system;
(3) establishment of a mechanism to validate qualifications, knowledge, and skills of nursing personnel;
(4) provision of orientation and educational opportunities related to expected nursing performance and maintenance of records pertaining thereto;
(5) implementation of a system for performance evaluation;
(6) provision of nursing care services in conformance with G.S. 90-171.20(7) and G.S. 90-171.20(8);
(7) assignment of nursing staff to clinical or managerial responsibilities based upon educational preparation, in conformance with licensing laws and an assessment of current competence; and
(8) staffing nursing units with personnel in accordance with a written plan of care to meet the needs of the patients.

History Note: *Authority G.S. 143B-165;*
Eff. January 1, 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .3802 NURSING STAFF

(a) Licensed nurses and other nursing personnel shall be qualified by training, education, experience and demonstrated abilities to provide nursing care within their scope of practice.

(b) Staffing schedules which reflect personnel assignment by date and service unit shall be kept on file for at least three years by hospital management.

(c) The facility shall establish policies for the provision of services for all contractual agreement personnel that include at a minimum the following:

(1) verification of licensure or certification by the appropriate occupational board;
(2) delivery and documentation of care;
(3) participation on interdisciplinary care planning activities; and
(4) supervision of contractual agreement personnel.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3803 NURSING POLICIES AND PROCEDURES

(a) Nursing policies and procedures shall be available to the nursing staff in each nursing care unit and service area and shall include the following:

(1) method of noting diagnostic and therapeutic orders;
(2) method of assigning nursing care of patients;
(3) infection control measures;
(4) patient safety measurers; and
(5) method of implementing orders for medication or treatment.

(b) Each unit shall have relevant clinical reference materials available. The following shall be provided to each unit:

(1) a facility formulary or comparable drug reference;
(2) a policy and procedure manual; and
(3) a medical dictionary.

(c) The facility shall provide a program of inservice education which shall be maintained and documented for all nursing staff personnel. Annual inservices shall include infection control measures, cardiopulmonary resuscitation and fire and safety.

(d) Nursing care policies and procedures shall be reviewed at least every three years by the nursing staff and facility management and revised as necessary. They shall include the date to indicate the time of the most recent review or revision.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3804 PATIENT CARE

(a) Each patient's need for nursing care related to his or her admission shall be determined by a registered nurse. Patient needs shall be reassessed when warranted by the patient's condition.

(b) Each patient's nursing care shall be based upon assessed needs and shall be coordinated with the therapies of other disciplines.

(c) The patient's medical record shall include documentation of:

(1) the initial assessment and reassessments of patient clinical status;
(2) patient care needs;
(3) interventions performed to meet the patient's nursing care needs;
(4) implementation of physician's orders;
(5) the nursing care provided; and
(6) the patient's response to, and the outcomes of, the care provided.

(d) Each plan of care shall be initiated within 24 hours of admission. The plan of care shall become a part of the clinical record.

(e) The nursing care plan shall be readily available to all physicians and facility personnel involved with the care of the patient.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .3900 - MEDICAL RECORD SERVICES

10A NCAC 13B .3901 ORGANIZATION

(a) The facility shall establish a medical record service. It shall be directed, staffed and equipped to accurately process, index, and file all medical records. Orientation, on-the-job training and inservice programs for medical records personnel shall be provided.

(b) The medical record service shall be equipped to enable its personnel to maintain medical records so that they are readily accessible and secure from unauthorized use.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3902 MANAGER

(a) The medical records service shall be directed and supervised by a qualified medical records manager. If the manager is not a registered record administrator or an accredited records technician, the facility shall retain a person with those qualifications on a part-time or consulting basis.

(b) The manager of the medical record service shall advise, administer, supervise and perform work involved in the development, analysis, maintenance and use of medical records and reports.

(c) Where the manager is employed on a part-time or consulting basis, he or she shall organize the department, train the regular personnel and make periodic visits to the facility. The manager shall evaluate the records and the operation of the service and document the visits by written reports. A written contract specifying his or her duties and responsibilities shall be kept on file and made available for inspection by the Division's surveyor.

(d) The manager of the medical record service shall maintain a system of identification and filing to facilitate the prompt location of medical record of any patient.

(e) The manager of the medical records service shall store medical records in such a manner as to provide protection from loss, damage, and unauthorized access.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of Statutory Authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3903 PRESERVATION OF MEDICAL RECORDS

(a) The manager of the medical records service shall maintain medical records that were created when the patient was an adult, whether original, computer media, or digital archived for 11 years following the discharge of an adult patient.

(b) The manager of medical records shall maintain medical records that were created when the patient was a minor, whether original, computer media, or digital archived, until the patient's 30th birthday. If a minor patient is readmitted as an adult, the manager of the medical records shall maintain medical records according to Paragraph (a) of this Rule.

(c) If a hospital discontinues operation, its management shall make known to the Division where its records are stored. Records shall be stored in a business offering retrieval services for 11 years after the closure date or according to Paragraph (b) of this Rule if the patient was a minor.

(d) The manager of medical records may authorize the digital archiving of medical records. Digital archiving may be done on or off the premises. If done off the premises, the facility shall provide for the confidentiality and safekeeping of the records. The original of digital archived medical records shall not be destroyed until the medical records department has had an opportunity to review the digital record for content.

(e) Nothing in this Section shall be construed to prohibit the use of automation in the medical records service, provided that all of the provisions in this Rule are met and the information is readily available for use in patient care.

(f) Only personnel authorized by State laws and the Health Insurance Portability and Accountability Act (HIPAA) found in 42 CFR 482, which is incorporated by reference including subsequent amendments and editions, shall have access to medical records. This regulation may be obtained free of charge at https://www.govinfo.gov/help/cfr. Where the written authorization of a patient is required for the release or disclosure of health information, the written authorization of the patient or authorized representative shall be maintained in the original record as authority for the release or disclosure.

(g) Medical records are the property of the hospital, and shall remain the property of the hospital, except through a court order. Copies shall be made available for authorized purposes such as insurance claims and physician review.

History Note: *Authority G.S. 131E-97; 143B-165;*
Eff. January 1, 1996;
Amended Eff. July 1, 2009;
Readopted Eff. August 1, 2023.

10A NCAC 13B .3904 PATIENT ACCESS

The manager of medical records shall provide patients or patient designees, when requested, access to or a copy of their medical records, or both. Upon the death of a patient, the executor of the decedent's estate, or in the absence of an executor, the next of kin responsible for the disposition of the remains, shall have access to all medical records of the deceased patient. The patient or the patient's next of kin may be charged for the cost of reproducing copies.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3905 PATIENT MEDICAL RECORDS

(a) Hospital management shall maintain medical records for each patient treated or examined in the facility.

(b) The medical record or medical record system shall provide data for each episode of care and treatment rendered by the facility.

(c) Where the medical record does not combine all episodes of inpatient, outpatient and emergency care, the medical records system shall:

(1) assemble, upon request of the physician, any or all divergently located components of the medical record when a patient is admitted to the facility or appears for outpatient or clinic services; or

(2) require placing copies of pertinent portions of each inpatient's medical record, such as the discharge resume, the operative note and the pathology report, in the outpatient or combined outpatient emergency unit record file as directed by the medical staff.

(d) The manager of medical records shall ensure that:

(1) each patient's medical record is complete, readily accessible and available to the professional staff concerned with the care and treatment of the patient;

(2) all clinical information pertaining to a patient is incorporated in his medical record;

(3) all entries in the record are dated and authenticated by the person making the entry;

(4) symbols and abbreviations are used only when they have been approved by the medical staff and when there exists a legend to explain them;

(5) verbal orders include the date and signature of the person recording them. They shall be given and authenticated in accordance with the provisions of Rule .3707(c) of this Subchapter; and

(6) records of patients discharged are completed within 30 days following discharge or disciplinary action is initiated as defined in the medical staff bylaws.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
Eff. January 1, 1996;
Amended Eff, April 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3906 CONTENTS

(a) The medical record shall contain sufficient information to justify the diagnosis, verify the treatment and document the course of treatment and results accurately.

(b) All in-patient records shall include the following information:

(1) identification data (name, address, age, sex) and, when the identification data is not obtainable, the reason for such;
(2) date and time of admission and discharge;
(3) medical history:
  (A) chief complaint;
  (B) details of the present illness;
  (C) relevant past, social, and family histories; and
  (D) reports of relevant physical examinations;
(4) diagnostic and therapeutic orders;
(5) reports of procedures, tests and their results;
(6) provisional or admitting diagnosis;
(7) evidence of appropriate informed consent or a written statement explaining why consent was not obtained;
(8) clinical observations, including results of therapy;
(9) record of medication and treatment administration;
(10) progress notes of all disciplines;
(11) conclusions at termination of hospitalization or evaluation and treatment;
(12) all relevant diagnosis established by the time of discharge;
(13) consultation reports;
(14) surgical record, including anesthesia record, pre-operative diagnosis, surgeon's operative report and post-operative orders and any instructions given to the patient or family; and
(15) autopsy findings, if performed.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .3907 MEDICAL RECORDS REVIEW

The medical staff shall review medical records periodically for completeness and shall:

(1) establish requirements regarding completion of medical records, including a system for disciplinary actions for those who do not complete records in a timely manner; and

(2) make recommendations to the medical records department regarding clinical information sufficient for medical care evaluation.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4000 - OUTPATIENT SERVICES

10A NCAC 13B .4001 ORGANIZATION

(a) The facility shall establish and maintain outpatient care services in accordance with the facility's written mission statement.

(b) The relationship of outpatient services to other divisions within the facility, including channels of responsibility and authority, shall be documented and made available for review by the facility.

(c) The facility shall vest the direction of outpatient services in one or more individuals whose qualifications, authority and duties are defined in writing.

(d) The facility shall establish and maintain procedures for the review and evaluation of outpatient services.

(e) Each medical staff member shall have privileges delineated in accordance with criteria established by the medical staff by-laws, rules, or regulations.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4002 STAFFING

(a) The director of outpatient services shall require that ambulatory care services are staffed with sufficient personnel in accordance with a written plan.

(b) The responsibility for the delivery of outpatient services by the professional staff shall be defined and documented by the director of ambulatory care services.

(c) The facility shall provide education programs specifically related to outpatient care for the staff and document the extent of participation in education and training programs.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4003 POLICIES AND PROCEDURES

(a) The provision of outpatient services shall be guided by written policies and procedures which shall be developed by the facility and approved by the medical staff. The policies and procedures shall be reviewed by the medical staff at least every three years.

(b) The policies shall include the following:

(1) patient access to outpatient services;
(2) the process of obtaining informed consent;
(3) the location, storage and procurement of medications, supplies and equipment; and
(4) the mechanism to be used to contact patients for necessary follow-up.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4004 OUTPATIENT SURGICAL AND ANESTHESIA SERVICES

(a) When surgical or anesthesia services are provided in an outpatient setting, the facility shall require that the medical staff approve all types of surgical procedures to be offered. The facility shall maintain and make available a current listing of approved outpatient procedures.

(b) The facility shall define the scope of anesthesia services that may be provided, the locations where such anesthesia services may be administered and who shall provide anesthesia services.

(c) The facility shall require that standards for informed consent, history and physical examination, preoperative studies, administration of anesthesia, medical records and discharge criteria meet the same standards of care as apply for inpatient surgery unless otherwise specified by the medical staff.

(d) The facility shall provide for back-up service by other departments in the case of emergencies or complications.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4005 MEDICAL RECORDS

(a) The manager of outpatient services shall require that a record of outpatient care and services for each patient is maintained either in the ambulatory care services or medical records department.

(b) The facility shall develop a system of identification and filing to prepare for safe storage and prompt retrieval of records upon subsequent inpatient or outpatient visits.

(c) The facility shall establish medical records procedures which include provisions for maintaining the confidentiality of patient information and for the release of information to authorized individuals.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4100 - EMERGENCY SERVICES

10A NCAC 13B .4101 EMERGENCY RESPONSE CAPABILITY REQUIRED

The medical staff of each facility shall require that facility personnel are capable of initiating life-saving measures at a first-aid level of response for any patient or person in need of such services. This shall include:

(1) initiating basic cardio-respiratory resuscitation according to American Red Cross or American Heart Association standards;
(2) availability of first-line emergency drugs as specified by the medical staff;
(3) availability of IV fluids and supplies required to establish IV access; and
(4) establishing protocols or agreements for the transfer of patients to a facility for a higher level of care when these services are not available on site.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4102 CLASSIFICATION OF OPTIONAL EMERGENCY SERVICES

(a) Any facility providing emergency services shall classify its capability in providing such services according to the following criteria:

(1) Level I:

(A) the facility shall have a comprehensive, 24-hour-per-day emergency service with at least one physician experienced in emergency care on duty in the emergency care area;

(B) the facility shall have in-hospital physician coverage by members of the medical staff or by senior-level residents for at least medical, surgical, orthopedic, obstetric, gynecologic, pediatric and anesthesia services;

(C) services of other medical and surgical specialists shall be available; and

(D) the facility shall provide prompt access to labs, radiology, operating suites, critical care and obstetric units and other services as defined by the governing body.

(2) Level II:

(A) the facility shall have 24-hour per day emergency service with at least one physician experienced in emergency care on duty in the emergency care area; and

(B) the facility shall have consultation available within 30 minutes by members of the medical staff or by senior level residents to meet the needs of the patient. Consultation by phone is acceptable.

(3) Level III: The facility shall have emergency service available 24 hours per day with at least one physician available to the emergency care area within 30 minutes through a medical staff call roster.

(b) Facilities seeking trauma center designation shall comply with G.S. 131E-162.

(c) The location of the emergency access area shall be identified by clearly visible signs.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4103 PROVISION OF EMERGENCY SERVICES

(a) Any facility providing emergency services shall establish and maintain policies requiring medical screening, treatment and transfer services for any individual who presents to the facility emergency department and on whose behalf treatment is requested regardless of that person's ability to pay for medical services and without delay to inquire about the individual's method of payment.

(b) Any facility providing emergency services under the rules of this Section shall install, operate, and maintain, on a 24-hour per day basis, an emergency two-way radio capable of accessing the North Carolina Voice Interoperability Plan for Emergency Responders (VIPER) radio network for voice communication with EMS providers transporting patients to the facility or provide on-line medical direction for EMS personnel.

(c) All communication equipment shall be in compliance with the rules set forth in 10A NCAC 13P, Emergency Medical Services and Trauma Rules.

History Note: *Authority G.S. 143B-165;*
Eff. January 1, 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4104 MEDICAL DIRECTOR

(a) The governing body shall establish the qualifications, duties, and authority of the director of emergency services. Appointments shall be recommended by the medical staff and approved by the governing body.

(b) The medical staff credentials committee shall approve the mechanism for emergency privileges for physicians employed for brief periods of time such as evenings, weekends, or holidays.

(c) Level I and II emergency services shall be directed and supervised by a physician.

(d) Level III services shall be directed and supervised by a physician.

History Note: *Authority G.S. 131E-85(a); 143B-165;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4105 NURSING

(a) Level I and Level II emergency services shall have one or more registered nurses assigned and on duty within the emergency service area at all times.

(b) A Level III emergency service shall have a registered nurse available on at least an on-call, in-house basis at all times.

(c) The facility shall document that all emergency services nursing personnel shall have orientation, training and continuing education in the reception and care of emergency patients.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4106 POLICIES AND PROCEDURES

Each emergency department shall establish written policies and procedures that specify the scope and conduct of patient care to be provided in the emergency areas. They shall include the following:

(1) the location, storage, and procurement of medications, blood, supplies, equipment, and the procedures to be followed in the event of equipment failure;

(2) the initial management of patients with burns, hand injuries, head injuries, fractures, multiple injuries, poisoning, animal bites, gunshot or stab wounds, and other acute problems;

(3) the provision of care to an unemancipated minor not accompanied by a parent or guardian, or to an unaccompanied unconscious patient;

(4) management of alleged or suspected child, elder, or adult abuse;

(5) the management of pediatric emergencies;

(6) the initial management of patients with actual or suspected exposure to radiation;

(7) management of alleged or suspected rape victims;

(8) the reporting of individuals dead on arrival to the proper authorities;

(9) the use of standing orders;

(10) tetanus and rabies prevention or prophylaxis; and

(11) the dispensing of medications in accordance with State and federal laws.

History Note: *Authority G.S. 143B-165;*
Eff. January 1, 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4107 EMERGENCY RECORDS

(a) The facility shall require all levels of emergency departments to maintain a continuous control register on each patient seen for services which shall include at least the name, age, sex, date, time, and means of arrival, nature of complaint, disposition, and time of discharge.

(b) The facility shall maintain a record for each patient seeking emergency care. This shall include:

(1) patient identification, time and means of arrival;
(2) pertinent history and physical findings and patient vital signs;
(3) diagnostic and therapeutic orders;
(4) clinical observations including results of treatment;
(5) reports of procedures, tests and results;
(6) diagnostic impression; and
(7) discharge or transfer summary of treatment including final disposition, the patient's condition, and any instructions given to the patient and or family for follow-up care.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4108 OBSERVATION BEDS

When observation beds are used, the facility shall implement written policies and procedures that address the type of patient use, the mechanism for providing appropriate clinical monitoring, the length of time services may be provided in this setting and documentation requirements.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4109 TRANSFER

(a) The facility shall establish and implement protocols for stabilization and transportation of emergency patients.

(b) A facility with specialized capabilities, such as burn units, shock-trauma units and neonatal intensive care units, shall not refuse to accept an appropriate transfer for those services if the hospital has the capacity to treat the individual.

(c) The facility shall not transfer a patient until the receiving organization has consented to accept the patient and the patient is sufficiently stable for transport.

(d) If the patient or the person acting on the patient's behalf refuses transfer, the facility staff shall:

(1) explain to the individual or his representative the risks and benefits of transfer; and

(2) shall request the patient's or his representative's refusal of transfer in writing.

(e) The facility shall forward at the time of transfer a copy of all medical records related to the emergency condition for which the individual has presented.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4110 DISASTER AND MASS CASUALTY PROGRAM

(a) The facility shall describe:

(1) the level of emergency services available during an external disaster;

(2) the emergency department's role in the facility's external disaster plan;

(3) procedures to be followed in the event of an internal disaster; and

(4) the facility's connection to other community services such as fire, police and the American Red Cross.

(b) The medical staff and governing body shall approve the plan, review it and revise it if needed, annually.

(c) The plan shall:

(1) provide for prompt medical attention for all emergency patients as their needs may dictate;

(2) include protocols for handling non-emergency cases;

(3) establish medical staff coverage procedures or methods;

(4) specify drugs, solutions and equipment to be continuously available;

(5) provide for the evacuation and transfer for all inpatients as their needs may indicate in the event of an internal disaster; and

(6) include mutual support agreements with area providers.

(d) Schedules, names and telephone numbers of all physicians and others on emergency duty shall be maintained by the facility.

(e) Names and telephone numbers of those to be contacted in the event of an internal disaster shall be maintained by the facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4200 - SPECIAL CARE UNITS

10A NCAC 13B .4201 ORGANIZATION

(a) The governing body shall approve the type and scope of special care units.

(b) The facility shall document the relationship of the special care units to the other departments within the hospital, including channels of responsibility and authority.

(c) The facility shall provide necessary equipment and supplies for delivery of nursing care specific to the unit population for each special care unit.

(d) The facility shall provide sufficient emergency drugs and equipment to meet anticipated needs as determined by the medical staff.

(e) The governing body shall delegate to the medical and nursing staff the responsibility to develop policies and procedures concerning the scope and provision of safe care in each unit.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4202 MEDICAL STAFF

(a) The governing body shall provide that each special care unit or group of similar units be directed by qualified members of the medical staff whose clinical and administrative privileges have been approved by the governing board.

(b) The governing body shall designate the director to be responsible for making decisions in consultation with the physician responsible for the patient, for the disposition of a patient when patient load exceeds optimal operation capacity.

(c) The governing body shall require that the medical staff provide medical staff coverage sufficient to meet the specific needs of the patients on a 24-hour basis.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4203 NURSING STAFF

The supervision of nursing care for each special care unit shall be provided by a qualified registered nurse and shall include the following:

(1) unit-specific orientation and competency evaluation for each staff member;

(2) a staffing plan based upon the needs of the patient population which is implemented to ensure a sufficient number of qualified Registered Nurses are on duty when patients are in the unit;

(3) assessment, planning, implementation and evaluation of nursing care which is documented according to policy; and

(4) delivery of nursing care in accordance with the North Carolina Nurse Practice Act.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4204 POLICIES AND PROCEDURES

(a) The facility in conjunction with the medical and nursing staff shall develop written policies and procedures which guide the provision of care in a special care unit. These policies and procedures shall be approved by the medical staff and include:

(1) patient admission and discharge criteria;
(2) notification of appropriate medical staff for changes in the condition of the patient;
(3) use of standing orders and emergency protocols;
(4) designation of staff members authorized to perform special procedures and special circumstances requiring such authorization;
(5) patient care procedures, including medication administration;
(6) infection control;
(7) pertinent safety practices;
(8) use of equipment and procedures to be followed in the event of equipment failure;
(9) regulations governing visitors and traffic control; and
(10) role of special care unit in internal and external disaster plans.

(b) The governing body shall review, update and approve regularly, but at least every three years, its policies and procedures.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4300 - MATERNAL - NEONATAL SERVICES

10A NCAC 13B .4301 ORGANIZATION MATERNAL SERVICES

(a) The governing body shall approve the scope of obstetric services offered based upon the level of patient need, qualifications of the credentialed staff, and resources of the facility.

(b) The following capabilities and minimum services shall be made available when obstetric services are provided:

(1) identification of high-risk mothers and fetuses;
(2) continuous electronic fetal monitoring;
(3) cesarean delivery capability within 30 minutes of decision;
(4) blood or fresh frozen plasma for transfusion;
(5) anesthesia on a 24-hour or on-call basis;
(6) radiology and ultrasound examination;
(7) stabilization of unexpectedly small or sick neonates before transfer;
(8) neonatal resuscitation;
(9) laboratory services on a 24-hour or on-call basis;
(10) consultation and transfer agreements;
(11) assessment and care for the neonates; and
(12) nursery or other appropriate space for care of the neonates.

(c) In a facility without intensive care nursery services, the facility management shall establish and maintain a plan for the stabilization and transportation of sick newborns to a regional neonatal unit.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4302 MEDICAL STAFF MATERNAL SERVICES

(a) The medical staff shall require that each birth be attended by a physician or certified nurse midwife who has documented evidence of current competence and appropriate privileges.

(b) At all times medical staff with obstetrical privileges shall be available within 30 minutes to provide services and attend deliveries. An on-call schedule shall be available to the Division for review.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4303 NURSING SERVICES MATERNAL SERVICES

(a) The nurse executive or the decentralized nursing management staff shall designate a registered nurse who has education, training, and experience in obstetrical care as supervisor of obstetrical services.

