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: 958 004 649 #

FEBRUARY 7, 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. 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**)

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** for selected application information

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)

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. **Hospital 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)

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.

XII. Meeting Adjournment

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
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OR
TEAMS Video Conference: Join the meeting now
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Dial-IN: 1-984-204-1487 / Passcode: 205 068 007#

November 22, 2024 (Friday)
9:00 a.m.
MINUTES

I. Meeting Attendance

MEMBERS PRESENT	MEMBERS ABSENT
John J. Meier, IV, M.D., Chairman Joseph D. Crocker, Vice-Chairman Kathy G. Barger Paul R. G. Cunningham, M.D. Bryant C. Foriest Linwood B. Hollowell, III 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 **DIVISION OF HEALTH SERVICE REGULATION STAFF** S. Mark Payne, Director, DHSR/MCC Secretary Emery E. Milliken, Deputy Director, DHSR Geary W. Knapp, JD, CPA, Assistant Secretary, MCC Jeff Harms, Acting Construction Chief, DHSR Tammy Sylvester, Assistant Construction Chief, DHSR Shanah F. Black, Rule Making Coordinator, DHSR Eric R. Hunt, Attorney General's Office	Sally B. Cone Eileen C. Kugler, RN MSN, MPH, FNP Jeffrey S. Wilson Ashley H. Lloyd, D.D.S.

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

- **August 19, 2024** (Medical Care Commission Special Meeting) (**See Exhibit A**)
- **September 20, 2024** (Executive Committee) (**See Exhibit B/1**)
  - Issuance of EveryAge Series 2024B
- **October 25, 2024** (Executive Committee) **(See Exhibit B/2**)
  - Issuance of Penick Village Series 2024A, B1, B2, & B3

***COMMISSION ACTION**: A motion was made to approve the minutes by Dr. Paul Cunningham, seconded by Joseph Crocker, and unanimously approved.*

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

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

B. Notices & Non-Action Items & Technical Rule Changes

September 9, 2024 – EveryAge Series 2024A (Refunding Taxable Series 2021D)

- Par Value Outstanding: $17,785,000
- Series 2024A is a tax-exempt bond

VII. Bond Projects (Action Item)…….……..Geary W. Knapp

A. **Affordable Senior Housing Foundation** (Multiple Locations)

Resolution: The Commission grants preliminary approval to a transaction for Affordable Senior Housing Foundation to purchase the following 12 facilities (Assisted Living / Memory Care / Independent Living with services):

- Cambridge House (Hildebran)
- Dayspring of Wallace (Wallace)
- Greenbrier of Fairmont (Fairmont)

- Heath House (Lincolnton)
- Hickory Village (Hickory)
- Prestwick Village (Laurinburg)
- Rolling Ridge Assisted Living (Newton Grove)
- The Villas at Rolling Ridge (Newton Grove)
- Southfork (Winston-Salem)
- Twelve Oaks (Mt. Airy)
- Wexford House (Denver)
- Woodridge (Monroe)

Capital expenditures for the proposed purchase 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	$	90,000,000.00
Total Sources	**$**	**90,000,000.00**
ESTIMATED USE OF FUNDS		
Portfolio Purchase Price	$	83,020,000.00
Working Capital	$	3,700,000.00
Bond Insurance/Letter of Credit	$	710,000.00
Debt Service Reserve Fund	$	670,000.00
Underwriter Placement Fee	$	870,000.00
Feasibility Study Fee	$	84,000.00
Accountant Fee	$	40,000.00
Corporate Counsel	$	175,000.00
Bond Counsel	$	183,000.00
Trustee Fee	$	28,000.00
Bank Counsel	$	200,000.00
Property and Environmental Reports	$	60,000.00
Liquidity Support Fund	$	260,000.00
Total Uses	**$**	**90,000,000.00**

Tentative approval is given with the understanding that the governing board of Affordable Senior Housing Foundation 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 residents.

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

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.

Based on information furnished by applicant, the project is:

Financially Feasible: YES
Related Costs are Reasonable: YES

See **Exhibit G** & **H** for compliance, selected application information, and presentation.