(b) A registered nurse shall be responsible for providing the type and amount of nursing care needed by each patient. A staffing plan shall be available to the Division for review.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4304 POLICIES AND PROCEDURES MATERNAL SERVICES

(a) The provision of patient care shall be guided by written policies and procedures developed by the medical and nursing staff and approved by the medical staff.

(b) Written policies shall relate to at least the following:

(1) a system for informing the physician or certified nurse midwife responsible for a patient of the following:
  (A) the patient's admission;
  (B) the onset of labor; and
  (C) pertinent information about progress of labor or changes in patient's condition.

(2) emergency response protocols for patients who demonstrate evidence of maternal, fetal or neonatal distress;

(3) a program to prevent isoimmunization of RH-negative mothers;

(4) administration of oxytocic agents when used for induction or stimulation of labor;

(5) the use and administration of analgesics and anesthetics;

(6) administration of magnesium sulfate when and for the treatment preeclampsia;

(7) the location and storage of medications, supplies, and special equipment;

(8) the method of identification for the neonates;

(9) assessment and care of the neonates;

(10) provision of resuscitation, stabilization, and preparation for the transport of sick neonates at any hour; and

(11) an infection control plan.

(c) Accurate and complete medical records shall be provided for each obstetric patient.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 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) LEVEL I: Full-term and pre-term neonates that are stable without complications. This may include infants who are small for gestational age or neonates who are large for gestational age.

(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 under 32 weeks of gestational age, or infants, requiring constant nursing care or supervision that includes 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. 143B-165;*
Eff. January 1, 1996;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, 2003;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4306 MEDICAL STAFF OF NEONATAL SERVICES

The medical staff shall require that the director or other designated physician in charge of the neonatal special or intensive care unit has training and experience in care of the neonate.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4307 NURSING STAFF OF NEONATAL SERVICES

(a) The nurse executive or the decentralized nursing management staff shall designate a registered nurse who has training and experience in the care of neonates as supervisor of neonatal services.

(b) A registered nurse shall be responsible for providing the type and amount of nursing care needed by each patient. A staffing plan shall be available to the Division for review.

(c) The nursing staff shall provide educational opportunities for parents of neonates on routine care and procedures needed by the neonate.

(d) The nursing staff shall provide opportunities for parental participation in care of the neonate to facilitate bonding and family adjustment to the neonate's needs.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4308 POLICIES AND PROCEDURES OF NEONATAL SERVICES

(a) The provision of neonatal care at all levels shall be guided by written policies and procedures developed and approved by the medical and nursing staffs.

(b) The policies and procedures shall include but are not limited to:

(1) emergency resuscitation and stabilization of the neonate;
(2) equipment for routine and emergency care of the neonate;
(3) continuous oxygen supply and means of administration including ventilators;
(4) administration of medications;
(5) insertion and care of invasive lines;
(6) prevention of infectious diseases or processes; and
(7) family involvement in care of the neonate.

(c) The medical and nursing staff shall review, update and approve its policies and procedures every three years.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4400 - RESPIRATORY CARE SERVICES

10A NCAC 13B .4401 ORGANIZATION

(a) The governing body shall appoint a medical director of the respiratory care service who is an anesthesiologist, pulmonologist or other qualified physician.

(b) The facility shall appoint a qualified individual as the director of respiratory care services.

(c) When the facility is without a distinct respiratory care service, the facility shall:

(1) designate the department responsible for the delivery of respiratory care services;

(2) designate a person to supervise the delivery of respiratory care services; and

(3) establish and maintain policies and procedures for the delivery of respiratory care services offered.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4402 STAFFING

(a) Staffing numbers shall be determined by the types and complexities of the services offered.

(b) The director of the service shall provide for the availability of trained respiratory technicians, Certified Respiratory Therapy Technicians, registry eligible or Registered Respiratory Therapist needed for the scope of services offered.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4403 POLICIES AND PROCEDURES

The facility shall establish and maintain written policies and procedures for the services offered. These shall include but are not limited to:

(1) scope of services and treatment offered;
(2) medication administration;
(3) cleaning, assembly and storage of equipment;
(4) safety;
(5) infection control;
(6) documentation of delivered care or treatments; and
(7) care and supervision of all ventilated patients.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4500 - PHARMACY SERVICES AND MEDICATION ADMINISTRATION

10A NCAC 13B .4501 PROVISION OF SERVICE

The facility shall provide for pharmaceutical services which are administered in accordance with the pharmacy laws of North Carolina including but not limited to G.S. 90 and G.S. 106.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4502 PHARMACIST

(a) The pharmacy service shall be directed by a pharmacist licensed by the State of North Carolina. If a facility has a limited service as defined by the N.C. Board of Pharmacy, a part-time director of pharmacy shall have responsibility for control and dispensing of drugs.

(b) The director of pharmacy shall be responsible to the chief executive officer or his designee for developing, supervising, and coordinating all the activities of pharmacy services throughout the facility.

(c) The director of pharmacy shall require that the pharmacists are trained in the specialized functions of facility pharmacy.

(d) The dispensing of drugs in the absence of a pharmacist shall be done by facility staff under the direct supervision of staff approved by the pharmacy committee and who are responsible for following policies established by the pharmacy committee.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4503 STAFF

The director of pharmacy shall be assisted by additional pharmacists and such other personnel as the activities of the pharmacy may require to meet the pharmaceutical needs of the patients served.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4504 PHARMACY COMMITTEE

(a) A pharmacy committee or its equivalent, to include physicians, registered nurses, pharmacists and the administrator or designee shall be established.

(b) The committee shall meet at least quarterly, record its proceedings and report to the medical staff. It shall assist in the formulation of broad professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use and safety procedures, and all other matters relating to drugs in the facility. This shall include a mechanism to review and evaluate adverse drug reactions and drug usage evaluations, offering appropriate recommendations, actions, and follow-up if necessary. The committee shall:

(1) serve as an advisory group to the medical staff and the pharmacy director on matters pertaining to drug selection;
(2) develop an ongoing mechanism to review a formulary or drug list for use in the hospital;
(3) recommend and develop policies regarding the use and control of investigational drugs and research in the use of U.S. Food and Drug Administration approved drugs;
(4) evaluate clinical data concerning new drugs or preparations requested for use in the facility;
(5) make recommendations concerning drugs to be stocked on the nursing units and by other services;
(6) establish mechanisms which will prevent formulary duplication;
(7) establish policies and procedures that address therapeutic drug substitution;
(8) establish a policy describing the duration of drug therapy or number of doses for all medication orders; and
(9) make recommendations regarding medication administration policies and procedures.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4505 PHARMACY FACILITIES

(a) The facility shall provide sufficient space for the pharmaceutical service to carry out its professional and administrative functions.

(b) Equipment shall be provided for the storage, preparation, dispensing, distributing and safeguarding of drugs throughout the hospital.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4506 SUPPLIES

The director of pharmacy shall maintain an inventory of drugs and pharmaceutical devices to meet the needs of the patients as described in the facility's formulary.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4507 STORAGE

(a) All drugs and related pharmaceutical supplies located throughout the facility shall be under the control of the pharmacy service.

(b) All areas where drugs and related pharmaceutical supplies are stored shall be monitored at least monthly by the pharmacy service.

(c) The director of pharmacy shall require that corresponding records are maintained of drug inventory variances and the corrective action taken.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4509 SECURITY

(a) The director of pharmacy shall require that all drugs and related pharmaceutical supplies be stored in a lockable environment except when under the direct supervision of personnel authorized by the pharmacy committee to handle drugs.

(b) Controlled substances and other drugs the facility deems subject to abuse shall be stored as outlined in the U.S. Controlled Substance Act, 21 CFR 1301.41 and the N.C. Controlled Substances Act, G.S. 90, Article 5. These rules are available from the N.C. Drug Control Unit of the N.C. Division of Mental health, Development Disabilities & Substance Abuse Services, 3008 Mail Service Center, Raleigh, NC 27699-3008 (919-733-1765) without charge to current registrants.

(c) All keys and other locking devices to the pharmacy and controlled substances throughout the facility shall be under the control of the director of pharmacy and the facility management.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

10A NCAC 13B .4510 RECORDS

(a) The director of pharmacy shall provide that all drug transactions of the pharmacy shall be recorded as described in policies approved by the pharmacy committee.

(b) The director of pharmacy shall establish and maintain a system of records and bookkeeping in accordance with the policies of the facility in order to maintain adequate control over the requisitioning and dispensing of all drugs and pharmaceutical supplies and over patient billing for all drugs and pharmaceutical supplies.

(c) The director of pharmacy shall maintain records for all drugs purchased, ordered, dispensed, distributed, returned and disposed of in accordance with the pharmacy laws of North Carolina from the pharmacy.

(d) Verbal orders for drugs shall be subject to medical staff policies.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4511 MEDICATION ADMINISTRATION

(a) A facility shall establish and maintain policies and procedures governing the administration of medications which shall be enforced and implemented by administration and staff. Policies and procedures shall include:

(1) accountability of controlled substances as defined by the G.S. 90, Article 5; and

(2) storage, distribution, administration and monitoring the effects of medications.

(b) All medications and treatments shall be administered and discontinued in accordance with signed medical staff orders which are recorded in the patient's medical record.

(c) The categories of staff that are privileged to administer medications shall be delineated by the operational policies of the facility. These policies shall be in agreement with current rules of North Carolina Occupational Boards for each category of staff.

(d) Medications shall be scheduled and administered according to the established policies of the facility.

(e) Variances to the medication administration policy shall be reviewed and evaluated by the nurse executive or her designee.

(f) The person administering medications shall identify each patient in accordance with the facility's policies and procedures prior to administering any medication.

(g) Medication administered to a patient shall be recorded in the patient's medication administration record immediately after administration in accordance with the facility's policies and procedures.

(h) Omission of medication and the reason for the omission shall be indicated in the patient's medical record.

(i) The person administering medications which are ordered to be given as needed (PRN) shall justify the need for the same in the patient's medical record.

(j) Medication administration records shall provide identification of the drug and strength of drug, quantity of drug administered, route administered, name and title of person administering the medication, and time and date of administration.

(k) Self-administration of medications shall be permitted only if prescribed by the medical staff. Directions must be printed on the container.

(l) The administration of one patient's medications to another patient is prohibited except in the case of an emergency. In the event of such as emergency, steps shall be taken by a pharmacist to ensure that the borrowed medications shall be replaced and so documented.

(m) Verbal orders shall be signed in accordance with Rule .3707(c) of this Subchapter.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Amended Eff. November 1, 2005; May 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4512 MEDICATIONS DISPENSED

(a) Except as provided in Paragraph (c) of this Rule, the pharmacy shall dispense only those drugs which are listed in one or more of the references listed in Paragraph (b) of this Rule. No drug which is listed in Paragraph (b) of this Rule shall be used for any purpose which is not approved by the U.S. Food and Drug Administration unless the use has been approved by the facility's pharmacy committee.

(b) References:

(1) United States Pharmacopoeia;
(2) National Drug Formulary;
(3) Evaluations of Drug Interactions by the American Pharmaceutical Association;
(4) American Hospital Formulary Service; and
(5) Other references approved by the Pharmacy Committee.

(c) Any drug approved for use as an investigational drug or otherwise by the U.S. Food and Drug Administration but not listed in Paragraph (b) of this Rule may be used in accordance with standards established by the facility's pharmacy committee, or its equivalent and approved by the U.S. Food and Drug Administration, Dockets Management Branch, Room 1061, 5630 Fishers Lane, Rockfield, Maryland 20852, at a cost dependent on the material requested.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

10A NCAC 13B .4513 DRUG DISTRIBUTION SYSTEMS

(a) The pharmacy committee shall develop written policies and procedures pertaining to the intra-facility drug distribution system. In developing such policies the committee shall utilize representatives of other disciplines within the facility, including nursing services.

(b) The label of each patient's individual medication container shall bear all information required by the Pharmacy Laws of North Carolina.

(c) The pharmacist, with the advice and guidance of the pharmacy committee or its equivalent, shall be responsible for specifications as to quality, quantity and source of supplies of all drugs.

(d) There shall be a formulary or list of drugs accepted for use in the facility which shall be developed and amended as necessary by the pharmacy committee.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4514 EMERGENCY PHARMACEUTICAL SERVICES

The director of pharmacy shall be responsible for emergency pharmaceutical services as currently described in the Pharmacy Laws of North Carolina.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4515 DISPOSITION

Drugs, and pharmaceutical devices which are outdated, visibly deteriorated, unlabeled, inadequately labeled, recalled, discontinued or obsolete shall be identified by a pharmacist and shall be disposed of in compliance with applicable state and federal laws and regulations.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4516 COMMERCIAL PHARMACEUTICAL SERVICE

A facility using an outside pharmacist or pharmaceutical service must have a contract with that pharmacist or service. As part of the contract, the pharmacist or service shall be required to maintain at least the standards for operation of the pharmaceutical services outlined in this Subchapter.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4600 - SURGICAL AND ANESTHESIA SERVICES

10A NCAC 13B .4601 ORGANIZATION

(a) The governing body shall approve the types of surgery and types of anesthesia services to be available throughout the hospital consistent with identified needs and resources.

(b) The facility shall require that surgical or anesthesia procedures are performed only when the necessary equipment and personnel are available.

(c) A facility that provides surgical or obstetric services shall provide anesthesia services on a 24-hour basis.

(d) The requirements and standards identified in this Section apply when any patient, in any setting, receives for any purpose, by any route:

(1) general, spinal or other major regional anesthesia; or

(2) sedation or analgesia that may result in the loss of protective reflexes; or

(3) surgery or other invasive procedure while receiving such anesthesia.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4602 DIRECTOR OF SURGICAL SERVICES

(a) Each department or service providing surgical services shall be directed by members of the medical staff whose clinical and administrative privileges have been approved by the governing body.

(b) The medical staff shall establish and maintain a system for monitoring and evaluating the quality and appropriateness of the care and treatment of surgical patients, and for monitoring the clinical performance of all individuals with clinical privileges.

(c) In facilities where there is no anesthesiologist on staff the facility shall:

(1) with review of the medical staff, establish a consultation agreement with a board-certified or board-eligible anesthesiologist for the purpose of establishing policies and procedures that relate to the safe administration of anesthesia in all departments or services of the facility;

(2) assume the responsibility for establishing general policies for anesthesia services; and

(3) establish a line of communication and supervision for staff.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4603 SURGICAL AND ANESTHESIA STAFF

(a) The facility shall develop processes which require that each individual provides only those services for which proof of licensure and competency can be demonstrated.

(b) The facility shall require that:

(1) when anesthesia is administered, a qualified physician is immediately available in the facility to provide care in the event of a medical emergency;

(2) a roster of practitioners with a delineation of current surgical and anesthesia privileges is available and maintained for the service;

(3) an on-call schedule of surgeons with privileges to be available at all times for emergency surgery and for post-operative clinical management is maintained;

(4) the operating room is supervised by a qualified registered nurse or doctor of medicine or osteopathy; and

(5) an operating room register which shall include date of the operation, name and patient identification number, names of surgeons and surgical assistants, name of anesthetists, type of anesthesia given, pre- and post-operative diagnosis, type and duration of surgical procedure, and the presence or absence of complications in surgery is maintained.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
RRC objection due to lack of statutory authority Eff. August 22, 2022.

10A NCAC 13B .4604 DIRECTION OF ANESTHESIA SERVICES

(a) The facility shall be organized, directed and integrated with other related services or departments of the facility.

(b) The department of anesthesia shall require that all anesthetics are administered according to procedures established in medical staff rules. In facilities where there is no department of anesthesia, the medical staff shall assume the responsibility for establishing general policies and for supervising the administration of anesthetics.

(c) The facility shall provide that anesthesia services be directed by a member, or members, of the medical staff whose responsibilities shall be approved by the governing body and shall include:

(1) establishment of criteria and procedures for the evaluation of the quality of all anesthesia care rendered;

(2) review of clinical privileges for all licensed practitioners whose primary clinical activity is the provision of anesthesia services; and

(3) establishment of written policies and procedures for anesthesia services.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4605 POLICIES AND PROCEDURES

(a) The director of surgical services shall develop policies and procedures for surgical and anesthesia services which shall be available to the medical, surgical, anesthesia staff and nursing personnel.

(b) The facility shall require that policies on anesthesia procedures include the delineation of pre-anesthesia and post-anesthesia responsibilities.

(c) The facility shall require that the policies listed in this Paragraph are followed and that each surgical patient's record contain the following documentation:

(1) a complete history and physical documented in the record of every patient prior to surgery, including clinical indications for the surgical procedure;

(2) written evidence of informed consent, in the patient's record before surgery. If prior written consent was not obtained, the record shall contain a written explanation of why prior consent was not obtained;

(3) an evaluation of the patient and anesthesia planned, documented according to medical staff bylaws by an individual qualified to administer anesthesia services. Re-evaluation of the patient immediately prior to the induction of anesthesia shall be performed prior to surgery;

(4) an operative report describing techniques, findings, tissue removed or altered, and pre and post-surgical diagnosis. This report must be written or dictated following surgery and signed by the surgeon in compliance with medical staff rules;

(5) an intraoperative anesthesia record including the dosage of all drugs and agents used, the duration of anesthesia, and the type and amount of all fluids or blood and blood products administered shall be documented;

(6) evaluation and documentation of the postoperative status of the patient on admission to and discharge from the post-anesthesia recovery area.

(d) The director of anesthesia services shall establish criteria for discharge and facility management shall require that a physician or CRNA with appropriate clinical privileges be responsible for the decision to discharge a patient from a post-anesthesia recovery area.

(e) The facility shall establish regulations governing visitors and traffic control.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4700 - NUTRITION AND DIETETIC SERVICES

10A NCAC 13B .4701 PROVISION OF SERVICES

The nutrition and dietetic services shall be organized, directed, staffed and integrated with other facility departments to provide optimal nutritional therapy and quality food service to patients. Nutrition therapy shall apply the principles of the science of nutrition and be administered in accordance with the law and rules including but not limited to G.S. 90, Article 25.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4702 ORGANIZATION

(a) The nutrition and dietetic services shall be under the full-time direction of a person who is trained or experienced in food services administration and therapeutic diets. The director shall be one of the following:

(1) A qualified dietitian;
(2) Bachelor's degree in Foods and Nutrition or Food Service Management;
(3) Dietetic Technician Registered (DTR); or
(4) Certified Dietary Manager (CDM); or
(5) An individual who is enrolled in a program to complete the minimum qualifications in Paragraph (a)(1)(2)(A)(B)(C) of this Rule.

(b) The nutrition and dietetic services of the facility shall have at least one dietitian either full-time, part-time, or as consultant. The qualifications of the dietitian shall be included in the personnel files. If the director of nutrition and dietetic services is not a registered dietitian, there shall be an established method of communication between the director and the dietitian which ensures that the dietitian supervises the nutritional aspects of patient care and ensures that quality nutritional care is provided to patients. Dietitians or qualified designees shall attend and participate in meetings relevant to patient nutritional care, including but not limited to patient care conferences and discharge planning.

(c) When a dietitian serves only in a consultant capacity, the facility management shall establish and maintain a written contract with the individual defining the responsibilities of the dietician including requirements for submission of written reports to the hospital administrator and the director of the nutrition and dietetic services describing the extent and quality of the services provided. Frequency of visits of the consultant dietitian shall be defined in the contract. The consultant dietitian shall provide, on site, no less than eight hours of service every two weeks to provide the nutritional aspects of patient care including but not limited to the following:

(1) approval of regular and modified menus, including standardized recipes;
(2) performance of nutritional assessments;
(3) development of nutrition care plans;
(4) provision of nutrition therapy;
(5) participation in development of policies and procedures; and
(6) monitoring and evaluation of the effectiveness and appropriateness of nutrition and dietetic services.

(d) The facility shall establish and maintain written policies and procedures to govern all nutrition and dietetic service activities. These policies shall be developed by the nutrition and dietetic services in cooperation with personnel from other departments or services which are involved with nutrition and dietetic services and they shall be reviewed at least every three years, revised as necessary, and dated to indicate the time of last review. Administrative policies and procedures concerning food procurement, preparation, and service shall be written by the director of the nutrition and dietetic services. Nutritional care policies and procedures shall be written by the qualified dietitian. The nutrition and dietetic service policies and procedures shall include, but not be limited to the following:

(1) provision of food and nutrition therapy prescriptions/orders;
(2) development, approval and provision of regular and modified menus, including standardized recipes;
(3) food purchasing, storage, inventory, preparation and service;
(4) identification system designed to ensure that each patient receives appropriate diet as ordered;
(5) ancillary dietetic services, as appropriate, including food storage and kitchens on patient care units, formula supply, cafeterias, vending operations and ice making;
(6) preparation, storage, distribution, and administration of enteral nutrition programs;
(7) assessment and monitoring of patients receiving enteral and total parenteral nutrition;
(8) personal hygiene and health of dietetic personnel;
(9) infection control measures to minimize the possibility of contamination and transfer of infection, including establishment of monitoring procedure to ensure that personnel are free from communicable infections and open skin lesions; and
(10) pertinent safety practices, including control of electrical, flammable, mechanical, and radiation hazards.

(e) Nutrition and dietetic services shall be provided by qualified personnel under supervision to meet needs of patients. The director of the nutrition and dietetic services shall require that personnel assigned to the department perform all functions necessary to meet the nutritional needs of patients. The director or qualified designee shall

attend and participate in meetings, including that of department heads, and function as an integral member of the facility.

(f) A facility which has a contract with an outside food management service, shall require as a part of the contract that the company complies with all applicable requirements and standards outlined in Section .4700 of this Subchapter for such service. The contract shall be available for review by the Division.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4703 SANITATION AND SAFETY

(a) The nutrition and dietetic service shall comply with current laws and rules for sanitation as promulgated by the Commission for Public Health, including but not limited to 15A NCAC 18A .1300. Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Environmental Health Section, Division of Public Health, N.C. Department of Health and Human Services, 1632 Mail Service Center, Raleigh, NC 27699-1632. The facilities and equipment of the nutrition and dietetic services shall also comply with applicable and safety laws and rules.

(b) Sufficient space and equipment shall be provided for the nutrition and dietetic services to accomplish the following:

(1) store food and nonfood supplies under sanitary and secure conditions;
(2) store food separately from nonfood supplies. When storage facilities are limited, paper products may be stored with food supplies;
(3) prepare and distribute food, including therapeutic diets;
(4) clean and sanitize utensils and dishes apart from food preparation areas; and
(5) allow personnel to perform their duties.

(c) Cleaning schedules and instructions for cleaning all equipment and work and storage areas shall be posted and followed in the nutrition and dietetic services area and accessible to all nutrition and dietetics staff. Procedures for cleaning all equipment and work areas shall be followed consistently and documented to safeguard the health of the patient.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

10A NCAC 13B .4704 DISTRIBUTION OF FOOD

(a) Food shall be transported and displayed pursuant to the rules adopted by the Commission for Public Health.

(b) At the time of serving, the temperature of hot foods shall be no less than:

(1) Hot liquids - 150 degrees Fahrenheit (minimum);

(2) Hot Cereal - 150 degrees Fahrenheit (minimum);

(3) Hot Soups - 130 degrees Fahrenheit (minimum); and

(4) Other hot foods - 110 degrees Fahrenheit (minimum).

(c) At the time of serving, the temperature of cold foods shall be no more than:

(1) Cold liquids - 50 degrees Fahrenheit (maximum); and

(2) Other cold foods - 65 degrees Fahrenheit (maximum).

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4705 NUTRITIONAL SUPPORT

(a) The administration of the nutritional support shall be directed by a qualified dietitian. Observations and information pertinent to nutrition therapy shall be documented in the medical record of the patient.

(b) The facility shall have a current nutrition care manual accessible to hospital personnel. The nutrition care manual shall be reviewed every three years, revised as necessary by a qualified dietitian, and approved jointly by the nutrition service and medical staff.

(c) Therapeutic diets and enteral and parenteral nutrition therapy shall be prescribed in written orders on the medical records and provided as ordered.

(d) The nutrition care manual shall reflect the standards for nutrition care in accordance with those referenced in the most current edition of "Recommended Dietary Allowance" of the Food and Nutrition Board of the National Research Council of the National Academy of Sciences which are hereby incorporated by reference. These standards include any subsequent amendments and editions of the referenced material and are available from the National Academy Press, 2101 Constitution Avenue, N.W., Lockbox 285, Washington, D.C. 20055 at a cost of six dollars ($6.00) per copy. The nutrition deficiencies of any modified diet that is not in compliance with the recommended dietary allowances shall be specified in the nutrition care manual.

(e) The qualified dietitian shall be responsible for the development of a nutritional care plan in compliance with medical staff's orders to meet the nutritional needs of the patient. The nutrition care plan shall be included in the medical record of the patient on his discharge plan and transfer orders to the extent necessary for continuity of care. Facilities with long term care units shall have at least a three week menu cycle in the long term care units.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4800 - DIAGNOSTIC IMAGING

10A NCAC 13B .4801 ORGANIZATION

(a) Imaging services shall be under the supervision of a full-time radiologist, consulting radiologist, or a physician.
(b) Radio-therapy is a type of imaging service.
(c) All imaging equipment shall be operated under professional supervision by personnel trained in the use of imaging equipment and knowledgeable of all applicable safety precautions required by the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section set forth in 10A NCAC 15, hereby incorporated by reference including subsequent amendments.

History Note: *Authority G.S. 143B-165;*
RRC objection due to lack of statutory authority and ambiguity Eff. July 13, 1995;
Eff. January 1, 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4802 RECORDS

(a) A documented record on each imaging examination shall be included in the patient's medical record.

(b) Imaging reports shall be signed by the physician interpreting the study.

(c) Copies of current reports made by private physicists or governing authority surveying the radiographic facilities shall be available to the Division.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4803 STAFFING

(a) The staffing of the imaging department shall be determined by the radiologist in charge or by another person designated by hospital management.

(b) There shall be a minimum of one radiologic technologist available to the department on at least an on-call basis.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4804 MONITORING RADIATION EXPOSURE OF PERSONNEL

(a) The facility shall establish procedures for the monitoring of personnel and shall maintain a record for each individual working in the area of radiation where there is a reasonable probability of receiving one-fourth of the maximum permissible dose.

(b) Records documenting the monitoring of personnel receiving radiation exposure through the use of film badges or dosimeters must also be maintained by the facility. Readings from badges or dosimeters shall be recorded on at least a monthly basis.

(c) Upon termination of employment, each employee shall be provided with a summary of his exposure record.

(d) Permanent records of radiological exposure on all monitored personnel shall be maintained for review by the Division.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4805 SAFETY

(a) The facility shall require that all imaging equipment is operated under the supervision of a physician and by qualified personnel.

(b) The facility shall require that proper caution is exercised to protect all persons from exposure to radiation.

(c) Safety inspections of the imaging department, including equipment, shall be conducted by the North Carolina Division of Environmental Health, Radiation Protection Services Section. Copies of the report shall be available for review by the Division.

(d) The governing authority shall appoint a radiation safety committee. The committee shall include but is not limited to:

(1) a physician experienced in the handling of radio-active isotopes and their therapeutic use; and

(2) other representatives of the medical staff.

(e) All radio-active isotopes, whether for diagnostic, therapeutic, or research purposes shall be received, handled, and disposed of in accordance with the requirements of the North Carolina Department of Environment and Natural Resources, Division of Environmental Health, Radiation Protection Services Section. Copies of regulations are available from the North Carolina Department of Environment, Health, and Natural Resources, Division of Radiation Protection, 3825 Barrett Drive, Raleigh, NC 27609 at a cost of six dollars ($6.00) each.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
RRC objection due to lack of statutory authority and ambiguity Eff. August 22, 2022.

10A NCAC 13B .4806 NUCLEAR MEDICINE SERVICES

When nuclear medicine services are offered, the facility shall establish and maintain written policies and procedures for the provision of those services which shall provide for the safety of patients and staff, management of radioactive isotopes and the maintenance of equipment according to the manufacturers' recommendations.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .4900 - LABORATORY SERVICES AND PATHOLOGY

10A NCAC 13B .4901 ORGANIZATION

The laboratory shall be under the supervision of a clinical pathologist, or a physician who has training in clinical laboratory diagnosis designated by the governing body.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4902 RECORDS

(a) All requests for laboratory services shall be documented.

(b) All reports of laboratory services performed, including autopsy, shall be placed in the patient's medical record.

(c) Records of proficiency testing appropriate to the scope of services offered shall be available to the Division for review.

(d) Records of equipment calibration and quality controls as recommended by the manufacturer shall be maintained and be available to the Division for review.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4903 STAFFING

The laboratory supervisor or his appointed designee, shall require that:

(1) procedures and tests conducted are within the scope of the laboratory as approved by the hospital;
(2) at least one qualified medical technologist is available at all times; and
(3) qualified staff are available to carry out the functions of the laboratory.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4904 TESTS

(a) Laboratory tests to be performed on a patient at the time of admission (if any) shall be established by the medical staff and be approved by the governing board of the hospital. In the event the medical staff and governing body elect not to establish routine laboratory tests for new admissions, the request for such tests shall be left to the discretion of the attending medical staff members.

(b) Serological tests for patients admitted shall be optional with the hospital. However, there shall be records indicating that obstetrical patients have had a serological test during their current pregnancy.

(c) When laboratories outside of the facility are used, such laboratories shall be approved by the governing body and medical staff of the facility. In case of such usage, a legible copy of the laboratory report must be included in the patient record.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4905 TISSUE REMOVAL AND DISPOSAL

(a) The medical staff shall establish and maintain written policies for pathological examination of tissue and specimens removed during surgery.

(b) Pathological waste disposal shall comply with the rules Governing the Sanitation of Hospitals, Nursing and Rest Homes, Sanitariums, Sanatoriums, and Educational and Other Institutions, contained in 15A NCAC 18A .1300. Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Environmental Health Section, Division of Public Health, N.C. Department of Health and Human Services, 1632 Mail Service Center, Raleigh, NC 27699-1632.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

10A NCAC 13B .4906 BLOOD BANK

(a) Facilities which provide for procurement, storage and transfusion of blood shall meet the standards of the American Association of Blood Banks as outlined in the most current edition of Standards of Blood Banks and Transfusion Services, which is incorporated by reference, including all subsequent amendments and additions, and which is available from the American Association of Blood Banks, 8101 Glenbrook Road, Bethesda, Maryland 20814-2749 at a cost of thirty-three dollars and fifty cents ($33.50) per copy.

(b) The governing body shall approve the pathologist or physician as physician-in-charge of the blood bank service.

(c) Records shall be kept on file indicating the receipt and disposition of all blood handled. Care shall be taken to ascertain that blood administered has not exceeded its expiration date, and meets all criteria for safe administration.

(d) The facility shall make arrangements to secure on short notice all necessary supplies of blood, typed and cross-matched as required, for emergencies.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .4907 MORGUE AND AUTOPSY FACILITIES

(a) Morgue and autopsy services shall be provided either on site or by written agreement with a facility that provides those services.

(b) Procedures for the transport and storage of deceased patients shall be established and maintained by the facility.

(c) Procedures for post mortem cleaning of patients with diagnosed contagious diseases shall be established and maintained by the facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .5000 - PHYSICAL REHABILITATION SERVICES

10A NCAC 13B .5001 ORGANIZATION

The facility shall designate an individual responsible for the administration and supervision of each rehabilitation service.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5002 DELIVERY OF CARE

(a) A member of the medical staff shall be responsible for the general medical care of the inpatient.

(b) The delivery of all rehabilitation services shall be provided by practitioners credentialed or licensed in their respective fields.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5003 POLICIES AND PROCEDURES

The facility shall establish and maintain written policies and procedures that include but are not limited to:

(1) provision for assessment and evaluation of the services performed;
(2) safety measures;
(3) infection control measures; and
(4) procedures for referral to other facilities for services not available on site.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5004 PATIENT RECORDS

The patient record shall contain documentation of physical rehabilitation services utilized that include but is not limited to:

(1) diagnosis to support the services requested;
(2) assessment of patient's rehabilitative status;
(3) re-assessment and progress of patient's rehabilitative status;
(4) individualized plan of care and goals of rehabilitation; and
(5) discharge plan.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5005 CARDIAC REHABILITATION PROGRAM

When a facility elects to provide an outpatient cardiac rehabilitation program, the program shall be subject to 10 NCAC 3S, Sections .0300 - .1000, which are incorporated by reference with all subsequent amendments. Referenced rules are available from the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Licensure and Certification Section, 2711 Mail Service Center, Raleigh, NC 27699 at a cost of three dollars ($3.00) each.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .5100 - INFECTION CONTROL

10A NCAC 13B .5101 ORGANIZATION

(a) The governing body shall establish and maintain an infection control program that includes all patient care and patient care support services and departments for the surveillance, prevention and control of infection.
(b) The infection control committee shall include representatives of the medical staff, nursing staff, administration and the person directly responsible for the surveillance program activities.
(c) The infection control committee shall assume responsibility for the infection control program.
(d) The facility shall designate a person to manage the infection control, prevention and surveillance program.
(e) The infection control committee shall involve facility departments and services as needed to maintain the infection control program.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5102 POLICY AND PROCEDURES

(a) Each facility department or service shall establish and maintain the following written infection control policies and procedures:

(1) the role and scope of the service or department in the infection control program;
(2) the role and scope of surveillance activities in the infection control program;
(3) the methodology used to collect and analyze data, maintain a surveillance program on nosocomial infection, and the control and prevention of infection;
(4) the specific precautions to be used to prevent the transmission of infection and isolation methods to be utilized;
(5) the method of sterilization and storage of equipment and supplies, including the reprocessing of disposable items;
(6) the cleaning of patient care areas and equipment;
(7) the cleaning of non-patient care areas; and
(8) exposure control plans.

(b) The infection control committee shall approve all infection control policies and procedures. The committee shall review all policies and procedures every three years and indicate the last date of review.

(c) The infection control committee shall meet quarterly and maintain minutes of meetings.

History Note: *Authority G.S. 143B-165;*
Eff. January 1, 1996;
Readopted Eff August 1, 2023.

10A NCAC 13B .5103 LAUNDRY SERVICE

The facility shall provide, directly or by contract, a laundry service or department that provides the following:

(1) 24 hour a day availability of clean linen for patient care needs; and

(2) delivery of clean linen and removal of soiled linen in a manner that reduces the spread of infection.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5104 ENVIRONMENTAL SERVICES

The facility shall require that environmental services (housekeeping) provide the following:

(1) 24 hour a day availability of personnel or supplies and equipment for the cleaning of patient rooms, patient care equipment, and the cleaning of spills;

(2) a routine cleaning schedule for all areas of the facility to assist in the prevention and spread of disease; and

(3) removal and appropriate disposal of waste materials including biologicals.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5105 STERILE SUPPLY SERVICES

The facility shall provide for the following:

(1) decontamination and sterilization of equipment and supplies;
(2) monitoring of sterilizing equipment on a routine schedule;
(3) establishment of policies and procedures for the use of disposable items; and
(4) establishment of policies and procedures addressing shelf life of stored sterile items.

History Note: *Authority G.S. 143B-165;*
Eff. January 1, 1996;
Readopted Eff. August 1, 2023.

SECTION .5200 - PSYCHIATRIC SERVICES

10A NCAC 13B .5201 PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES: APPLICABILITY OF RULES

The rules contained in this Section shall apply to all psychiatric and substance abuse services provided by any facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5202 DEFINITIONS APPLICABLE TO PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES

(a) "Certified counselor" means an alcoholism, drug abuse or substance abuse counselor who is certified by the North Carolina Substance Abuse Professional Certification Board.

(b) "Certified substance abuse counselor/supervisor" means an individual who is a "certified counselor" as defined in 10 NCAC 3C .5202(a) and is designated by the North Carolina Substance Abuse Professional Certification Board as a qualified substance abuse supervisor.

(c) "Clinical/professional supervision" means regularly scheduled assistance by a qualified mental health, professional or a qualified substance abuse professional to a staff member who is providing direct, therapeutic intervention to a client or clients. The purpose of clinical supervision is to ensure that each client receives appropriate treatment or habilitation which is consistent with accepted standards of practice and the needs of the client.

(d) "Detoxification service" means a unit or department whose primary purpose is the medical management or care of persons who are under the influence of alcohol or drugs.

(e) "Direct care staff" means an individual who provides active direct care, treatment, or rehabilitation or habilitation services to clients on a continuous and regularly scheduled basis.

(f) "Psychiatric nurse" means an individual who is licensed to practice as a registered nurse in North Carolina by the North Carolina Board of Nursing; and has:

(1) a graduate degree from an accredited master's level program in psychiatric mental health nursing with two years of experience; or

(2) a master's degree in behavioral science with two years of supervised clinical experience in psychiatric mental health nursing; or

(3) a baccalaureate degree in behavioral science with four years of supervised clinical experience in psychiatric mental health nursing.

(g) "Psychiatric service" means an inpatient or outpatient unit or department whose primary purpose is the treatment of mental illness. It also means the mental health treatment provided in such a unit or department.

(h) "Psychiatric social worker" means an individual who holds a master's degree in social work from an accredited school of social work and has two years of clinical social work experience.

(i) "Psychiatrist" means an individual who is licensed to practice medicine in North Carolina and who has completed an accredited training program in psychiatry.

(j) "Psychologist" means an individual licensed to practice psychology in North Carolina by the North Carolina State Board of Examiners of Practicing Psychologists.

(k) "Qualified mental health professional" means any one of the following: psychiatrist, psychiatric nurse, practicing psychologist, psychiatric social worker, an individual with at least a masters degree in a related human service field and two years of supervised clinical experience in mental health services or an individual with a baccalaureate degree in a related human service field and four years of supervised clinical experience in mental health services.

(l) "Qualified substance abuse professional" means an individual who is:

(1) certified by the North Carolina Substance Abuse Professional Certification Board;

(2) certified by the National Consortium of Chemical Dependency Nurses, Inc;

(3) certified by the National Nurses Society on Addictions; or

(4) a graduate of a college or university with a baccalaureate or advanced degree in a human service related field with documentation of at least two years of supervised experience in the profession of alcoholism and drug abuse counseling.

(m) "Restraint" means the limitation of one's freedom of movement and includes the following:

(1) mechanical restraint which means restraint of a client with the intent of controlling behavior with mechanical devices which include, but are not limited to, cuff, ankle straps, sheets or restraining shirts; or

(2) physical restraint which means restraint of a client until calm. As used in these Rules, the term physical restraint does not apply to the use of professionally recognized methods for therapeutic holds of brief duration (five minutes or less).

(n) "Restrictive facility" means a facility so designated by the Division of Health Service Regulation which uses mechanical restraint or seclusion in accordance with G.S. 122C-60 in order to restrain a client's freedom of movement.

(o) "Seclusion" means isolating a client in a separate locked room for the purpose of controlling a client's behavior.

(p) "Substance abuse service" means inpatient or outpatient unit or department whose primary purpose is the treatment of chemical dependency. It also means the chemical dependency treatment provided in such a unit or department.

History Note: *Authority G.S. 131E-79;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5203 STAFFING FOR PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES

(a) General Requirements:

(1) A physician shall be present in the facility or on call 24 hours per day. The medical appraisal and medical treatment of each patient shall be the responsibility of a physician;

(2) Each facility shall determine its overall staffing requirements based upon the age categories (child, adolescent, adult, elderly), clinical characteristics, treatment requirements and numbers of patients;

(3) There shall be a sufficient number of appropriately qualified clinical and support staff to assess and address the clinical needs of the patients;

(4) Staff members shall have training or experience in the provision of care in each of the age categories assigned for treatment.

(b) Psychiatric Services:

(1) Staff coverage for psychiatric services shall include at least one each of the following: psychiatrist, psychiatric nurse, psychologist, and psychiatric social worker;

(2) A qualified mental health professional shall be available by telephone or page and able to reach the facility within 30 minutes on a 24 hour basis;

(3) Each clinical or direct care staff member who is not a qualified mental health professional shall receive professional supervision from a qualified mental health professional;

(4) When detoxification services are provided, there shall be liaison and consultation with a qualified substance abuse professional prior to the discharge of a client.

(c) Substance Abuse Services:

(1) At least one registered nurse shall be on duty during each shift;

(2) Certified substance abuse counselors or qualified substance abuse professionals shall be employed at the ratio of one staff member for each 10 inpatients or fraction thereof. In documented instances of bona fide shortages of certified persons, uncertified individuals expecting to become certified may be employed for a maximum of 38 months without qualifications;

(3) The facility shall have a minimum of two staff members providing care, treatment and services directly to patients on duty at all times and maintain a shift ratio of one staff member for each 20 or less inpatients with the following exceptions:

(A) When there are minor inpatients there shall be staff available on the ratio of one staff member for each five minor inpatients or fraction thereof during each shift from 7:00 a.m. - 11:00 p.m.;

(B) When detox services are offered there shall be no less than one staff member for each nine inpatients or fraction thereof on each shift.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5204 PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES RECORD REQUIREMENTS

(a) In addition to the general record keeping requirements of 10A NCAC 13B .3906, specialized assessment and treatment plans for individuals undergoing psychiatric or substance abuse treatment are as follows:

(1) Within 24 hours following admission each individual shall have a completed admission assessment. The initial assessment shall include the reason for admission, admitting diagnosis, mental status including suicide potential, diagnostic tests or evaluations, and a determination of the need for additional information to include the potential for the physical abuse of self or others and a family assessment when a minor is involved;

(2) Within 72 hours following admission, a preliminary individual treatment plan shall be completed and implemented; and

(3) Within five days following admission, a comprehensive individual treatment plan shall be developed and implemented. For outpatient services, the plan shall be developed and implemented within 30 days of admission to treatment.

(b) Individual treatment plans for psychiatric and substance abuse patients shall be developed in partnership with the patient or individual acting on behalf of the patient. Clinical responsibility for the development and implementation of the plan shall be clearly designated. Minimum components of the comprehensive treatment plan shall include diagnosis and time specific short and long term measurable goals, strategies for reaching goals, and staff responsibility for plan implementation. The plan shall be revised as medically or clinically indicated.

(c) Progress notes shall be entered in each individual's record. Included is information which may have a significant impact on the individual's condition or expected outcome such as family conferences or major events related to the patient. Patient status shall be documented each shift for any inpatient psychiatric or substance abuse services, and on a per visit basis for outpatient psychiatric and substance abuse services.

(d) For each individual to whom substance abuse services are provided, a written plan for aftercare services shall be developed which minimally includes:

(1) plan for delivering aftercare services, including the aftercare services which are provided; and

(2) provision for agreements with individuals or organizations if aftercare services are not provided directly by the facility.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5205 SECLUSION

At least one seclusion room shall be provided in all hospitals licensed to provide a psychiatric program, a substance abuse program or both.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5206 COMPLIANCE WITH STATUTORY REQUIREMENTS

(a) Facilities providing psychiatric or substance abuse services shall develop procedures to protect the rights of psychiatric and substance abuse patients in accordance with North Carolina statutes addressing the rights of psychiatric and substance abuse patients. Statutes addressing such rights are as follows:

(1) G.S. 122C-51. Declaration of policy on clients' rights;
(2) G.S. 122C-52. Right to confidentiality;
(3) G.S. 122C-53. Exceptions; client;
(4) G.S. 122C-54. Exceptions; abuse reports and court proceedings;
(5) G.S. 122C-55. Exceptions; care and treatment;
(6) G.S. 122C-56. Exceptions; research and planning;
(7) G.S. 122C-57. Right to treatment and consent to treatment;
(8) G.S. 122C-58. Civil rights and civil remedies;
(9) G.S. 122C-59. Use of corporal punishment;
(10) G.S. 122C-60. Use of physical restraints or seclusion;
(11) G.S. 122C-61. Treatment rights in 24-hour facilities;
(12) G.S. 122C-62. Additional rights in 24-hour facilities;
(13) G.S. 122C-65. Offenses relating to clients; and
(14) G.S. 122C-66. Protection from abuse and exploitation; reporting.

(b) Facilities providing psychiatric or substance abuse services shall develop procedures to protect confidentiality of information regarding communicable disease and conditions in compliance with G.S. 130A-143.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5207 PSYCHIATRIC OR SUBSTANCE ABUSE OUTPATIENT SERVICES

Partial hospitalization, outpatient and day treatment facilities shall be subject to 10A NCAC 27G .1100, 10A NCAC 27G .3500, and 10A NCAC 27G .3700 respectively, which are incorporated by reference with all subsequent amendments. Referenced rules are available from the N.C. Division of Mental Health, Developmental Disabilities, and Substance Abuse Services, Advocacy, Client Rights and Quality Improvement Section, 3009 Mail Service Center, Raleigh, NC 27699-3009 at a cost of five dollars and seventy-five cents ($5.75) per copy.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

SECTION .5300 - NURSING AND ADULT CARE HOME BEDS

10A NCAC 13B .5301 THE LICENSURE OF NURSING AND ADULT CARE HOME BEDS IN A HOSPITAL

When a facility has nursing facility beds or adult care home beds, the beds shall be provided under the hospital's license as provided in Rule .3101 of this Subchapter. The nursing facility beds and the adult care home beds shall be subject to the rules in 10A NCAC 13D with the exception that the following rules shall not apply: 10A NCAC 13D .2001(4); .2101 - .2108; .2201; .2208; .2209; .2211; .2212; .2302; .2401; .2402; .2503; .2504; .2602; .2607; .2701; and .2901. With these exceptions, the rules in 10A NCAC 13D are incorporated by reference with all subsequent amendments. Referenced rules are available from the NC Division of Health Service Regulation, 2711 Mail Service Center, Raleigh, N.C. 27699-2711 at a cost of six dollars ($6.00) per copy.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

SECTION .5400 - COMPREHENSIVE INPATIENT REHABILITATION

10A NCAC 13B .5401 DEFINITIONS

The following definitions shall apply to inpatient rehabilitation facilities or units only:

(1) "Case management" means the coordination of services, for a given patient, between disciplines so that the patient may reach optimal rehabilitation through the judicious use of resources.

(2) "Comprehensive, inpatient rehabilitation program" means a program for the treatment of persons with functional limitations or chronic disabling conditions who have the potential to achieve a significant improvement in activities of daily living. A comprehensive, rehabilitation program shall utilize a coordinated and integrated, interdisciplinary approach, directed by a physician, to assess patient needs and to provide treatment and evaluation of physical, psycho-social and cognitive deficits.

(3) "Inpatient rehabilitation facility or unit" means a free-standing facility or a unit (unit pertains to contiguous dedicated beds and spaces) approved in accordance with G.S. 131E, Article 9 to establish inpatient, rehabilitation beds and to provide a comprehensive, inpatient rehabilitation program within an existing licensed health service facility.

(4) "Medical consultations" means consultations which the rehabilitation physician or the attending physician determine are necessary to meet the acute medical needs of the patient and do not include routine medical needs.

(5) "Occupational therapist" means any individual licensed in the State of North Carolina as an occupational therapist in accordance with the provisions of G.S. 90, Article 18D.

(6) "Occupational therapist assistant" means any individual licensed in the State of North Carolina as an occupational therapist assistant in accordance with the provisions of G.S. 90, Article 18D.

(7) "Psychologist" means a person licensed as a practicing psychologist in accordance with G.S. 90, Article 18A.

(8) "Physiatrist" means a licensed physician who has completed a physical medicine and rehabilitation residency training program approved by the Accreditation Council of Graduate Medical Education or the American Osteopathic Association.

(9) "Physical therapist" means any person licensed in the State of North Carolina as a physical therapist in accordance with the provisions of G.S. 90, Article 18B.

(10) "Physical therapist assistant" means any person licensed in the State of North Carolina as a physical therapist assistant in accordance with the provisions of G.S. 90-270.24, Article 18B.

(11) "Recreational therapist" means a person certified by the State of North Carolina Therapeutic Recreational Certification Board.

(12) "Rehabilitation aide" means an unlicensed assistant who works under the supervision of a registered nurse, licensed physical therapist or occupational therapist in accordance with the appropriate occupational licensure laws governing his or her supervisor and consistent with staffing requirements as set forth in Rule .5508 of this Section. The rehabilitation aide shall be listed on the North Carolina Nurse Aide Registry and have received additional staff training as listed in Rule .5509 of this Section.

(13) "Rehabilitation nurse" means a registered nurse licensed in North Carolina, with training, either academic or on-the-job, in physical rehabilitation nursing and at least one year experience in physical rehabilitation nursing.

(14) "Rehabilitation physician" means a physiatrist or a physician who is qualified, based on education, training and experience regardless of specialty, of providing medical care to rehabilitation patients.

(15) "Social worker" means a person certified by the North Carolina Social Work Certification and Licensure Board in accordance with G.S. 90B-3.

(16) "Speech and language pathologist" means any person licensed in the State of North Carolina as a speech and language pathologist in accordance with the provisions of G.S. 90, Article 22.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5402 PHYSICIAN REQUIREMENTS FOR INPATIENT REHABILITATION FACILITIES OR UNITS

(a) In a rehabilitation facility or unit, a physician shall participate in the provision and management of rehabilitation services and in the provision of medical services.

(b) In a rehabilitation facility or unit, a rehabilitation physician shall be responsible for a patient's interdisciplinary treatment plan. Each patient's interdisciplinary treatment plan shall be developed and implemented under the supervision of a rehabilitation physician.

(c) The rehabilitation physician shall participate in the preliminary assessment within 48 hours of admission, prepare a plan of care and direct the necessary frequency of contact based on the medical and rehabilitation needs of the patient. The frequency shall be appropriate to justify the need for comprehensive inpatient rehabilitation care.

(d) An inpatient rehabilitation facility or unit's contract or agreements with a rehabilitation physician shall require that the rehabilitation physician shall participate in individual case conferences or care planning sessions and shall review and sign discharge summaries and records. When patients are to be discharged to another health care facility, the discharging facility shall ensure that the patient has been provided with a discharge plan which incorporates post discharge continuity of care and services. When patients are to be discharged to a residential setting, the facility shall ensure that the patient has been provided with a discharge plan that incorporates the utilization of community resources when available and when included in the patient's plan of care.

(e) The intensity of physician medical services and the frequency of regular contacts for medical care for the patient shall be determined by the patient's pathophysiologic needs.

(f) Where the attending physician of a patient in an inpatient rehabilitation facility or unit orders medical consultations for the patient, such consultations shall be provided by qualified physicians within 48 hours of the physician's order. In order to achieve this result, the contracts or agreements between inpatient rehabilitation facilities or units and medical consultants shall require that such consultants render the requested medical consultation within 48 hours.

(g) An inpatient rehabilitation facility or unit shall have a written procedure for setting the qualifications of the physicians, rendering physical rehabilitation services in the facility or unit.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5403 ADMISSION CRITERIA FOR INPATIENT REHABILITATION FACILITIES OR UNITS

(a) The facility shall have written criteria for admission to the inpatient rehabilitation facility or unit. A description of programs or services for screening the suitability of a given patient for placement shall be available to staff and referral sources.

(b) For patients found unsuitable for admission to the inpatient rehabilitation facility or unit, there shall be documentation of the reasons.

(c) Within 48 hours of admission, a preliminary assessment shall be completed by members of the interdisciplinary team to insure the appropriateness of placement and to identify the immediate needs of the patients.

(d) Patients admitted to an inpatient rehabilitation facility or unit must be able to tolerate a minimum of three hours of rehabilitation therapy, five days a week, including at least two of the following rehabilitation services: physical therapy, occupational therapy or speech therapy.

(e) Patients admitted to an inpatient rehabilitation facility or unit must be medically stable, have a prognosis indicating a progressively improved medical condition and have the potential for increased independence.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5404 COMPREHENSIVE INPATIENT REHABILITATION EVALUATION

(a) A comprehensive, inpatient rehabilitation evaluation is required for each patient admitted to an inpatient rehabilitation facility or unit. At a minimum this evaluation shall include the reason for referral, a summary of the patient's clinical condition, functional strengths and limitations, and indications for specific services. This evaluation shall be completed within three days.

(b) Each patient shall be evaluated by the interdisciplinary team to determine the need for any of the following services: medical, dietary, occupational therapy, physical therapy, prosthetics and orthotics, psychological assessment and therapy, therapeutic recreation, rehabilitation medicine, rehabilitation nursing, therapeutic counseling or social work, vocational rehabilitation evaluation and speech-language pathology.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5405 COMPREHENSIVE INPATIENT REHABILITATION INTER-DISCIPLINARY TREAT/PLAN

(a) The interdisciplinary treatment team shall develop an individual treatment plan for each patient within seven days after admission. The plan shall include evaluation findings and information about the following:

(1) prior level of function;
(2) current functional limitations;
(3) specific service needs;
(4) treatment, supports and adaptations to be provided;
(5) specified treatment goals;
(6) disciplines responsible for implementation of separate parts of the plan; and
(7) anticipated time frames for the accomplishment of specified long-term and short-term goals.

(b) The treatment plan shall be reviewed by the interdisciplinary team at least every other week. All members of the interdisciplinary team, or a representative of their discipline, shall attend each meeting. Documentation of each review shall include progress toward defined goals and identification of any changes in the treatment plan.

(c) The treatment plan shall include provisions for all of the services identified as needed for the patient in the comprehensive inpatient rehabilitation evaluation completed in accordance with Rule .5404 of this Section.

(d) Each patient shall have a designated case manager who shall be responsible for the coordination of the patient's individualized treatment plan. The case manager shall be responsible for promoting the program's responsiveness to the needs of the patient and shall participate in all team conferences concerning the patient's progress toward the accomplishment of specified goals. Any of the professional staff involved in the patient's care may be the designated case manager for one or more cases.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5406 DISCHARGE CRITERIA FOR INPATIENT REHABILITATION FACILITIES OR UNITS

(a) Discharge planning shall be an integral part of the patient's treatment plan and shall begin upon admission to the facility. After goals of care have been reached, or a determination by the interdisciplinary care team has been made to return to the setting from which the patient was admitted, or that further progress is unlikely, the patient shall be discharged to another inpatient or residential health care facility that can address the patient's needs including skilled nursing homes, assisted living facilities, nursing homes, or other hospitals. Other reasons for discharge may include an inability or unwillingness of patient or family to cooperate with the planned therapeutic program or medical complications that preclude a further intensive rehabilitative effort. The facility shall involve the patient, family, staff members, and community-based services such as home health services, hospice or palliative care, respiratory services, rehabilitation services to include occupational therapy, physical therapy, and speech therapy, end stage renal disease, nutritional, medical equipment and supplies, transportation services, meal services, and household services such as housekeeping in discharge planning.

(b) The case manager shall facilitate the discharge or transfer process in coordination with the facility social worker.

(c) If a patient is being referred to another facility for further care, documentation of the patient's current status shall be forwarded with the patient. A discharge summary shall be forwarded within 48 hours following discharge and shall include the reasons for referral, the diagnosis, functional limitations, services provided, the results of services, referral action recommendations, and activities and procedures used by the patient to maintain and improve functioning.

History Note: *Authority G.S. 143B-165;*
Eff. March 1, 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .5407 COMPREHENSIVE REHABILITATION PERSONNEL ADMINISTRATION

(a) The facility shall have qualified staff members, consultants and contract personnel to provide services to the patients admitted to the inpatient rehabilitation facility or unit.

(b) Personnel shall be employed or provided by contractual agreement in sufficient types and numbers to meet the needs of all patients admitted for comprehensive rehabilitation.

(c) Written agreements shall be maintained by the facility when services are provided by contract on an ongoing basis.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5408 COMPREHENSIVE INPATIENT REHABILITATION PROGRAM STAFFING REQUIREMENTS

(a) The staff of the inpatient rehabilitation facility or unit shall include:

(1) the inpatient rehabilitation facility or unit shall be supervised by a rehabilitation nurse as defined in Rule .5401 of this Section. The facility shall assign staff qualified to meet the needs of the patient;

(2) the minimum nursing hours per patient in the rehabilitation unit shall be 5.5 nursing hours per patient day. At no time shall direct care nursing staff be less than two full-time equivalents, one of which must be a registered nurse;

(3) the inpatient rehabilitation unit shall employ or provide by contractual agreements therapists to provide three hours of specific (physical, occupational or speech) or combined rehabilitation therapy services per patient day;

(4) rehabilitation aides shall have documented training appropriate to the activities to be performed and the occupational licensure laws of his or her supervisor. Supervision by the physical therapist or by the occupational therapist is limited to that time when the therapist is on-site and directing the rehabilitation activities of the aide; and

(5) hours of service by the rehabilitation aide are counted toward the required nursing hours when the aide is working under the supervision of the nurse. Hours of service by the rehabilitation aide are counted toward therapy hours during that time the aide works under the immediate, on-site supervision of the physical therapist or occupational therapist. Hours of service shall not be dually counted for both services. Hours of service by rehabilitation aides in performing nurse-aide duties in areas of the facility other than the rehabilitation unit shall not be counted toward the 5.5 hour minimum nursing requirement described for the rehabilitation unit.

(b) Additional personnel shall be provided as required to meet the needs of the patient, as defined in the comprehensive inpatient rehabilitation evaluation.

History Note: *Authority G.S. 143B-165;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .5409 STAFF TRAINING FOR INPATIENT REHABILITATION FACILITIES OR UNIT

Prior to the provision of care, all rehabilitation personnel, excluding physicians, assigned to the rehabilitation unit shall be provided training or shall provide documentation of training that includes at a minimum the following:

(1) active and passive range of motion;
(2) assistance with ambulation;
(3) transfers;
(4) maximizing functional independence;
(5) the psycho-social needs of the rehabilitation patient;
(6) the increased safety risks of rehabilitation training (including falls and the use of restraints);
(7) proper body mechanics;
(8) nutrition, including dysphagia and restorative eating;
(9) communication with the aphasic and hearing impaired patient;
(10) behavior modification;
(11) bowel and bladder training; and
(12) skin care.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5410 EQUIPMENT REQUIREMENTS/COMPREHENSIVE INPATIENT REHABILITATION PROGRAMS

(a) The facility shall provide each discipline with the necessary equipment and treatment methods to achieve the short and long-term goals specified in the comprehensive inpatient rehabilitation interdisciplinary treatment plans for patients admitted to these facilities or units.

(b) Each patient's needs for a standard wheelchair or a specially designed wheelchair or additional devices to allow safe and independent mobility within the facility shall be met.

(c) Special physical therapy and occupational therapy equipment for use in fabricating positioning devices for beds and wheelchairs shall be provided including splints, casts, cushions, wedges and bolsters.

(d) Physical therapy devices shall be provided, including a mat, table, parallel bars, sliding boards, and special adaptive bathroom equipment.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5412 ADDITIONAL REQUIREMENTS FOR TRAUMATIC BRAIN INJURY PATIENTS

(a) Inpatient rehabilitation facilities providing services to patients with traumatic brain injuries shall provide staff to meet the needs of patients in accordance with the patient assessment, treatment plan, and physician orders.

(b) The facility shall provide special equipment to meet the needs of patients with traumatic brain injury, including specially designed wheelchairs, tilt tables and standing tables.

(c) The facility shall provide the consulting services of a neuropsychologist.

(d) The facility shall provide continuing education in the care and treatment of brain injury patients for all staff.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;
Readopted Eff. April 1, 2020.

10A NCAC 13B .5413 ADDITIONAL REQUIREMENTS FOR SPINAL CORD INJURY PATIENTS

(a) Inpatient rehabilitation facilities providing services to patients with spinal cord injuries shall provide staff to meet the needs of patients in accordance with the patient assessment, treatment plan, and physician orders.

(b) The facility shall provide special equipment to meet the needs of patients with spinal cord injury, including specially designed wheelchairs, tilt tables and standing tables.

(c) The facility shall provide continuing education in the care and treatment of spinal cord injury patients for all staff.

(d) The facility shall provide specific staff training and education in the care and treatment of spinal cord injury.

History Note: *Authority G.S. 131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;
Readopted Eff. April 1, 2020.

10A NCAC 13B .5414 DEEMED STATUS FOR INPATIENT REHABILITATION FACILITIES OR UNIT

(a) If an inpatient rehabilitation facility or unit with a comprehensive inpatient rehabilitation program is surveyed and accredited by The Joint Commission (TJC) or the Commission on Accreditation of Rehabilitation Facilities (CARF) and has been approved by the Department in accordance with G.S. 131E, Article 9, the Department deems the facility to be in compliance with Rules .5401 through .5413 of this Section.

(b) Deemed status shall be provided only if the inpatient rehabilitation facility or unit provides copies of survey reports to the Department. The TJC report shall show that the facility or unit was surveyed for rehabilitation services. The CARF report shall show that the facility or unit was surveyed for comprehensive rehabilitation services. The facility or unit shall sign an agreement (Memorandum of Understanding) with the Department specifying these terms.

(c) The inpatient rehabilitation facility or unit shall be subject to inspections or complaint investigations by representatives of the Department at any time. If the facility or unit is found not to be in compliance with the rules listed in Paragraph (a) of this Rule, the facility shall submit a plan of correction and be subject to a follow-up visit to ensure compliance.

(d) If the inpatient rehabilitation facility or unit loses or does not renew its accreditation, the facility or unit shall notify the Division in writing within 30 days.

History Note: *Authority G.S. 131E-79;*
Eff. March 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017;
Amended Eff. October 1, 2019.

SECTION .5500 – SUPPLEMENTAL RULES FOR HOSPITALS PROVIDING LIVING ORGAN DONATION TRANSPLANT SERVICES

10A NCAC 13B .5501 APPLICABILITY OF RULES

The rules contained in this Section shall apply to hospitals providing living organ donation transplant services.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
Eff. April 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5502 INDEPENDENT DONOR ADVOCATE TEAM

(a) The facility shall appoint an Independent Donor Advocate Team (IDAT) whose sole purpose is to represent and ensure the well-being of the potential donor, making sure he or she is aware of the risks and benefits of donation and that the choice to donate is voluntary. The IDAT shall ensure the potential donor learns about the entire donation process. This would include the selection of recipients for the transplant, the procedures to be employed for both the donor and recipient, and possible outcomes. Sufficient time for the discussion, supplemented with written materials, must be allowed for comprehension and assimilation of the information about transplantation and the ramifications of donation. Written and verbal presentations shall be in language in accordance with the person's ability to understand.

(b) The IDAT shall consist of a physician, a clinical transplant coordinator, and a social worker or qualified mental health professional as defined in Rule .5202(k) of this Subchapter. The physician shall be the leader of the IDAT. The IDAT members shall have experience in organ transplantation processes and programs and shall be able to act for the interests of the potential donor independent of any financial or facility influence. Based on the outcome of the evaluation of the potential donor pursuant to Rule .5504 of this Section, if the IDAT determines any potential donor is unsuitable for donation, it shall provide the reasons both verbally and in writing.

(c) In order to ensure the well-being of the potential donor, the IDAT shall:

(1) Protect and represent the interests of the potential donor;
(2) Make it clear to the potential donor that the choice to donate is entirely his or hers;
(3) Inform and discuss with the potential donor the medical, psychosocial and financial aspects related to the live donation;
(4) Explain to the potential donor the evaluation process, what it means and his or her option to stop at any time;
(5) Determine the intellectual and emotional ability of the potential donor to understand the legal and ethical aspects of informed choice;
(6) Assess if the potential donor has understood the risks and the benefits and how they impact on his or her own core beliefs and values; and
(7) Identify for the potential donor resources that will be available to provide continuous care during hospitalization and referrals in medicine, psychiatry or social work, which may be needed or required following discharge.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
Eff. May 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5503 INFORMED CHOICE

(a) The potential donor must be free to make an informed independent decision, which has been termed informed choice. Informed choice addresses the decision process of the potential donor as he or she determines whether or not to donate. Informed choice has several aspects. First, the potential donor must know he or she has a choice, meaning he or she can freely decide either to donate or not to donate an organ. Second, the potential donor must be aware of both the risks and benefits of donation. The potential donor must be able to weigh the positive aspects of the donation as well as take into account the technical aspects such as the surgery, recovery, financial impact and any unexpected but potential consequences that may result such as a change in the patient's life, health, insurability, employment or emotional stability.

(b) The person who consents to be a live organ donor shall be:

(1) Legally competent;
(2) Willing to donate;
(3) Free from coercion, including financial coercion, actual or implied;
(4) Medically suitable;
(5) Informed and able to express understanding of the risks and benefits of donation; and
(6) Informed of the risks, benefits and alternative treatment regimens available to the recipient.

(c) A statement signed by the potential donor that his or her participation is completely voluntary and may be withdrawn at any time shall be placed in the medical record.

(d) Understanding

(1) The potential donor shall be able to demonstrate that he or she understands the essential elements of the donation process with emphasis on the risks associated with the procedure;
(2) With the potential donor's permission, the donor's designee, family or next of kin shall be given the opportunity to openly discuss the donor's concerns in a safe and non-threatening environment; and
(3) The potential donor shall understand, agree to, and commit to postoperative follow-up and testing by the facility performing the surgical removal of the organ and subsequent organ transplant.

(e) Disclosure

(1) The donor surgical team and the IDAT shall disclose any facility affiliations to the potential donor;
(2) The potential donor shall have a period of reflection appropriate to the acuity of the clinical condition of the recipient and reaffirmation of the decision to donate subsequent to the completion of the medical work-up and final approval to proceed by the IDAT. After the period of reflection the potential donor may sign the consent for the donation procedure;
(3) Non-English speaking candidates and hearing impaired candidates must be provided with a non-family interpreter who understands the donor's language and culture;
(4) A member of the IDAT shall witness the potential donor signing the consent documents for removal of the donor organ; and
(5) The overall donation process and experience shall be explained to the potential donor and shall be provided in writing to include:
    (A) Donor evaluation procedure;
    (B) Surgical procedure;
    (C) Recuperative period;
    (D) Short-term and long term follow-up care;
    (E) Alternative donation and transplant procedure;
    (F) Potential psychological benefits to donor;
    (G) Transplant facility and surgeon-specific statistics of donor and recipient outcomes;
    (H) Confidentiality of the donor's information and decisions;
    (I) Donor's ability to opt out at any point in the process;
    (J) Information about how the facility performing the transplant will attempt to follow the health of the donor; and
    (K) Need for the donor to review potential personal insurability for future insurance coverage.

(f) The IDAT shall make the potential donor aware of the following risk factors:

(1) Physical
    (A) Potential for surgical complications including risk of donor death;
    (B) Potential for organ failure and the need for future organ transplant for the donor;

(C) Potential for other medical complications including long-term complications and complications currently unforeseen;
(D) Scars;
(E) Pain;
(F) Fatigue; and
(G) Abdominal or bowel symptoms such as bloating and nausea.

(2) Psychosocial
(A) Potential for problems with body image;
(B) Possibility of transplant recipient death;
(C) Possibility of transplant recipient rejection and need for re-transplantation;
(D) Possibility of recurrent disease in a transplant recipient;
(E) Possibility of post surgery adjustment problems;
(F) Impact on the donor's family or next of kin;
(G) Impact on the transplant recipient's family or next of kin; and
(H) Potential impact of donation on the donor's lifestyle.

(3) Financial
(A) Out of pocket expenses;
(B) Child care costs;
(C) Possible loss of employment;
(D) Potential impact on the ability to obtain future employment; and
(E) Potential impact on the ability to obtain or afford health and life insurance.

(g) The potential donor shall provide assurance and consent that the following areas have been addressed:
(1) That there is no monetary profit to the potential donor. Coverage for expenses incurred as a result of the organ donation is not considered monetary profit;
(2) That family members or others did not coerce the potential donor into making his or her decision;
(3) That the potential donor has been provided with a general statement of unsuitability for donation if requested. Medical information regarding the potential donor shall not be falsified to provide the donor with an excuse to decline donation;
(4) That the potential donor is intellectually and emotionally capable of participation in a discussion of potential risks and benefits;
(5) That the potential donor has been provided adequate information to ensure his or her understanding regarding the risks of the donation;
(6) That the potential donor has been educated regarding the recipient's options for organs from deceased persons, including risks and outcomes; and
(7) That the potential donor understands that he or she may decline to donate at any time.

(h) Documentation
(1) A medical record, separate and distinct from the transplant recipient's record, shall be maintained to protect donor confidentiality; and
(2) The informed choice process and evaluation protocol shall be documented and placed in the potential donor's medical record.

(i) Decision to Donate. Once the IDAT determines the suitability of the potential donor the IDAT shall discuss with the potential donor's surgical team and transplant team its decision prior to its presentation to the potential donor. If the potential donor wishes to donate, but the IDAT does not agree, the IDAT's opposition shall be so noted in a report to the donor surgeon, who shall document reasons for proceeding against the IDAT advice. The reason why the IDAT has objections shall be explained to the potential donor. For example, the potential donor may not have the ability to understand the information provided to him or her or the donor may be unable to integrate the degree of risk pertinent to his or her situation or there may be a lack of balance between the risks to the potential donor and potential benefits to the transplant recipient. Even if the potential donor is willing to donate his or her organ, the final review and decision whether or not to proceed with the donation rests with the donor surgical team and transplant team.

(j) In cases involving living liver donation, prior to reaching a decision to donate the potential donor shall be provided in writing the U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation (ACOT) recommendations entitled "Living Liver Donor Initial Consent for Evaluation" which is hereby incorporated by reference with all subsequent amendments. The ACOT recommendations can be obtained free of charge via the internet at: http://www.organdonor.gov/acotrecs.html. The items contained in the ACOT recommendations must be explained to the potential donor in language and terms which he or she can understand

and then be signed by the donor and the signature witnessed. Subsequent to this, if all the facts show that the potential donor is, in fact, in all respects a viable potential donor, then he or she shall execute the ACOT recommended form entitled "Living Liver Donor Informed Consent for Surgery" which is hereby incorporated by reference with all subsequent amendments. In addition, this form shall comply with G.S. 90-21.13 Informed Consent which is hereby incorporated by reference with all subsequent amendments.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
Eff. May 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5504 EVALUATION PROTOCOL FOR LIVING ORGAN DONORS

Hospitals shall complete the following evaluation protocols prior to living organ donation:

(1) The facility shall confirm the potential donor's ABO blood type.

(2) Only individuals 18 years of age or older shall be considered for living organ donation. The facility shall complete a screening interview with the potential donor which confirms the donor's age, height, weight, demographic information, medical and surgical history, medications, drug or alcohol history, smoking history, and a family or social history. Insurance issues (health and life) shall also be discussed with the potential donor and an attempt shall be made to answer any questions asked by the donor. Written information on the living donor process shall be made available to the potential donor.

(3) The donor surgical team shall determine whether the potential donor shall be excluded based on the medical information or family history: for example, exclusionary criteria may include the presence of diabetes, uncontrolled hypertension, liver, pulmonary or cardiac disease, renal dysfunction or high Body Mass Index (BMI).

(4) An IDAT shall be assigned for the potential donor pursuant to Rule .5502(c) of this Section. The IDAT leader shall not be a physician who is the primary physician of the potential transplant recipient.

(5) The IDAT leader shall conduct a medical evaluation of the potential donor. The medical evaluation shall include a full and frank discussion of the risks associated with the evaluation tests with the potential donor and the donor's chosen designee. If the potential donor wishes to proceed, laboratory and diagnostic tests shall be ordered as necessary.

(6) An IDAT member shall conduct a psychosocial evaluation of the potential donor. The IDAT member shall also discuss financial considerations.

(7) The IDAT shall review the laboratory and diagnostic test results, as well as psychosocial evaluation and discuss them with the donor to decide whether to move forward with the potential donor's evaluation.

(8) The donor surgeon shall evaluate the mortality and morbidity risks associated with donation and disclose those risks to the potential donor with adequate time for any questions to be answered in detail. The donor's designee shall also be present at this appointment.

(9) The IDAT shall perform a final review and makes its recommendation as set out in Rule .5503(i) of this Section.

(10) The hospital shall schedule an appointment for pre-operative screening with the potential donor after the entire process of evaluation is complete. An informed consent as required in Rule .4605(c)(2) of this Subchapter is necessary for the donation and surgical procedure and shall be completed by this time. In addition, where applicable, the potential donor shall be given ample time for autologous blood donation through the American Red Cross.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
Eff. May 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5505 PERIOPERATIVE CARE AND FACILITY SUPPORT

(a) The donor surgical team shall have primary concern and responsibility for the donor's care and welfare throughout his or her entire hospital stay. The donor surgical team consists of the donor surgeon, his or her surgical and medical partners, fellows, residents, and physician assistants or nurse practitioners.

(b) Preoperative Preparation

(1) The facility shall have the ability to allow donors to bank a minimum of one unit of blood before surgery. Facilities shall have the ability to store and transfuse autologous blood;

(2) The transplant coordinator or another team member shall be assigned the responsibility of providing updates to the families of both the donor and transplant recipient during the surgical procedures; and

(3) For live donor liver procedures, surgeries shall be scheduled only when staffing will be available for the postoperative period. If surgery is scheduled on a Thursday or Friday, the hospital shall ensure that there is adequate attending physician, resident physician, physician assistant or nurse practitioner, and registered nursing coverage during the weekend.

(c) Postoperative Care

(1) After live donor nephrectomy, the patient shall receive post-operative care equivalent to that provided for abdominal procedures under general anesthesia; and

(2) For live liver donors:

(A) Day 0-1: The live adult liver donor shall receive care in the intensive care unit (ICU) or post-anesthesia care unit (PACU);

(B) Day 2: If stable and cleared for transfer by the donor surgical team, the donor shall be cared for in a hospital unit that is dedicated to the care of transplant recipients or a hospital unit in which patients who undergo hepatobiliary resectional surgery are provided care. Liver donors shall not at any time be cared for on any other unit unless a specific medical condition of the donor warrants such a transfer;

(C) The donor shall be evaluated at least daily by a liver transplant attending physician with documentation in the medical record;

(D) The donor surgical team shall be responsible for the clinical management of the donor;

(E) The patient care staff shall be familiar with the common complications associated with the donor and transplant recipient operations and have appropriate monitoring in place to detect these problems if they arise; and

(F) If there is an emergent complication requiring re-operation, these patients shall be prioritized for access to the operating room based on the facility's operating room policies and guidelines.

(d) Medical Staffing. For live donor nephrectomy patients, there shall be continuous physician coverage available for patient evaluation as needed. These patients shall be provided post-operative care equivalent to patients undergoing a nephrectomy.

(e) Nurse Staffing

(1) Nursing staff shall be familiar with recovery of nephrectomy patients. They shall be aware of the signs and symptoms of hypovolemia due to post-operative bleeding or to excessive diuresis. They shall have ready access to the surgical team responsible for the patient's post-operative care;

(2) For live liver donors, nursing staff shall have ongoing education and training in live donor liver transplantation nursing care for both donors and recipients. This shall include education on the pain management issues particular to the donor. The registered nursing to patient ratio in the ICU or PACU level setting shall be appropriate for the acuity level of the patients. For live liver donors, the same registered nurse shall not take care of both the donor and the recipient. For live liver donors, the nursing service shall provide the potential donor with pre-surgical information including, if possible, a tour of the unit before surgery; and

(3) For all donors, the names and beeper numbers of the donor surgical team or team responsible for the donor's post-operative surgical care (e.g. urology service or laparoscopic general surgery service for some donor nephrectomy patients) shall be posted on all units receiving transplant donors.

(f) Radiology. For facilities performing live donor nephrectomies, radiological staff shall be available for pre-operative assessment, peri-operative care, and post-operative follow-up as required.

History Note: Authority G.S. 131E-75; 131E-79; 143B-165;

Eff. April 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .5506 DISCHARGE PLANNING

(a) Pre-Donation. At the time of evaluation by the IDAT, a discussion shall be held between the IDAT social worker and the potential donor and his or her family or next of kin to address the following areas:

(1) Living arrangements after discharge from the surgery or while the donor recuperates until able to travel;

(2) Transportation arrangements from the hospital to the donor's accommodations or back to follow up appointments;

(3) Caregivers to provide assistance or support upon discharge; if the donor has children or other dependents, a plan for the children's or dependent's care while the donor recuperates;

(4) Financial considerations: Encourage donor to discuss with employer about medical leave or disability. This discussion shall include checking with health or life insurance carriers about future "pre-existing conditions" or "exclusions" that may result from donation;

(5) Provided consent is first obtained, referrals to other living organ donors from that particular facility and suggestions from other resources such as publications and websites; and

(6) Emotional issues surrounding the organ donation process.

(b) Day of Discharge

(1) A written discharge plan shall be provided to the donor with the following instructions:

(A) Restrictions on activities;

(B) Permitted activities (i.e. return to work);

(C) Diet;

(D) Pain medication with prescription;

(E) Follow up appointments with surgeon;

(F) Contact numbers for the Independent Donor Advocate Team should the donor have questions, concerns or problems; and

(G) Additional instructions for caregivers, if any.

(2) The discharge plan shall be reviewed with the donor by the facility discharge planner or primary care nurse.

(c) Post Discharge medical follow-up, social, psychological and financial support

(1) Post-operative visits shall be scheduled by the donor with the surgeon to assess the following:

(A) Wound healing;

(B) Signs and symptoms of infections; and

(C) Laboratory results as appropriate to the organ type, as well as any imaging or other diagnostic findings.

(2) Dictated summaries of surgery and follow-up visits shall be sent to the donor's primary care physician by the facility to ensure appropriate medical care.

(3) Referrals shall be made to community agencies to address the donor's emotional and psychological issues if needed or requested by the donor, his or her designee, family, next of kin or the IDAT to;

(A) Provide the donor the opportunity to participate in a support group; and

(B) Provide the donor recognition as determined by the facility.

(d) Any questions or concerns regarding the discharge plan or discharge planning process by the donor, the donor's designee, the donor's next of kin or legally responsible party shall be addressed by facility staff.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
Eff. April 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.

10A NCAC 13B .6003 DEFINITIONS

In addition to the definitions set forth in G.S. 131E-76, the following definitions shall apply in Sections .6000 through .6200 of this Subchapter:

(1) "Addition" means an extension or increase in floor area or height of a building.

(2) "Alteration" means any construction or renovation to an existing building other than construction of an addition.

(3) "Construction documents" means final building plans and specifications for the construction of a facility that a governing body submits to the Construction Section for approval as specified in Rule .3102 of this Subchapter.

(4) "Construction Section" means the Construction Section of the Division of Health Service Regulation.

(5) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.

(6) "Facility" means a hospital as defined in G.S. 131E-76.

History Note: *Authority G.S. 131E-76; 131E-79; S.L. 2017-174;*
Temporary Adoption Eff. December 1, 2017;
Eff. March 21, 2019

SECTION .6100 – GENERAL REQUIREMENTS

10A NCAC 13B .6101 LIST OF REFERENCED CODES, RULES, REGULATIONS, AND STANDARDS

For the purposes of the rules in this Subchapter, the following codes, rules, regulations, and standards are incorporated herein by reference including subsequent amendments and editions. Copies of these codes, rules, regulations, and standards may be obtained or accessed from the online addresses listed:

(1) the North Carolina State Building Codes with copies that may be purchased from the International Code Council online at http://shop.iccsafe.org/ at a cost of five hundred seventy-one dollars ($571.00) or accessed electronically free of charge at http://codes.iccsafe.org/North%20Carolina.html;

(2) 42 CFR Part 482.41, Condition of Participation: Physical Plant, that is incorporated herein by reference including all subsequent amendments and editions; however, Part 482.41(c)(1) shall not be incorporated by reference. Copies of this regulation may be accessed free of charge at https://www.gpo.gov/fdsys/pkg/CFR-2017-title42-vol5/xml/CFR-2017-title42-vol5-sec482-41.xml or purchased online at https://bookstore.gpo.gov/products/cfr-title-42-pt-482-end-code-federal-regulationspaper-201-7 for a cost of seventy-seven dollars ($77.00);

(3) the following National Fire Protection Association standards, codes, and guidelines with copies of these standards, codes, and guidelines that may be accessed electronically free of charge at https://www.nfpa.org/Codes-and-Standards/All-Codes-and-Standards/List-of-Codes-and-Standards or may be purchased online at https://catalog.nfpa.org/Codes-and-Standards-C3322.aspx for the costs listed:

(a) NFPA 22, Standard for Water Tanks for Private Fire Protection for a cost of fifty-four dollars ($54.00);

(b) NFPA 53, Recommended Practice on Materials, Equipment, and Systems Used in Oxygen-Enriched Atmospheres for a cost of fifty-three dollars ($53.00);

(c) NFPA 59A, Standard for the Production, Storage, and Handling of Liquefied Natural Gas for a cost of fifty-four dollars ($54.00);

(d) NFPA 255, Standard Method of Test of Surface Burning Characteristics of Building Materials for a cost of forty-two dollars ($42.00);

(e) NFPA 407, Standard for Aircraft Fuel Servicing for a cost of forty-nine dollars ($49.00);

(f) NFPA 705, Recommended Practice for a Field Flame Test for Textiles and Films for a cost of forty-two dollars ($42.00);

(g) NFPA 780, Standard for the Installation of Lightning Protection Systems for a cost of sixty-three dollars and fifty cents ($63.50);

(h) NFPA 801, Standard for Fire Protection for Facilities Handling Radioactive Materials for a cost of forty-nine dollars ($49.00); and

(i) Fire Protection Guide to Hazardous Materials for a cost of one hundred and thirty-five dollars and twenty-five cents ($135.25);

(4) 42 CFR Part 482.15 Condition of participation: Emergency preparedness with copies of this regulation that may be accessed free of charge at https://www.gpo.gov/fdsys/pkg/CFR-2017-title42-vol5/xml/CFR-2017-title42-vol5-sec482-15.xml or purchased online at https://bookstore.gpo.gov/products/cfr-title-42-pt-482-end-code-federal-regulationspaper-201-7 for a cost of seventy-seven dollars ($77.00);

(5) the "Rules Governing the Sanitation of Hospitals, Nursing Homes, Adult Care Homes, and Other Institutions" 15A NCAC 18A .1300 with copies of these rules that may be accessed electronically free of charge at http://reports.oah.state.nc.us/ncac/title%2015a%20-%20environmental%20quality/chapter%2018%20-%20environmental%20health/subchapter%20a/15a%20ncac%2018a%20.1301.pdf; and

(6) the rules for ambulatory surgical facilities in 10A NCAC 13C, Licensing of Ambulatory Surgical Facilities with copies of these rules that may be accessed electronically free of charge at http://reports.oah.state.nc.us/ncac/title%2010a%20-%20health%20and%20human%20services/chapter%2013%20-%20nc%20medical%20care%20commission/subchapter%20c/subchapter%20c%20rules.pdf.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;

Readopted Eff. April 1, 2019.

10A NCAC 13B .6102 GENERAL

(a) A new facility or any addition or alteration to an existing facility whose construction documents were approved by the Construction Section on or after April 1, 2019 shall comply with the requirements provided in the codes, regulations, rules, and standards incorporated by reference in Rule .6101(1) through (3) of this Section. An existing facility whose construction documents were approved by the Construction Section prior to April 1, 2019 shall comply with the codes, regulations, rules, and standards incorporated by reference in Rule .6101(1) through (3) of this Section that were in effect at the time construction documents were approved by the Construction Section.

(b) The facility shall develop and maintain an emergency preparedness program as required by 42 CFR Part 482.15 Condition of Participation: Emergency Preparedness. The emergency preparedness program shall be developed with input from the local fire department and local emergency management agency. Documentation required to be maintained by 42 CFR Part 482.15 shall be maintained at the facility for at least three years and shall be made available to the Division during an inspection upon request.

(c) The facility shall comply with the "Rules Governing the Sanitation of Hospitals, Nursing Homes, Adult Care Homes, and Other Institutions," 15A NCAC 18A .1300 of the North Carolina Division of Public Health, Environmental Health Services Section.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. April 1, 2019.

10A NCAC 13B .6103 EQUIVALENCY AND CONFLICTS WITH REQUIREMENTS

(a) The Division may grant an equivalency to allow an alternate design or functional variation from the requirements in Rule .3102 and the Rules contained in Sections .6000 through .6200 of this Subchapter. The equivalency may be granted by the Division if a governing body submits a written equivalency request to the Division that states the following:

(1) the rule citation and the rule requirement that will not be met;
(2) the justification for the equivalency; and
(3) how the proposed equivalency meets the intent of the corresponding rule requirement.

In determining whether to grant an equivalency request the Division shall consider whether the request will reduce the safety and operational effectiveness of the facility design and layout. The governing body shall maintain a copy of the approved equivalence issued by the Division.

(b) If the rules, codes, or standards contained in this Subchapter conflict, the most restrictive requirement shall apply.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. April 1, 2019.

10A NCAC 13B .6105 INCORPORATION BY REFERENCE AND APPLICATION OF THE REQUIREMENTS OF THE FGI GUIDELINES

(a) For the purposes of Sections .6000 through .6200 of this Subchapter, the Guidelines for the Design and Construction of Hospitals and Outpatient Facilities shall be referred to as the FGI Guidelines.

(b) The FGI Guidelines are incorporated herein by reference, including all subsequent amendments and editions; however, the following chapters of the FGI Guidelines shall not be incorporated herein by reference:

(1) Chapter 3.1;
(2) Chapter 3.2;
(3) Chapter 3.3;
(4) Chapter 3.4;
(5) Chapter 3.5;
(6) Chapter 3.6;
(7) Chapter 3.7;
(8) Chapter 3.8;
(9) Chapter 3.9;
(10) Chapter 3.10;
(11) Chapter 3.11;
(12) Chapter 3.12; and
(13) Chapter 3.14.

(c) The FGI Guidelines incorporated by this Rule may be purchased from the Facility Guidelines Institute online at https://www.fgiguidelines.org/guidelines-main/purchase/ at a cost of two hundred dollars ($200.00) or accessed electronically free of charge at https://www.fgiguidelines.org/guidelines-main/.

(d) A new facility or any additions or alterations to an existing facility whose construction documents were approved by the Construction Section on or after January 1, 2018 shall meet the requirements set forth in:

(1) Sections .6000 through .6200 of this Subchapter; and
(2) the edition of the FGI Guidelines that was in effect at the time the construction documents were approved by the Construction Section.

(e) An existing facility whose construction documents were approved by the Construction Section prior to January 1, 2018 shall meet those standards established in Sections .6000 through .6200 of this Subchapter that were in effect at the time the construction documents were approved by the Construction Section.

(f) Any existing building converted from another use to a new facility shall meet the requirements of Paragraph (d) of this Rule.

(g) Previous versions of the Rules of Sections .6000 through .6200 of this Subchapter can be accessed online at https://www.ncdhhs.gov/dhsr/const/index.html.

History Note: *Authority G.S. 131E-79; S.L. 2017-174;*
Temporary Adoption Eff. December 1, 2017;
Eff. March 21, 2019.

10A NCAC 13B .6207 OUTPATIENT SURGICAL FACILITIES

(a) If a facility elects to share outpatient surgical facilities with inpatient surgical facilities, the outpatient operating room and support areas shall meet the requirements set forth in Sections .6000 through .6200 of this Subchapter.

(b) If a facility elects to provide separate, non-sharable outpatient surgical facilities, the operating rooms and support areas shall meet the requirements set forth in 10A NCAC 13C .1400.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, 1996;
Readopted Eff. April 1, 2019.

10A NCAC 13B .6228 NEONATAL LEVEL I, II, III, AND IV NURSERIES

A facility that provides neonatal services as specified in Rule .4305 of this Subchapter shall meet the requirements of the FGI Guidelines as follows:

(1) a Neonatal Level I nursery shall comply with the requirements of Sections 2.2-2.12 Nursery Unit and 2.2-2.12.3.1 Newborn Nursery;

(2) a Neonatal Level II nursery shall comply with the requirements of Sections 2.2-2.12 Nursery Unit and 2.2-2.12.3.3 Continuing Care Nursery;

(3) a Neonatal Level III nursery shall comply with the requirements of Section 2.2-2.10 Neonatal Intensive Care Unit; and

(4) a Neonatal Level IV nursery shall comply with the requirements of Section 2.2-2.10 Neonatal Intensive Care Unit.

History Note: *Authority G.S. 131E-79; S.L. 2017-174;*
Temporary Adoption Eff. December 1, 2017;
Eff. March 21, 2019.

G.S. 150B-21.3A Report for 10A NCAC 13B, LICENSING OF HOSPITALS

Agency - Medical Care Commission

Comment Period - May 19, 2025 - July 18, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
	SECTION .1900 SUPPLEMENTAL RULES FOR THE LICENSURE OF THE SKILLED: INTERMEDIATE: ADULT CARE HOME BEDS IN A HOSPITAL	10A NCAC 13B .1901	SUPPLEMENTAL RULES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1902	DEFINITIONS	Readopted Eff. April 1, 2020	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1903	INSPECTIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1904	PROCEDURE FOR APPEAL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1905	ADMISSIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1906	POLICIES AND PROCEDURES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1907	GENERAL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1908	FREQUENCY: METHOD AND CONTENT OF ASSESSMENT: PLANNING	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1909	IMPLEMENTATION OF HEALTH PLAN	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1910	NURSING/HEALTH CARE ADMINISTRATION AND SUPERVISION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1911	VACANT DIRECTOR OF NURSING POSITION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1912	NURSE STAFFING REQUIREMENTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1915	ADULT CARE HOME PERSONNEL REQUIREMENTS	Readopted Eff. April 1, 2020	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1916	REHABILITATIVE NURSING AND DECUBITUS CARE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1917	MEDICATION ADMINISTRATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1918	TRAINING	Readopted Eff. April 1, 2020	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1919	DENTAL CARE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1920	AVAILABILITY OF PHARMACEUTICAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1921	DINING FACILITIES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13B, LICENSING OF HOSPITALS

Agency - Medical Care Commission

Comment Period - May 19, 2025 - July 18, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		10A NCAC 13B .1922	ACTIVITIES AND RECREATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1923	SOCIAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1924	RESTRAINTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1925	REQUIRED SPACES	Readopted Eff. April 1, 2020	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1926	NURSING HOME PATIENT OR RESIDENT RIGHTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1927	BRAIN INJURY LONG TERM CARE PHYSICIAN SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1929	SPECIAL NURSING REQUIREMENTS FOR BRAIN INJURY LONG TERM CARE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1930	VENTILATOR DEPENDENCE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1931	PHYSICIAN SERVICES FOR VENTILATOR DEPENDENT PATIENTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .1932	EMERGENCY ELECTRICAL SERVICE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
	SECTION .2000 – SPECIALIZED REHABILITATIVE AND HABILITATIVE SERVICES	10A NCAC 13B .2020	DEFINITIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .2033	DEEMED STATUS FOR INPATIENT REHABILITATION FACILITIES OR UNITS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
	SECTION .2100 – TRANSPARENCY IN HEALTH CARE COSTS	10A NCAC 13B .2101	DEFINITIONS	Eff. September 30, 2015	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .2102	REPORTING REQUIREMENTS	Amended Eff. January 31, 2017	Necessary	Yes If yes, include the citation to the federal law	45 CFR Part §164	Select One	Select One	Select One	Select One	Select One
	SECTION .3000 - GENERAL INFORMATION	10A NCAC 13B .3001	DEFINITIONS	Readopted Eff. April 1, 2020	Necessary	Yes If yes, include the citation to the federal law	CFR Part §482	Select One	Select One	Select One	Select One	Select One
	SECTION .3100 - PROCEDURE	10A NCAC 13B .3101	GENERAL REQUIREMENTS	Readopted Eff. April 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3102	PLAN APPROVAL	Readopted Eff. April 1, 2019	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3103	CLASSIFICATION OF MEDICAL FACILITIES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.13	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3104	LENGTH OF LICENSE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3105	STATISTICAL INFORMATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13B, LICENSING OF HOSPITALS

Agency - Medical Care Commission

Comment Period - May 19, 2025 - July 18, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		10A NCAC 13B .3106	LICENSURE SURVEYS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3107	DENIAL, AMENDMENT OR REVOCATION OF LICENSE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3108	SUSPENSION OF ADMISSIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3109	PROCEDURE FOR APPEAL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3110	ITEMIZED CHARGES	Readopted Eff. April 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3111	TEMPORARY CHANGE IN BED CAPACITY	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11	Select One	Select One	Select One	Select One	Select One
	SECTION .3200 - GENERAL HOSPITAL REQUIREMENTS	10A NCAC 13B .3201	HOSPITAL REQUIREMENTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3202	ADMISSION AND DISCHARGE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3203	DISCHARGE PLANNING	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.43	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3204	TRANSFER AGREEMENT	Readopted Eff. April 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3205	DISCHARGE OF MINOR OR INCOMPETENT	Readopted Eff. April 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11	Select One	Select One	Select One	Select One	Select One
	SECTION .3300 - PATIENT'S BILL OF RIGHTS	10A NCAC 13B .3301	PRINCIPLE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3302	MINIMUM PROVISIONS OF PATIENT'S BILL OF RIGHTS	Readopted Eff. April 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.13	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3303	PROCEDURE	Readopted Eff. April 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.13	Select One	Select One	Select One	Select One	Select One
	SECTION .3400 - SUPPLEMENTAL RULES FOR THE LICENSURE OF CRITICAL ACCESS HOSPITALS	10A NCAC 13B .3401	SUPPLEMENTAL RULES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §485	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3402	DEFINITIONS	Amended Eff. October 1, 2019	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §485	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3405	DESIGNATED CRITICAL ACCESS HOSPITALS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §485	Select One	Select One	Select One	Select One	Select One
	SECTION .3500 - GOVERNANCE AND MANAGEMENT	10A NCAC 13B .3501	GOVERNING BODY	Amended Eff. July 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3502	REQUIRED FACILITY BYLAWS, POLICIES, RULES, AND REGULATIONS	Readopted Eff. July 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3503	FUNCTIONS	Readopted Eff. July 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13B, LICENSING OF HOSPITALS

Agency - Medical Care Commission

Comment Period - May 19, 2025 - July 18, 2025

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Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
	SECTION .3600 - MANAGEMENT AND ADMINISTRATION OF OPERATIONS	10A NCAC 13B .3601	CHIEF EXECUTIVE OFFICER	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3602	RESPONSIBILITIES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3603	PERSONNEL POLICIES AND PRACTICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3604	JOB DESCRIPTIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3605	PERSONNEL RECORDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3606	EDUCATION PROGRAMS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3607	PERSONNEL HEALTH REQUIREMENTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3608	INSURANCE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3609	AUDIT OF FINANCIAL OPERATIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11	Select One	Select One	Select One	Select One	Select One
	SECTION .3700 - MEDICAL STAFF	10A NCAC 13B .3701	GENERAL PROVISIONS	Readopted Eff. July 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.22	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3703	APPOINTMENT	Amended Eff. July 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.22	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3704	ESTABLISHMENT AND CATEGORIES OF MEDICAL STAFF MEMBERSHIP	Readopted Eff. July 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.22	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3705	MEDICAL STAFF BYLAWS, RULES, AND REGULATIONS	Readopted Eff. July 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.22	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3706	ORGANIZATION AND RESPONSIBILITIES OF THE MEDICAL STAFF	Readopted Eff. July 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.22	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3707	MEDICAL ORDERS	Readopted Eff. July 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.22	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3708	MEDICAL STAFF RESPONSIBILITIES FOR QUALITY IMPROVEMENT REVIEW	Amended Eff. July 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.22	Select One	Select One	Select One	Select One	Select One
	SECTION .3800 - NURSING SERVICES	10A NCAC 13B .3801	NURSE EXECUTIVE	Readopted Eff. August 1, 2023	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3802	NURSING STAFF	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3803	NURSING POLICIES AND PROCEDURES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3804	PATIENT CARE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.23	Select One	Select One	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13B, LICENSING OF HOSPITALS

Agency - Medical Care Commission

Comment Period - May 19, 2025 - July 18, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
	SECTION .3900 - MEDICAL RECORD SERVICES	10A NCAC 13B .3901	ORGANIZATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.24	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3902	MANAGER	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.24	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3903	PRESERVATION OF MEDICAL RECORDS	Readopted Eff. August 1, 2023	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.24	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3904	PATIENT ACCESS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.24 42 CFR Part §482.13	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3905	PATIENT MEDICAL RECORDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.24	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3906	CONTENTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.24	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .3907	MEDICAL RECORDS REVIEW	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.24	Select One	Select One	Select One	Select One	Select One
	SECTION .4000 - OUTPATIENT SERVICES	10A NCAC 13B .4001	ORGANIZATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.54	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4002	STAFFING	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.54	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4003	POLICIES AND PROCEDURES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.54	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4004	OUTPATIENT SURGICAL AND ANESTHESIA SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.54	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4005	MEDICAL RECORDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.24	Select One	Select One	Select One	Select One	Select One
	SECTION .4100 - EMERGENCY SERVICES	10A NCAC 13B .4101	EMERGENCY RESPONSE CAPABILITY REQUIRED	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.55	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4102	CLASSIFICATION OF OPTIONAL EMERGENCY SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.55	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4103	PROVISION OF EMERGENCY SERVICES	Readopted Eff. August 1, 2023	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.55	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4104	MEDICAL DIRECTOR	Readopted Eff. August 1, 2023	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.55	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4105	NURSING	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4106	POLICIES AND PROCEDURES	Readopted Eff. August 1, 2023	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.55	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4107	EMERGENCY RECORDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4108	OBSERVATION BEDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13B, LICENSING OF HOSPITALS

Agency - Medical Care Commission

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		10A NCAC 13B .4109	TRANSFER	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.55 42 CFR Part §489.24	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4110	DISASTER AND MASS CASUALTY PROGRAM	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.55	Select One	Select One	Select One	Select One	Select One
	SECTION .4200 - SPECIAL CARE UNITS	10A NCAC 13B .4201	ORGANIZATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4202	MEDICAL STAFF	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.22	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4203	NURSING STAFF	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.11 42 CFR Part §482.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4204	POLICIES AND PROCEDURES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
	SECTION .4300 - MATERNAL - NEONATAL SERVICES	10A NCAC 13B .4301	ORGANIZATION MATERNAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4302	MEDICAL STAFF MATERNAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.22	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4303	NURSING SERVICES MATERNAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4304	POLICIES AND PROCEDURES MATERNAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4305	ORGANIZATION OF NEONATAL SERVICES	Readopted Eff. August 1, 2023	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.12	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4306	MEDICAL STAFF OF NEONATAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.22	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4307	NURSING STAFF OF NEONATAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4308	POLICIES AND PROCEDURES OF NEONATAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.12 42 CFR Part §482.23	Select One	Select One	Select One	Select One	Select One
	SECTION .4400 - RESPIRATORY CARE SERVICES	10A NCAC 13B .4401	ORGANIZATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.57	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4402	STAFFING	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.57	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4403	POLICIES AND PROCEDURES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.57	Select One	Select One	Select One	Select One	Select One
	SECTION .4500 - PHARMACY SERVICES AND MEDICATION ADMINISTRATION	10A NCAC 13B .4501	PROVISION OF SERVICE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4502	PHARMACIST	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13B, LICENSING OF HOSPITALS

Agency - Medical Care Commission

Comment Period - May 19, 2025 - July 18, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		10A NCAC 13B .4503	STAFF	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4504	PHARMACY COMMITTEE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4505	PHARMACY FACILITIES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4506	SUPPLIES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4507	STORAGE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4509	SECURITY	Amended Eff. October 1, 2019	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4510	RECORDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4511	MEDICATION ADMINISTRATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25 42 CFR Part §482.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4512	MEDICATIONS DISPENSED	Amended Eff. October 1, 2019	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4513	DRUG DISTRIBUTION SYSTEMS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4514	EMERGENCY PHARMACEUTICAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4515	DISPOSITION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4516	COMMERCIAL PHARMACEUTICAL SERVICE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.25	Select One	Select One	Select One	Select One	Select One
	SECTION .4600 - SURGICAL AND ANESTHESIA SERVICES	10A NCAC 13B .4601	ORGANIZATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.51 42 CFR Part §482.52	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4602	DIRECTOR OF SURGICAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.51 42 CFR Part §482.52	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4603	SURGICAL AND ANESTHESIA STAFF	Readopted Eff. August 1, 2023	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.51 42 CFR Part §482.52	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4604	DIRECTION OF ANESTHESIA SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.51 42 CFR Part §482.52	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4605	POLICIES AND PROCEDURES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.51 42 CFR Part §482.52	Select One	Select One	Select One	Select One	Select One
	SECTION .4700 - NUTRITION AND DIETETIC SERVICES	10A NCAC 13B .4701	PROVISION OF SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.28	Select One	Select One	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13B, LICENSING OF HOSPITALS

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Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		10A NCAC 13B .4702	ORGANIZATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.28	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4703	SANITATION AND SAFETY	Amended Eff. October 1, 2019	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.28	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4704	DISTRIBUTION OF FOOD	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.28	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4705	NUTRITIONAL SUPPORT	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.28	Select One	Select One	Select One	Select One	Select One
	SECTION .4800 - DIAGNOSTIC IMAGING	10A NCAC 13B .4801	ORGANIZATION	Readopted Eff. August 1, 2023	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.26	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4802	RECORDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.26	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4803	STAFFING	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.26	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4804	MONITORING RADIATION EXPOSURE OF PERSONNEL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.26	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4805	SAFETY	Readopted Eff. August 1, 2023	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.26	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4806	NUCLEAR MEDICINE SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.53	Select One	Select One	Select One	Select One	Select One
	SECTION .4900 - LABORATORY SERVICES AND PATHOLOGY	10A NCAC 13B .4901	ORGANIZATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.27	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4902	RECORDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.27	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4903	STAFFING	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.27	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4904	TESTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.27	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4905	TISSUE REMOVAL AND DISPOSAL	Amended Eff. October 1, 2019	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.27	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4906	BLOOD BANK	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.27	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .4907	MORGUE AND AUTOPSY FACILITIES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.27	Select One	Select One	Select One	Select One	Select One
	SECTION .5000 - PHYSICAL REHABILITATION SERVICES	10A NCAC 13B .5001	ORGANIZATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.56	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5002	DELIVERY OF CARE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.56	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5003	POLICIES AND PROCEDURES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.56	Select One	Select One	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13B, LICENSING OF HOSPITALS

Agency - Medical Care Commission

Comment Period - May 19, 2025 - July 18, 2025

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Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		10A NCAC 13B .5004	PATIENT RECORDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.56	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5005	CARDIAC REHABILITATION PROGRAM	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.56	Select One	Select One	Select One	Select One	Select One
	SECTION .5100 - INFECTION CONTROL	10A NCAC 13B .5101	ORGANIZATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.42	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5102	POLICY AND PROCEDURES	Readopted Eff August 1, 2023	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.42	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5103	LAUNDRY SERVICE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.42	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5104	ENVIRONMENTAL SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.42	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5105	STERILE SUPPLY SERVICES	Readopted Eff. August 1, 2023	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.42	Select One	Select One	Select One	Select One	Select One
	SECTION .5200 - PSYCHIATRIC SERVICES	10A NCAC 13B .5201	PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES: APPLICABILITY OF RULES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5202	DEFINITIONS APPLICABLE TO PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.27 42 CFR Part §482.60 42 CFR Part §482.42	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5203	STAFFING FOR PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.27 42 CFR Part §482.60 42 CFR Part §482.42	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5204	PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES RECORD REQUIREMENTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.27 42 CFR Part §482.60 42 CFR Part §482.42	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5205	SECLUSION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.13 42 CFR Part §482.27 42 CFR Part §482.60 42 CFR Part §482.42	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5206	COMPLIANCE WITH STATUTORY REQUIREMENTS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5207	PSYCHIATRIC OR SUBSTANCE ABUSE OUTPATIENT SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	No		Select One	Select One	Select One	Select One	Select One
	SECTION .5300 - NURSING AND ADULT CARE HOME BEDS	10A NCAC 13B .5301	THE LICENSURE OF NURSING AND ADULT CARE HOME BEDS IN A HOSPITAL	Amended Eff. October 1, 2019	Necessary	No		Select One	Select One	Select One	Select One	Select One
	SECTION .5400 - COMPREHENSIVE INPATIENT REHABILITATION	10A NCAC 13B .5401	DEFINITIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482 42 CFR Part §412.22 42 CFR Part §412.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5402	PHYSICIAN REQUIREMENTS FOR INPATIENT REHABILITATION FACILITIES OR UNITS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482 42 CFR Part §412.22 42 CFR Part §412.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5403	ADMISSION CRITERIA FOR INPATIENT REHABILITATION FACILITIES OR UNITS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482 42 CFR Part §412.22 42 CFR Part §412.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5404	COMPREHENSIVE INPATIENT REHABILITATION EVALUATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482 42 CFR Part §412.22 42 CFR Part §412.23	Select One	Select One	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13B, LICENSING OF HOSPITALS

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		10A NCAC 13B .5405	COMPREHENSIVE INPATIENT REHABILITATION INTER-DISCIPLINARY TREAT/PLAN	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482 42 CFR Part §412.22 42 CFR Part §412.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5406	DISCHARGE CRITERIA FOR INPATIENT REHABILITATION FACILITIES OR UNITS	Readopted Eff. August 1, 2023	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482 42 CFR Part §412.22 42 CFR Part §412.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5407	COMPREHENSIVE REHABILITATION PERSONNEL ADMINISTRATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482 42 CFR Part §412.22 42 CFR Part §412.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5408	COMPREHENSIVE INPATIENT REHABILITATION PROGRAM STAFFING REQUIREMENTS	Readopted Eff. August 1, 2023	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482 42 CFR Part §412.22 42 CFR Part §412.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5409	STAFF TRAINING FOR INPATIENT REHABILITATION FACILITIES OR UNIT	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482 42 CFR Part §412.22 42 CFR Part §412.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5410	EQUIPMENT REQUIREMENTS/COMPREHENSIVE INPATIENT REHABILITATION PROGRAMS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482 42 CFR Part §412.22 42 CFR Part §412.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5412	ADDITIONAL REQUIREMENTS FOR TRAUMATIC BRAIN INJURY PATIENTS	Readopted Eff. April 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482 42 CFR Part §412.22 42 CFR Part §412.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5413	ADDITIONAL REQUIREMENTS FOR SPINAL CORD INJURY PATIENTS	Readopted Eff. April 1, 2020	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482 42 CFR Part §412.22 42 CFR Part §412.23	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5414	DEEMED STATUS FOR INPATIENT REHABILITATION FACILITIES OR UNIT	Amended Eff. October 1, 2019	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482 42 CFR Part §412.22 42 CFR Part §412.23	Select One	Select One	Select One	Select One	Select One
	SECTION .5500 – SUPPLEMENTAL RULES FOR HOSPITALS PROVIDING LIVING ORGAN DONATION TRANSPLANT SERVICES	10A NCAC 13B .5501	APPLICABILITY OF RULES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.72 -§482.74 42 CFR Part §482.80 -§482.104	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5502	INDEPENDENT DONOR ADVOCATE TEAM	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.72 -§482.74 42 CFR Part §482.80 -§482.104	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5503	INFORMED CHOICE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.72 -§482.74 42 CFR Part §482.80 -§482.104	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5504	EVALUATION PROTOCOL FOR LIVING ORGAN DONORS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.72 -§482.74 42 CFR Part §482.80 -§482.104	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5505	PERIOPERATIVE CARE AND FACILITY SUPPORT	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.72 -§482.74 42 CFR Part §482.80 -§482.104	Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .5506	DISCHARGE PLANNING	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017	Necessary	Yes If yes, include the citation to the federal law	42 CFR Part §482.72 -§482.74 42 CFR Part §482.80 -§482.104 42 CFR Part §482.43	Select One	Select One	Select One	Select One	Select One
	SECTION .6000 - PHYSICAL PLANT	10A NCAC 13B .6003	DEFINITIONS	Eff. March 21, 2019	Necessary	No		Select One	Select One	Select One	Select One	Select One
	SECTION .6100 – GENERAL REQUIREMENTS	10A NCAC 13B .6101	LIST OF REFERENCED CODES, RULES, REGULATIONS, AND STANDARDS	Readopted Eff. April 1, 2019	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .6102	GENERAL	Readopted Eff. April 1, 2019	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .6103	EQUIVALENCY AND CONFLICTS WITH REQUIREMENTS	Readopted Eff. April 1, 2019	Necessary	No		Select One	Select One	Select One	Select One	Select One

G.S. 150B-21.3A Report for 10A NCAC 13B, LICENSING OF HOSPITALS

Agency - Medical Care Commission

Comment Period - May 19, 2025 - July 18, 2025

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]	RRC Determination of Public Comments [150B-21.3A(c)(2)	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		10A NCAC 13B .6105	INCORPORATION BY REFERENCE AND APPLICATION OF THE REQUIREMENTS OF THE FGI GUIDELINES	Eff. March 21, 2019	Necessary	No		Select One	Select One	Select One	Select One	Select One
	SECTION .6200 - CONSTRUCTION REQUIREMENTS	10A NCAC 13B .6207	OUTPATIENT SURGICAL FACILITIES	Readopted Eff. April 1, 2019	Necessary	No		Select One	Select One	Select One	Select One	Select One
		10A NCAC 13B .6228	NEONATAL LEVEL I, II, III, AND IV NURSERIES	Eff. March 21, 2019	Necessary	No		Select One	Select One	Select One	Select One	Select One

SECTION .0900 - GENERAL

10A NCAC 13J .0901 DEFINITIONS

Terms used in this Subchapter have the meanings as defined in G.S. 131E-136 and as follows:

(1) "Activities of Daily Living" (ADL) means mobility, eating, bathing, dressing, and toileting.
(2) "Agency" means a home care agency.
(3) "Agency director" means the person having administrative responsibility for the operation of the agency.
(4) "Client" means as defined in G.S. 131E-136 (2b).
(5) "Clinical respiratory services" means the provision of respiratory equipment and services that involve the assessment of a client's pulmonary status, monitoring of a client's response to therapy, and reporting to the client's physician. Procedures include: oximetry, blood gases, delivery of medication via aerosolization, management of ventilatory support equipment, pulmonary function testing, and infant monitoring.
(6) "Department" means the North Carolina Department of Health and Human Services.
(7) "Extensive Assistance" means a client is totally dependent or requires hands on assistance more than half the time while performing part of an activity, and meets one of the following criteria:
    (a) requires extensive assistance in more than two activities of daily living (ADLs), as defined in Item (1) of this Rule;
    (b) needs an in-home aide to perform at least one task at the nurse aide II level; or
    (c) requires extensive assistance in more than one ADL and has a medical or cognitive impairment as defined in Item (19) of this Rule.
(8) "Follow-up care" means services provided to a licensed hospital's discharged client in their home by a hospital's employees. No services shall exceed three visits in any two month period and shall not extend beyond a 12 month period following discharge, except pulmonary care, pulmonary rehabilitation, or ventilator services.
(9) "Governing body" means the person or group of persons having legal authority for the operation of the agency.
(10) "Hands-on care" means any home care service that involves touching the patient in order to implement the patient's plan of care.
(11) "Health care practitioner" means as defined in G.S. 90-640(a).
(12) "Infusion nursing services" means those services related to the administration of pharmaceutical agents into a body organ or cavity. Routes of administration include sub-cutaneous intravenous, intraspinal, epidural, or intrathecal infusion. Administration shall be by or under the supervision of a registered nurse in accordance with their legal scope of practice.
(13) "In-home aide services" are hands-on services that assist individuals, their family, or both with home management tasks, personal care tasks, or supervision of the client's activities to enable the individual, their family, or both to remain and function at home.
(14) "In-home caregiver" means any individual who provides home care services as enumerated in G.S. 131E-136.
(15) "Instrumental Activities of Daily Living" (IADL) means meal preparation, housekeeping, medication reminders, shopping, errands, transportation, money management, phone use, reading, and writing.
(16) "Licensed Clinical Social Worker" means as defined in G.S. 90B-3(6a).
(17) "Licensed practical nurse" means as defined in G.S. 90-171.30 or G.S 90-171.32.
(18) "Limited Assistance" means care to a client who requires hands-on care involving guided maneuvering of limbs with eating, toileting, bathing, dressing, personal hygiene, self-monitoring of medications, or other tasks assigned that require hands on assistance half the time or less during the activity and does not meet the definition of extensive assistance.
(19) "Medical or cognitive impairment" means a diagnosis and client assessment that documents at least one of the following:
    (a) pain that is present more than half the time that interferes with an individual's activity or movement;
    (b) dyspneic or short of breath with minimal exertion during the performance of ADLs and requires continuous use of oxygen; or

(c) individual is not alert and oriented or is unable to shift attention and recall directions more than half the time.

(20) "Nursing registry" means a person or organization that maintains a list of nurses, in-home aides, or both that is made available to persons seeking nursing care or in-home aide service, but does not collect a placement fee from the worker or client, coordinate the delivery of services, or supervise or control the provision of services.

(21) "Nursing services" means professional services provided by a registered nurse or a licensed practical nurse under the supervision of a registered nurse.

(22) "Occupational therapist" means as defined in G.S. 90-270.67(2) or G.S. 90-270.72.

(23) "Occupational therapist assistant" means as defined in G.S. 90-270.67(3) or G.S. 90-270.72.

(24) "Occupational therapy" means as defined in G.S. 90-270.67(4).

(25) "On-call services" means unscheduled home care services made available to clients on a 24-hour basis.

(26) "Personal care" means assistance to an individual with ADL and medical monitoring.

(27) "Physical therapist" means as defined in G.S. 90-270-24(2), G.S. 90-270-30, or G.S. 90-270-31(b).

(28) "Physical therapist assistant" means as defined in G.S. 90-270.24(3) or G.S. 90-270-31(b).

(29) "Physical therapy" means as defined in G.S. 90-270.24(4).

(30) "Physician" means as defined in G.S.90-9.1 or G.S. 90-9.2.

(31) "Plan of care" means the written description of the authorized home care services and tasks to be provided to a client.

(32) "Practice of respiratory care" means as defined in G.S.90-648(10).

(33) "Premises" means the location or licensed site that the agency provides home care services or maintains client service records or advertises itself as a home care agency.

(34) "Qualified" means suitable for employment as a consequence of having met the standards of education, experience, licensure, or certification established in the applicable job description created and adopted by the agency.

(35) "Registered nurse" means as defined in G.S. 90-171.30 or G.S. 90.171.32.

(36) "Respiratory care practitioner" means as defined in G.S. 90-648(12).

(37) "Scope of services" means those specific services provided by a licensed agency as listed on their home care license.

(38) "Survey" means an inspection by the Division of Health Service Regulation in order to assess the compliance of agencies with the home care licensure rules.

(39) "Social worker" means as defined in G.S 90B-3(8).

(40) "Speech and language pathologist" means as defined in G.S. 90-293(5).

(41) "Skilled Services" means all home care services enumerated in G.S. 131E-136(3) with the exception of in-home aide services.

(42) "The practice of speech and language pathology" means as defined in G.S. 90-293(7).

History Note: *Authority G.S. 131E-136; 131E-140;*
Eff. July 1, 1992;
RRC Objection due to lack of statutory authority Eff. November 16, 1995;
Amended Eff. January 1, 2010; February 1, 1996;
Readopted Eff. June 1, 2018.

10A NCAC 13J .0902 LICENSE

Each agency premises shall obtain a license unless exempted by G.S. 131E-136(3).

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .0903 APPLICATION FOR AND ISSUANCE OF LICENSE

(a) An application for the operation of an agency premises shall be submitted to the Department prior to the scheduling of an initial licensure survey or the issuance of a license. The agency shall establish, maintain and make available for inspection such documents, records and policies as required in this Section and statistical data sufficient to complete the licensure application and upon request of the Department, to submit an annual data report, as noted in Rule .1002(b) of this Subchapter. If the applicant cannot demonstrate to the Division of Health Service Regulation that he or she has ever owned or operated a home care agency prior to submission of the application, the Division shall not issue a license until the applicant has received training approved by the Division which shall include the requirements for licensure, the licensure process, and the rules pertaining to the operation of a home care agency.

(b) The Department shall issue a license to each agency premises. Initial and ongoing licensure inspections may include all premises of an agency. Licensure shall be for a period of one year. Each license shall expire at midnight on the expiration date on the license and is renewable upon application.

(c) The license shall be posted in a prominent location accessible to public view within the premises. The agency shall also post a sign at the public access door with the agency name.

(d) The license shall be issued for the premises and persons named in the application and shall not be transferable. The name and street address under which the agency operates shall appear on the license. The license shall reflect the services provided by the agency.

(e) Prior to change of ownership or the establishment of a new agency, the agency must be in compliance with all the applicable statutes and rules. If the agency is authorized to provide Medicare certified Home Health Services, it shall also be in compliance with statutes and rules established under G.S. 131E, Article 9.

(f) The licensee shall notify the Department in writing of any proposed change in ownership or name at least 30 days prior to the effective date of the change.

(g) Any agency adding a new service category as outlined in G.S. 131E-136(3)(a) through (f) shall notify the Department in writing at least 30 days prior to the provision of that service to any clients. The Department shall approve the added service upon determining the agency is in compliance with the rules specific to the service being provided as contained in Section .1100 of this Subchapter.

(h) An agency shall notify the Department in writing if it discontinues or is unable to provide for a period of six continuous months any service category as outlined in G.S. 131E-136(3)(a) through (f) that is listed on the agency's license.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996; May 1, 1993;
Temporary Amendment Eff. April 1, 2006;
Amended Eff. November 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .0904 INSPECTIONS

(a) Any agency licensed by the Department shall be subject to proper inspections by authorized representatives of the Department at any time as a condition of holding such license.

(b) Any organization subject to licensure which presents itself to the public as a home care agency, which does not hold a license, and is or may be in violation of Rule .0902 of this Section and G.S. 131E-138 shall be subject to inspections at any time by authorized representatives of the Department.

(c) Authorized representatives of the Department shall make their identities known to the person in charge prior to inspection.

(d) Inspection of service records shall be carried out in accordance with G.S. 131E-141(b).

(e) An inspection shall be considered proper whenever the purpose of the inspection is to determine whether the agency complies with the provisions of this Subchapter or whenever there is reason to believe that some condition exists which is not in compliance with the rules in this Subchapter. The agency shall allow immediate access to its premises and the records necessary to conduct an inspection and determine compliance with the rules of this Subchapter. Failure to do so shall result in termination of the survey and may result in injunctive relief as outlined in G.S. 131E-142(b).

(f) An agency shall file a plan of correction for cited deficiencies within 10 working days of receipt. The Department shall review and respond to a written plan of correction within 10 working days of receipt.

(g) Representatives of the Department may visit clients in their homes to assess the agency's compliance with the clients' plans of care and with the licensure rules. Clients will be contacted by the agency staff in the presence of Department staff for permission to visit.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .0906 COMPLIANCE WITH LAWS

(a) The agency shall be in compliance with all applicable federal, state, and local laws, rules, and regulations including Title XI Part A Section 1128B of the Social Security Act - Criminal penalties for acts involving Federal health care programs. A failure to comply with Federal law may subject the agency to civil or criminal penalties as set forth in 42 U.S.C. §1320a-7a - Making or causing to be made false statements or representations - and 42 U.S.C. §1320a-7b - Illegal remunerations.

(b) Staff of the agency shall be currently licensed or registered in accordance with applicable laws of the State of North Carolina.

(c) Nothing in this Rule shall prohibit the Department from conducting inspections as provided for in Rule .0904 of this Section.

(d) Any agency deemed to be in compliance by virtue of accreditation by one of the specified accrediting bodies listed in G.S. 131E-138(g) shall submit to the Department a copy of its accreditation report within 30 days after the agency receives its report each time it is surveyed by the accrediting body. The agency shall notify the Department of any action taken that affects its accreditation status, either temporarily or permanently. The Department may conduct annual validation surveys to assure compliance.

History Note: *Authority G.S. 131E-138; 131E-140;*
Eff. July 1, 1992;
Amended Eff. October 1, 2006; February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .0905 MULTIPLE PREMISES

If a person operates multiple agency premises:

(1) the Department may conduct inspections at any or all of the premises and may issue a license to each of the premises based upon a sample inspection of any of the premises;

(2) with 72 hours advance notice, the Department may request records from any of the premises necessary to ensure compliance with the rules of this Subchapter be brought to the site being inspected, including the portions of personnel records subject to review. For agencies for whom a business or government policy precludes the disclosure of employee evaluations, a statement signed by the employee's supervisor attesting to its completion shall be accepted.

(3) the premises may share hands-on care staff or administrative staff, and may centralize the maintenance of records.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .0907 ADVERSE ACTION

(a) An agency may appeal any adverse decision made by the Department concerning its license by making such appeal in accordance with the Administrative Procedure Act, G.S. 150B and departmental rules 10A NCAC 01 et seq.

(b) The Department may amend a license by reducing it from a full license to a provisional license whenever the Department finds that:

(1) the licensee has substantially failed to comply with the provisions of G.S. 131E, Part C of Article 6 and the rules promulgated under that Part; and

(2) there is a reasonable probability that the licensee can remedy the licensure deficiencies within a reasonable length of time; and

(3) there is a reasonable probability that the licensee will be able thereafter to remain in compliance with the home care licensure rules for the foreseeable future.

The Department shall give the licensee written notice of the amendment of its license. This notice shall be given by registered or certified mail or by personal service and shall set forth the reasons for the action.

(c) The provisional license shall be effective immediately upon its receipt by the licensee and must be posted in a prominent location, accessible to public view, within the licensed premises in lieu of the full license. The provisional license shall remain in effect until:

(1) the Department restores the licensee to full licensure status; or

(2) the Department revokes the licensee's license; or

(3) the end of the licensee's licensure year. If a licensee has a provisional license at the time that the licensee submits a renewal application, the license, if renewed, shall also be a provisional license unless the Department determines that the licensee can be returned to full license status. A decision to issue a provisional license is stayed during the pendency of an administrative appeal and the licensee may continue to display its full license during the appeal.

(d) The Department may revoke a license whenever:

(1) The Department finds that:

(A) the licensee has substantially failed to comply with the provisions of G.S. 131E, Part C of Article 6 and the rules promulgated under those parts; and

(B) it is not reasonably probable that the licensee can remedy the licensure deficiencies within a reasonable length of time; or

(2) The Department finds that:

(A) the licensee has substantially failed to comply with the provisions of G.S. 131E, Part C of Article 6; and

(B) although the licensee may be able to remedy the deficiencies within a reasonable time, it is not reasonably probable that the licensee will be able to remain in compliance with the home care licensure rules for the foreseeable future; or

(3) The Department finds that there has been any failure to comply with the provisions of G.S. 131E, Part C of Article 6 and the rules promulgated under those parts that endangers the health, safety or welfare of the clients receiving services from the agency.

The issuance of a provisional license is not a procedural prerequisite to the revocation of a license pursuant to Subparagraphs (d)(1)(2) and (3) of this Rule.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

SECTION .1000 - ADMINISTRATION

10A NCAC 13J .1001 AGENCY MANAGEMENT AND SUPERVISION

(a) The governing body or its designee shall establish and implement written policies governing agency operation. Such policies shall be available for inspection by the Department. The policies shall include:

(1) a description of the scope of services offered;
(2) admission and discharge policies;
(3) supervision of personnel;
(4) development of, and updates to, the plan of care;
(5) management of emergency care situations in the home;
(6) time frame for completion and return of service records to the agency;
(7) personnel qualifications;
(8) an organizational chart;
(9) program evaluation;
(10) employee and client confidentiality; and
(11) coordination of and referral to and from other community agencies and resources.

(b) The agency shall designate an individual to serve as agency director. The agency director shall have the authority and responsibility for administrative direction of the agency and shall meet one or more of the following qualifications:

(1) a health care practitioner as defined in G.S. 90-640(a);
(2) an individual who has at least two years of supervisory or management experience in home care or any other provider licensed pursuant to G.S. 131E or G.S. 122C; or
(3) an individual who holds a bachelor's degree in health, business or public administration science and has at least one year of supervisory or management experience in home care or other licensed health care program.

Such qualifications do not apply with respect to persons acting in the capacity of agency director prior to October 1, 2006.

(c) The agency shall designate a person responsible for supervising each type of home care service contained in Section .1100 of this Subchapter that is provided by the agency either directly or by contract. This individual may be the supervisor for one or more home care services and may also serve as the agency director.

(d) There shall be written documentation that specifies the responsibilities and authority of the agency director and supervisor.

(e) If the position of agency director becomes vacant, the Department shall be notified within five working days in writing of such vacancy along with the name of the replacement, if available. Agency policies shall define the order of authority in the absence of the administrator.

(f) The agency shall have the ultimate responsibility for the services provided under its license; however, it may make arrangements with contractors and others to provide services in accordance with Rule .1111 of this Subchapter.

(g) An agency shall have written policies which identify the specific geographic area in which the agency provides each service. If an agency plans to expand its geographic service area without opening an additional site, the Department shall be notified in writing 30 days in advance.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. October 1, 2006; February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1002 ADMINISTRATIVE, FINANCIAL AND STATISTICAL RECORDS

(a) The agency shall establish, maintain and make available for inspection the home care annual budget.

(b) The agency shall record, maintain and make available as requested to the Department statistical records. The records shall include the following:

(1) Number of home care staff, and their full-time equivalents including administrative, clerical, professional and paraprofessional and their total number of units of services;

(2) Client demographics, including county of residence and age;

(3) Number of units of service by applicable service category; and

(4) Total charges and number of visits by payor source (for Medicare certified agencies).

(c) Records shall be retained for a period of not less than three years.

(d) When an agency operates as a part of a health care facility licensed under Article 5 or 6 of G.S. 131E, or as a part of a larger diversified agency, records of home care activities and expenditures that are separate and identifiable shall be maintained for the agency.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1003 PERSONNEL

(a) Written policies shall be established and implemented by the agency regarding infection control and exposure to communicable diseases consistent with Subchapter 19A of Title 15A, North Carolina Administrative Code. These policies shall include provisions for compliance with 29 CFR 1910 (Occupational Safety and Health Standards) which is incorporated by reference including subsequent amendments. Copies of Title 29 Part 1910 can be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-7954 or by calling Washington, D.C. (202) 512-1800. The cost is twenty-one dollars ($21.00) and may be purchased with a credit card.

(b) Hands-on care employees must have a baseline skin test for TB. Individuals who test positive must demonstrate noninfectious status prior to assignment in a client's home. Individuals who have previously tested positive to the TB skin test shall obtain a baseline and subsequent annual verification that they are free of TB symptoms. This verification shall be obtained from the local health department, a private physician or health nurse employed by the agency. The Tuberculosis Control Branch of the North Carolina Department of Health and Human Services, Division of Public Health, 1902 Mail Service Center, Raleigh, NC 27699-1902 shall provide, free of charge, guidelines for conducting verification and Form DHHS 3405 (Record of Tuberculosis Screening). Employees identified by agency risk assessment, to be at risk for exposure shall be subsequently tested at intervals prescribed by OSHA standards.

(c) The agency shall not hire any individual either directly or by contract who has a substantiated finding on the North Carolina Health Care Personnel Registry in accordance with G.S. 131E-256(a)(1).

(d) Written policies shall be established and implemented which include personnel record content, orientation and in-service education. Records on the subject of in-service education and attendance shall be maintained by the agency and retained as set out in Paragraph (f) of this Rule.

(e) Job descriptions for every position shall be established in writing which include qualifications and specific responsibilities. Individuals shall be assigned only to duties for which they are trained and competent to perform and when applicable for which they are licensed.

(f) Personnel records shall be established and maintained for each home care employee. When requested, the records shall be available on the agency premises for inspection by the Department. These records shall be maintained for at least one year after termination from agency employment. The records shall include the following:

(1) an application or resume which lists education, training and previous employment that can be verified, including job title;
(2) a job description with record of acknowledgment by the employee;
(3) reference checks or verification of previous employment;
(4) records of tuberculosis screening for employees for whom the test is necessary as described in Paragraph (a) of this Rule;
(5) documentation of Hepatitis B immunization or declination for hands-on care employees in accordance with the agency's exposure control plan;
(6) airborne and bloodborne pathogen training for hands on care employees, including annual updates, in compliance with 29 CFR 1910 and in accordance with the agency's exposure control plan;
(7) performance evaluations according to agency policy and at least annually. These evaluations may be confidential pursuant to Rule .0905 of this Subchapter;
(8) verification of employees' credentials as applicable; and
(9) records of the verification of competencies by agency supervisory personnel of all skills required of home care services personnel to carry out client care tasks to which the employee is assigned. The method of verification shall be defined in agency policy.

(g) For in-home aides not listed on the nurse aide registry, personnel records shall include verification of core competencies by a registered nurse that includes the following core personal care skills for in-home aides hired after April 1, 2009:

(1) Assisting with Mobility including ambulation, transfers and bed mobility;
(2) Assisting with Bath/Shower;
(3) Assisting with Toileting;
(4) Assisting with Dressing;
(5) Assisting with Eating; and
(6) Assisting with continence needs.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;

10A NCAC 13J .1004 EVALUATION

(a) The agency's governing body or its designee shall annually conduct a comprehensive evaluation of the agency's total operation.

(b) The evaluation shall review the quality of the agency's services with findings used to verify policy implementation, to identify problems, and to establish problem resolution and policy revision as necessary.

(c) The evaluation shall consist of a policy and administration review, including the scope of services offered, arrangements for services with other agencies or individuals, admission and discharge policies, supervision and plan of care, emergency care, service records, personnel qualifications, and program evaluation. Data to be assessed shall include the following:

(1) number of clients receiving each service;
(2) number of visits or hours for each service;
(3) client outcomes;
(4) adequacy of staff to meet client needs;
(5) numbers and reasons for nonacceptance of clients; and
(6) reasons for discharge.

(d) The agency's governing body or its designee shall evaluate the agency's client records every 90 days. The evaluation shall include a review of sample active and closed client records to ensure that agency policies are followed in providing services, both direct and under contract, and to assure the quality of service meets the client's needs. The review shall consist of a representative sample of all home care services provided by the agency.

(e) Documentation of the evaluation shall include the names and qualifications of the persons carrying out the evaluation, the criteria and methods used to accomplish it, and any action taken by the agency as a result of its findings.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
RRC Objection due to lack of statutory authority Eff. November 16, 1995;
Amended Eff. February 1, 1996;
Readopted Eff. June 1, 2018.

Amended Eff. February 1, 1996; June 1, 1994;
Temporary Amendment Eff. April 1, 2006;
Amended Eff. January 1, 2010; October 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1005 HOSPICE CARE

(a) If an agency offers or provides a hospice program of care, such services shall be in compliance with all provisions of 10A NCAC 13K (Hospice Licensing Rules), with the exception of rules requiring a separate hospice license.

(b) A hospice shall be eligible for a home care license if it meets the requirements of 10A NCAC 13J and meets the standards for the specific home care services offered. The extent of the licensure review shall be at the discretion of the Department.

(c) If an agency that operates a hospice, a hospice inpatient facility, or a hospice residential care facility, under its home care license, substantially fails to comply with the provisions of Article 10 of G.S. 131E or of 10A NCAC 13J, the Department may amend the agency's home care license by revoking the agency's right to operate a hospice, a hospice inpatient facility, or a hospice residential care facility, or offer hospice services under its home care license.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1006 NURSING POOL

(a) If an agency offers or provides a nursing pool, and does not wish to obtain a separate license for its nursing pool, such services shall be in compliance with all provisions of 10A NCAC 13L (Nursing Pool Licensing Rules).

(b) If an agency that operates a nursing pool under its home care license substantially fails to comply with the provisions of Part E of Article 6 of G.S. 131E or of 10A NCAC 13L, the Department may amend the agency's home care license by revoking the agency's right to operate a nursing pool under its home care license.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1007 CLIENT RIGHTS AND RESPONSIBILITIES

(a) An agency shall provide each client with a written notice of the client's rights and responsibilities in advance of furnishing care to the client or during the initial evaluation visit before the initiation of services. The agency shall maintain documentation showing that all clients have been informed of their rights and responsibilities as set forth in G.S. 131E-144.3.

(b) An agency shall provide notice to clients as set forth in G.S. 131E-144.4. The Division of Health Service Regulation shall investigate all allegations of non-compliance with rules of this Subchapter.

(c) An agency shall comply with G.S. 131E-144.6(b).

History Note: *Authority G.S. 131E-140; 131E-144.3;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Readopted Eff. June 1, 2018.

SECTION .1100 - SCOPE OF SERVICES

10A NCAC 13J .1101 ACCEPTANCE OF CLIENTS FOR SERVICE PROVISION

Within the scope of services provided, the agency shall develop and implement written policies governing the acceptance of clients and client services. These policies and procedures shall include the following:

(1) adequacy and suitability of agency personnel and resources to provide the services required by the client and information on resources available to cover staff absence;
(2) reasonable expectation that the client's need for requested services can be met adequately at home by the agency;
(3) adequate physical facilities in the client's home for their plan of care;
(4) availability or absence of family or substitute family member able and willing to participate in the client's care when necessary to ensure the safety of the client;
(5) information on the scope of services provided and the geographic area served with each service;
(6) notification to the referral source when one or more needed and requested services (including assessment) cannot be provided to a specific client within a time frame requested by the referral source and established by agency policy;
(7) advance notification of at least 48 hours to the client or responsible party when service provision is to be reduced or terminated, except in cases where the client is in agreement with changes, there is a danger to a client or staff member, or the physician terminates services; and
(8) referral to and coordination with other appropriate agencies when the agency is unable to respond to a request for service promptly, or to continue to provide service.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1103 PHYSICAL THERAPY SERVICES

(a) If an agency provides physical therapy services, such services shall be provided by or under the supervision of a licensed physical therapist and in accordance with G.S. Chapter 90, Article 18B, Physical Therapy, and the plan of care and shall include:

(1) assessment of the client to determine level of physical function;
(2) establishment and implementation of the physical therapy treatment plan;
(3) observation, recording, and reporting to the physician any reaction to treatment or changes in the client's condition;
(4) instruction of the family in the client's total physical therapy program; and
(5) instructing of family members, in-home aides and other health team personnel in performing appropriate therapy treatment.

(b) When a licensed physical therapist assistant is providing services in the home, the licensed physical therapist shall be accessible at all times clients are receiving services, and meet the supervisory requirements specified in Rule .1110 of this Section.

(c) The licensed physical therapist shall visit the client to perform all initial assessments, establish the plan of care, and perform all discharge assessments. The physical therapist shall visit to perform plan of care updates and assess the client's functional status, as prescribed in Rule .1202 of this Subchapter.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
RRC Objection due to lack of statutory authority Eff. November 16, 1995;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1102 NURSING SERVICES AND DUTIES

(a) If an agency provides nursing services, those services shall be provided by or under the supervision of a registered nurse and in accordance with the North Carolina Nursing Practice Act, G.S. Chapter 90, Article 9A, and the client's plan of care shall include the following as a minimum:

(1) regularly assess the nursing needs of the client;
(2) develop and implement the client's nursing plan of care;
(3) provide nursing services, treatment, and diagnostic and preventive procedures;
(4) initiate preventive and rehabilitative nursing procedures appropriate for the client's care and safety;
(5) observe signs and symptoms and report to the physician any reaction to treatment, drugs, or changes in the client's physical or emotional condition;
(6) teach, supervise, and counsel the client and family members about providing care for the client at home; and
(7) supervise and train other nursing service personnel.

(b) Licensed practical nurse duties are delegated by and performed under the supervision of a registered nurse. Consistent with the client's plan of care, duties may include:

(1) participating in assessment of the client's health status;
(2) implementing nursing activities, including the administration of prescribed medical treatments and medications;
(3) assisting in teaching the client and family members about providing care to the client at home; and
(4) delegating tasks to in-home aides and supervising their performance of tasks within the limitations established in 21 NCAC 36 .0225(d)(3) adopted by reference.

(c) If an agency provides nursing services, the agency shall provide on-call nursing services on a 24 hour basis, seven days a week. The agency shall retain current on-call schedules and previous schedules for one year and make them available, on request, to the Department.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
RRC Objection due to lack of statutory authority Eff. November 16, 1995;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1104 SPEECH THERAPY/PATHOLOGY SERVICES

If an agency provides speech therapy, or services in speech and language pathology or audiology such services shall be provided in accordance with G.S. 90, Article 22, North Carolina Licensure Act for Speech and Language Pathologists and Audiologists and the client's plan of care and shall include the following at a minimum:

(1) assessment of clients with speech, language, voice, dysphagia, and/or hearing disorders;
(2) establishment and implementation of the speech therapy treatment plan;
(3) recording and reporting to the physician any reaction to treatment or changes in the client's condition;
(4) teaching other health team personnel and family members techniques to help improve and correct the client's speech, language, voice, dysphagia, or hearing potential; and
(5) counseling the client and family about the client's speech, language, voice, dysphagia, and/or hearing disabilities.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1105 OCCUPATIONAL THERAPY SERVICES

(a) If an agency provides occupational therapy, such services shall be provided by or under the supervision of a licensed occupational therapist in accordance with G.S. Chapter 90, Article 18D, Occupational Therapy and the client's plan of care and shall include:

(1) assessment of the client's functional ability to perform activities of daily living;
(2) establishment and implementation of the occupational therapy treatment plan;
(3) observation, recording, and reporting to the physician any reaction to treatment and any changes in the client's condition;
(4) instruction of family members, in-home aides and other health team personnel in appropriate therapy methods; and
(5) design, development and fitting orthotic devices and self-help devices.

(b) When a certified occupational therapist assistant is providing services in the home, the licensed occupational therapist shall be accessible at all times clients are receiving services, and meet the supervisory requirements specified in Rule .1110 of this Section.

(c) The licensed occupational therapist shall visit the client to perform all initial assessments, establish the plan of care, and perform all discharge assessments. The occupational therapist shall visit to perform plan of care updates as described in Rule .1202 of this Subchapter.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
RRC Objection due to lack of statutory authority Eff. November 16, 1995;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1106 MEDICAL SOCIAL WORK SERVICES

If an agency provides medical social work services, such services shall be provided by or under the supervision of a medical social worker and in accordance with the client's plan of care and shall include the following:

(1) assisting the physician and other members of the health team in understanding the significant social and emotional factors related to the client's health problems;

(2) assessing social and emotional factors in order to estimate the client's capacity and potential to cope with problems of daily living;

(3) helping the client and family to understand, accept, and follow medical recommendations and provision of services planned to restore the client to optimum social and health adjustment within their capacity;

(4) assisting the client and family with personal and environmental difficulties which predispose toward illness or interfere with the client obtaining maximum benefits from medical care; and

(5) assisting the client and family in the utilization of appropriate community resources.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
RRC Objection due to lack of statutory authority Eff. November 16, 1995;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1108 INFUSION NURSING SERVICES

(a) If an agency provides infusion nursing services, the services shall be provided by or under the supervision of a registered nurse with training in infusion services or special training in the drug and nutritional therapies the agency offers, as identified in agency policies, and in accordance with the North Carolina Nursing Practice Act, G.S. Chapter 90, Article 9A, and a plan of care signed by a physician.

(b) If an agency provides or arranges for infusion services, the agency shall provide on-call infusion nursing services on a 24 hour basis, seven days a week.

(c) If the agency provides or contracts for infusion pharmacy services there shall be policies and procedures governing the scope of pharmacy services provided. Pharmacy services shall be provided in accordance with the Pharmacy Laws of North Carolina and related rules and shall be provided on a 24-hour basis, seven days a week.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
RRC Objection due to lack of statutory authority Eff. November 16, 1995;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1109 CLINICAL RESPIRATORY SERVICES, INCLUDING PULMONARY, OR VENTILATION SERVICES

(a) If an agency provides clinical respiratory services or ventilation services, the services shall be provided by or under the supervision of a respiratory therapist or a registered nurse with demonstrated competency in the delivery of respiratory services under a plan of care signed by a physician. Within the agency's defined scope of service, respiratory staff, including contractors, shall maintain an active license, certification or registry and shall demonstrate proof of education and experience sufficient for the safe delivery of service.

(b) Clinical respiratory services shall include the following:

(1) assessment of the client's ongoing need for services;
(2) teach and train client or caregivers to self-administer home respiratory care procedures;
(3) collect laboratory specimens;
(4) evaluate functioning of ventilator support equipment;
(5) evaluate functioning of infant monitors; and
(6) when ordered by a physician, administration of aerosolized medication.

(c) If an agency provides these services, the agency shall provide on-call respiratory services emergency response on a 24 hour basis, seven days a week.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
RRC Objection due to lack of statutory authority and ambiguity Eff. November 16, 1995;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1110 SUPERVISION AND COMPETENCY OF IN-HOME CAREGIVERS

(a) In-home caregivers subject to occupational licensing laws shall meet requirements consistent with the rules established by the occupational licensing board that they are subject. Each agency shall document that its in-home caregivers are competent to perform client care tasks or activities that they are assigned. Meeting competency includes a demonstration of tasks to the health care practitioner. In-home caregivers shall perform delegated activities under the supervision of persons authorized by state law to provide such supervision.

(b) Those in-home caregivers who are not subject to occupational licensing laws shall only be assigned client care activities that they have demonstrated competency, and the documentation of competency is maintained by the agency. Meeting competency includes a demonstration of tasks to the health care practitioner. Each agency shall document that its in-home caregivers demonstrate competence for all assigned client care tasks or activities. In-home caregivers shall be supervised by the health care practitioner who may further delegate specific supervisory activities to in-home caregivers as designated by agency policy, provided that the following criteria are met:

(1) there is availability of the health care practitioner for supervision and consultation; and

(2) accountability for supervisory activities delegated is maintained by the health care practitioner.

(c) In-home caregivers subject to Paragraph (a) of this Rule shall be subject to the method and frequency of supervision defined in the agency's policy. The health care practitioner shall supervise an in-home caregiver subject to Paragraph (b) of this Rule by making a supervisory visit to each client's place of residence every 90 days with or without the in-home caregiver's presence, and annually, while the in-home caregiver is providing care to each client. The supervisory visit shall include review of the client's general condition, progress, and response to the services provided by the in-home caregiver.

(d) Documentation of supervisory visits shall be maintained in the agency's records and shall contain date of visit, findings of visit, and signature of person performing the visit.

(e) When follow-up corrective action is needed for any type of in-home caregiver based on findings of the supervisory visit, documentation of such corrective action by the health care practitioner shall be maintained in the employee(s) record.

(f) A health care practitioner conducting a supervisory visit for any in-home caregiver may simultaneously conduct the case review every 90 days as required in Rule .1202 of this Subchapter.

(g) The health care practitioner shall be available for supervision during the hours that in-home care services are provided.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. July 1, 1993;
RRC Objection due to lack of statutory authority and ambiguity Eff. November 16, 1995;
Amended Eff. February 1, 1996;
Temporary Amendment Eff. April 1, 2006;
Amended Eff. November 1, 2006;
Readopted Eff. June 1, 2018.

10A NCAC 13J .1111 ARRANGEMENTS FOR SERVICES WITH OTHER AGENCIES OR INDIVIDUALS

(a) When an agency makes arrangements for providing services through other agencies or individuals, or where the agency contracts with a state or county agency to provide licensed home care services, there shall be a written agreement, signed by both parties, which includes the following:

(1) specific service to be provided;
(2) period of time the contract is to be in effect;
(3) availability of services;
(4) financial arrangements;
(5) verification that any individual providing service is appropriately licensed or registered as required by statute;
(6) provision for supervision of contract personnel where applicable;
(7) assurance that individuals providing services under contractual arrangements meet the same requirements as those specified for home care agency personnel;
(8) provision for the documentation of services rendered in the client's service record;
(9) provision for the sharing of assessment and plan of care data; and
(10) the geographic service area the contractor agrees to serve.

(b) All contract services shall be provided in accordance with the client's plan of care.

(c) The agency shall assure that all contract services are provided in accordance with the agreement. Agreements are to be reviewed and updated, if necessary, on an annual basis.

(d) The agency who is subcontracting its work must maintain or produce a complete home care record for the client.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1112 HOME MEDICAL EQUIPMENT AND SUPPLIES

If an agency provides medical supplies and equipment in conjunction with home care services as defined in G.S. 131E-136(3), the agency shall have policies and procedures governing their management. These policies shall address the following:

(1) set-up, delivery, electrical safety, and environmental requirements for equipment.
(2) proper cleaning and storage, preventive maintenance, and repair according to manufacturer's guidelines.
(3) transportation, tracking, and recall of equipment to meet all applicable regulatory requirements.
(4) emergency preparedness and backup of systems for equipment or power failure.
(5) client instruction materials for each item of home medical equipment or supplies provided.

History Note: *Authority G.S. 131E-140;*
Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

SECTION .1200 - CASE REVIEW AND PLAN OF CARE

10A NCAC 13J .1201 POLICIES

An agency shall develop and implement written policies and procedures to assure that services and items to be provided are specified under a plan of care.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1202 CASE REVIEW AND PLAN OF CARE

(a) The plan of care shall be established in collaboration with the client and incorporated in the service record. The plan of care shall be reviewed every 90 days by the health care practitioner and revised as needed based on the client's needs. If the client record is purged, the original and updated authorization or orders for care shall be maintained in the client's record. All records shall be available to Department staff for review if requested. If physician orders are needed for the services, the health care practitioner shall notify the physician of any changes in the client's condition that indicates the need for altering the plan of care or for terminating services. Based upon the findings of the client assessment, the plan of care shall include the following:

(1) type of service(s) and care to be delivered;
(2) frequency and duration of service;
(3) activity restrictions;
(4) safety measures; and
(5) service objectives and goals.

(b) Where applicable, the plan of care shall include:

(1) equipment required;
(2) functional limitations;
(3) rehabilitation potential;
(4) diet and nutritional needs;
(5) medications and treatments;
(6) specific therapies;
(7) pertinent diagnoses; and
(8) prognosis.

(c) If the health care practitioner is assigned responsibility for two or more of the following, these functions may be conducted during the same home visit:

(1) assessment of client's condition, progress, and response every 90 days;
(2) provision of regularly scheduled professional services; or
(3) supervision of in-home caregiver.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. May 1, 1993;
RRC Objection due to lack of statutory authority Eff. November 16, 1995;
Amended Eff. February 1, 1996;
Readopted Eff. June 1, 2018.

SECTION .1300 - PHARMACEUTICALS AND MEDICAL TREATMENT ORDERS

10A NCAC 13J .1301 POLICIES, PROCEDURES, AND STAFF RESPONSIBILITY

If the agency administers any pharmaceuticals or medical treatments, it shall develop and implement policies and procedures relative to the administration of pharmaceuticals and treatments. The policies shall specify staff accountability for:

(1) recognizing side effects;
(2) recognizing toxic effects;
(3) recognizing allergic reactions;
(4) recognizing immediate desired effects;
(5) recognizing unusual and unexpected effects;
(6) recognizing changes in the client's condition that contraindicates continued administration of the medication;
(7) anticipating those effects which may rapidly endanger a client's life or well-being; and
(8) notifying the physician of any problems.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1302 ORDERS

(a) Orders for pharmaceuticals and medical treatments, or orders for in-home aide services when orders for in-home aide services are required, shall be signed by the physician or other person authorized by State law to prescribe such treatments and the original incorporated in the client's service records. Care may commence in the interim with a verbal order.

(b) Verbal orders for the administration of pharmacological agents and other medical treatment interventions shall be given to a licensed nurse, or other person authorized by state law to receive such orders. The order once recorded shall include the date and signature of the person receiving the order, shall be recorded in the client record, and shall be countersigned by the physician or other person authorized by State law to prescribe.

(c) Verbal orders for allied health services personnel, other than nursing or other than in-home aide services, shall be given to either a licensed nurse or the appropriate health professional. The order once recorded shall include the date and signature of the person receiving the order, shall be recorded in the client record and shall be countersigned by the physician or other person authorized by State law to prescribe.

(d) The home care agency shall develop and implement written policies and procedures for obtaining countersignatures on verbal orders within 60 days of the date of the verbal order.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 2004; February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

SECTION .1400 - SERVICE RECORDS

10A NCAC 13J .1401 REQUIREMENT

(a) The agency shall develop and implement written policies governing content and handling of client records.

(b) The agency shall maintain a client record for each client. Each page of the client record shall have the client's name. All entries in the record shall reflect the actual date of entry. When agency staff make additional, late, or out of sequence entries into the client record, the documentation shall include the following applicable notations: addendum, late entry, or entry out of sequence, and the date of the entry. A system for maintaining originals and copies shall be described in the agency policies and procedures.

(c) The agency shall assure that originals of client records are kept confidential and secure on the licensed premises unless in accordance with Rule .0905 of this Subchapter, or subpoenaed by a court of legal jurisdiction, or to conduct an evaluation as required in Rule .1004 of this Subchapter.

(d) If a record is removed to conduct an evaluation, the record shall be returned to the agency premises within five working days. The agency shall maintain a sign out log that includes to whom the record was released, client's name and date removed. Only authorized staff or other persons authorized by law may remove the record for these purposes.

(e) A copy of the client record for each client must be readily available to the appropriate health professional(s) providing services or managing the delivery of such services.

(f) Client records shall be retained for a period of not less than five years from the date of the most recent discharge of the client, unless the client is a minor in which case the record must be retained until three years after the client's 18th birthday. When an agency ceases operation, the Department shall be notified in writing where the records will be stored for the required retention period.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1402 CONTENT OF RECORD

(a) If the agency is providing services to a client, the service record shall contain the following information:

(1) Admission data:

(A) identification data such as name, address, telephone number, date of birth, sex, and marital status;

(B) a copy of the signed client's rights form or documentation of its delivery;

(C) names of next of kin, legal guardian, or other family members;

(D) source of referral; and

(E) assessment of home environment.

(2) Service data:

(A) initial assessments by the health care practitioner of the client's functional status in the areas of social, mental, physical health, environmental, economic, ADLs, and IADLs;

(B) identification of problems, the establishment of goals and proposed intervention, and indication of the client's understanding of and approval for services to be provided. If the client is diagnosed as not competent, the approval of the client's responsible party shall be recorded;

(C) a record of all services provided with entries with date and time of service, and signed by the individual providing the service;

(D) discharge summary that includes an overall summary of services provided by the agency and the date and reason for discharge. When a specific service to a client is terminated and other services continue, there shall be documentation of the date and reason for terminating the specific service; and

(E) evidence of coordination of services when the client is receiving more than one in-home care service.

(b) If the agency is providing services to a client that require a physician's order, the service record shall include all of the items described in Paragraph (a) of this Rule and the following items:

(1) Admission data:

(A) admission and discharge dates from hospital or other institution when applicable; and

(B) names of physician(s) responsible for the client's care.

(2) Service data:

(A) client's diagnoses;

(B) physician's orders for pharmaceuticals and medical treatments; and

(C) if the agency is providing services to a hospital or nursing facility patient, the agency's record shall include referral information, dates and times of services, and documentation of services provided.

History Note: *Authority G.S. 131E-140;*
Eff. July 1, 1992;
Amended Eff. February 1, 1996;
Readopted Eff. June 1, 2018.

SECTION .1500 – COMPANION, SITTER, AND RESPITE SERVICES

10A NCAC 13J .1501 DEFINITIONS

The following definitions shall apply throughout this Section:

(1) "Companion, sitter, or respite services personnel" means an individual as used in G.S. 131E-136, who spends time with or provides non-hands-on care services for clients.

(2) "Non-Hands-on Care Services" means basic home management tasks, shopping, meal preparation, transportation, companion services, socialization, medication reminders, and other services that do not require the service provider to use "hands-on care" as defined in Rule .0901 of this Subchapter and which do not require training or verification of skills by a Registered Nurse.

(3) "Respite Care" means planned or emergency care provided to an individual in order to provide temporary relief to the family caregiver.

History Note: *Authority G.S. 131E-140;*
Eff. January 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1502 SCOPE OF SERVICES

(a) If an agency provides In-home companion, sitter, or respite services, the services shall be provided in accordance with the client's plan of care. Agencies participating in the Home and Community Care Block Grant or Social Services Block Grant through the Division of Aging and Adult Services shall comply with the service level rules contained in 10A NCAC 06A and 10A NCAC 06X. All other agencies providing in-home companion, sitter, or respite services shall comply with the provisions of the rules in this Section.

(b) In-home companion, sitter, or respite services personnel shall follow the plan of care written by the in-home companion, sitter, or respite services supervisor.

History Note: *Authority G.S. 131E-140;*
Eff. January 1, 2010;
Readopted Eff. June 1, 2018.

10A NCAC 13J .1503 AGENCY MANAGEMENT AND SUPERVISION

Notwithstanding the requirements in Rule .1001 of this Subchapter, the agency shall meet the following requirements:

(1) The agency shall designate an individual to serve as agency director. The agency director shall have the authority and responsibility for administrative direction of the agency. The agency director shall be a high school graduate, or be certified under the G.E.D. Program, and shall meet one or more of the following qualifications:
   (a) shall be a health care practitioner as defined in G.S. 90-640(a); or
   (b) shall have one year experience in home care, companion, sitter, or respite services, or any other provider licensed pursuant to G.S. 131E or G.S. 122C.

(2) The agency shall designate a person responsible for supervising non-hands-on care services that is provided by the agency either directly or by contract. This individual may be the supervisor for the companion, sitter, or respite services and may also serve as the agency director.

History Note: *Authority G.S. 131E-140;*
Eff. January 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

10A NCAC 13J .1504 SUPERVISION AND COMPETENCY OF COMPANION, SITTER, AND RESPITE SERVICES

In addition to the requirements in Rule .1110 of this Subchapter, an agency providing In-home companion, sitter, or respite care services shall meet the following requirements:

(1) Each agency shall have documentation that its companion and sitters are competent to perform client care tasks or activities to which they are assigned. Such individuals shall perform delegated activities under the supervision of a supervisor designated by agency policy for the services assigned.

(2) The agency designated supervisor shall supervise the companion and sitter staff by contacting the client receiving care every three months and by making a supervisory visit to each client's place of residence at least every six months, with or without the companion and sitter's presence, and at least annually, while the companion or sitter is in the home providing services to the client.

(3) The supervisory visit shall include a review of the client's general condition, monitoring progress and response to the services provided by the companion or sitter, and updates to the plan of care as needed.

(4) Documentation of supervisory visits shall be maintained in the agency's records and shall contain the following:
   (a) date of visit;
   (b) findings of visit; and
   (c) signature of person performing the visit.

(5) The agency designated supervisor conducting a supervisory contact for a companion, sitter, or respite provider may simultaneously conduct the quarterly case review as required in Rule .1202 of this Subchapter.

(6) The agency directed supervisor shall be available for supervision, on-site where services are provided when necessary, during the hours that companion, sitter, or respite services are provided.

History Note: *Authority G.S. 131E-140;*
Eff. January 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016.

G.S. 150B-21.3A Report for 10A NCAC 13J, THE LICENSING OF HOME CARE AGENCIES

Agency - Medical Care Commission

Comment Period -

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation					
SUBCHAPTER 13J – THE LICENSING OF HOME CARE AGENCIES	**SECTION .0900 - GENERAL**	10A NCAC 13J .0901	DEFINITIONS	Readopted Eff. June 1, 2018	Necessary	No						
		10A NCAC 13J .0902	LICENSE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .0903	APPLICATION FOR AND ISSUANCE OF LICENSE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .0904	INSPECTIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .0905	MULTIPLE PREMISES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .0906	COMPLIANCE WITH LAWS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .0907	ADVERSE ACTION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
	SECTION .1000 ADMINISTRATION	10A NCAC 13J .1001	AGENCY MANAGEMENT AND SUPERVISION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1002	ADMINISTRATIVE, FINANCIAL AND STATISTICAL RECORDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1003	PERSONNEL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1004	EVALUATION	Readopted Eff. June 1, 2018	Necessary	No						
		10A NCAC 13J .1005	HOSPICE CARE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1006	NURSING POOL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1007	CLIENT RIGHTS AND RESPONSIBILITIES	Readopted Eff. June 1, 2018	Necessary	No						
	SECTION .1100 SCOPE OF SERVICES	10A NCAC 13J .1101	ACCEPTANCE OF CLIENTS FOR SERVICE PROVISION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1102	NURSING SERVICES AND DUTIES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1103	PHYSICAL THERAPY SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1104	SPEECH THERAPY/PATHOLOGY SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1105	OCCUPATIONAL THERAPY SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1106	MEDICAL SOCIAL WORK SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1107	IN-HOME AIDE SERVICES	Readopted Eff. June 1, 2018	Necessary	No						

G.S. 150B-21.3A Report for 10A NCAC 13J, THE LICENSING OF HOME CARE AGENCIES

Agency - Medical Care Commission

Comment Period -

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation					
		10A NCAC 13J .1108	INFUSION NURSING SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1109	CLINICAL RESPIRATORY SERVICES, INCLUDING PULMONARY, OR VENTILATION SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1110	SUPERVISION AND COMPETENCY OF IN-HOME CAREGIVERS	Readopted Eff. June 1, 2018	Necessary	No						
		10A NCAC 13J .1111	ARRANGEMENTS FOR SERVICES WITH OTHER AGENCIES OR INDIVIDUALS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1112	HOME MEDICAL EQUIPMENT AND SUPPLIES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
	SECTION .1200 CASE REVIEW AND PLAN OF CARE	10A NCAC 13J .1201	POLICIES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1202	CASE REVIEW AND PLAN OF CARE	Readopted Eff. June 1, 2018	Necessary	No						
	SECTION .1300 PHARMACEUTICALS AND MEDICAL TREATMENT ORDERS	10A NCAC 13J .1301	POLICIES, PROCEDURES, AND STAFF RESPONSIBILITY	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1302	ORDERS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
	SECTION .1400 SERVICE RECORDS	10A NCAC 13J .1401	REQUIREMENT	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1402	CONTENT OF RECORD	Readopted Eff. June 1, 2018	Necessary	No						
	SECTION .1500 – COMPANION, SITTER, AND RESPITE SERVICES	10A NCAC 13J .1501	DEFINITIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1502	SCOPE OF SERVICES	Readopted Eff. June 1, 2018	Necessary	No						
		10A NCAC 13J .1503	AGENCY MANAGEMENT AND SUPERVISION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						
		10A NCAC 13J .1504	SUPERVISION AND COMPETENCY OF COMPANION, SITTER, AND RESPITE SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 25, 2016	Necessary	No						