***COMMISSION ACTION**: A motion was made to approve the Affordable Senior Housing Foundation resolution by Joseph Crocker, seconded by Dr. Robert Schaaf, and unanimously approved.*

B. **Affordable Senior Housing Foundation** (Multiple Locations**)**

Resolution: The Commission grants preliminary approval to a transaction for Affordable Senior Housing Foundation to purchase the following 4 facilities (Assisted Living / Memory Care):

- The Landings of Mills River (Mills River)
- The Drake (Concord)
- The Berkeley (Morganton)
- The Landings of Cabarrus (Kannapolis)

Capital expenditures for the proposed purchase 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	$	78,000,000.00
Total Sources	**$**	**78,000,000.00**

ESTIMATED USE OF FUNDS		
Portfolio Purchase Price	$	73,510,000.00
Working Capital	$	2,190,000.00
Bond Insurance/Letter of Credit	$	410,000.00
Debt Service Reserve Fund	$	200,000.00
Underwriter Placement Fee	$	520,000.00
Feasibility Study Fee	$	85,000.00
Accountant Fee	$	60,000.00
Corporate Counsel	$	210,000.00
Bond Counsel	$	225,000.00
Trustee Fee	$	35,000.00
Bank Counsel	$	230,000.00
Property and Environmental Reports	$	35,000.00
Liquidity Support Fund	$	290,000.00
Total Uses	**$**	**78,000,000.00**

Tentative approval is given with the understanding that the governing board of Affordable Senior Housing Foundation 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 residents.

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

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.

Based on information furnished by applicant, the project is:

Financially Feasible: YES
Related Costs are Reasonable: YES

See **Exhibit G** for compliance and selected application information.

***COMMISSION ACTION**: A motion was made to approve the Affordable Senior Housing Foundation resolution by Bryant Foriest, seconded by Dr. Robert Schaaf, and unanimously approved.*

VIII. Old Business (Discuss Rules, Fiscal Note, & Comments Submitted) (Action Item)

A. Rules for Adoption

1. Adult Care Home/Family Care Home Rules…....…S. Black & M. Lamphere

Readoption of 39 rules following Periodic Review: 33 readoptions, 6 amendments, 1 repeal

- 10A NCAC 13F .0206, .0301, .0302, .0304-.0307, .0309-.0311, .0801, .0802, .1304, .1501, .1601-.1605. 10A NCAC 13G .0206, .0301, .0302, .0305-.0309, .0312, .0315-.0318, .0801, .0802, and .1601-.1605

(**See Exhibits C thru C/3**)

COMMISSION ACTION*: A motion was made to approve the Adult Care/Family Care Home rules by Dr. Robert Schaaf, seconded by Joseph Crocker, and unanimously approved.*

IX. New Business (Discuss Rules & Fiscal Note) (Action Items)

A. Periodic Review Rules for Approval – Initial Category Determination

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

   8 Rules

- 10A NCAC 13L .0101, .0201 - .0204, .0301 - .0303

(**See Exhibits D thru D/1**)

COMMISSION ACTION*: A motion was made to approve the Nursing Pool Licensure rules by Bryant Foriest, seconded by Dr. Robert Schaaf, and unanimously approved.*

2. **Mammogram and Pap Smear Certification**….Shanah Black & Azzie Conley
   2 Rules

- 10A NCAC 13M .0101 and .0201

(**See Exhibits E thru E/1**)

COMMISSION ACTION*: A motion was made to approve the Mammogram and Pap Smear Certification rules by Joseph Crocker, seconded by Bryant Foriest, and unanimously approved.*

3. **Healthcare Personnel Registry**……Shanah Black, Jana Busick & Rita Horton

   5 Rules

- 10A NCAC 13O .0101, .0102, .0201, 0202, .0301

(**See Exhibits F thru F/1**)

COMMISSION ACTION*: A motion was made to approve the Healthcare Personnel Registry rules by Joseph Crocker, seconded by Dr. Paul Cunningham, and unanimously approved.*

X. Schedule of 2025 MCC Quarterly Meetings (Action Item)……Dr. John Meier

February 6-7, 2025
May 8-9, 2025
August 7-8, 2025
November 6-7, 2025

***COMMISSION ACTION**: Commission deferred action until a survey of members is completed to determine best quarterly schedule.*

XI. Appointment of two Executive Committee Members (Action Item)…..… Dr. John Meier

In accordance with 10A NCAC 13A.0101, the NCMCC's Chairman shall appoint two members to the Executive Committee to serve for a term of two years or until expiration of his/her regularly appointed term. No member of the Executive Committee, except the Chairman and Vice-Chairman, shall serve more than two two-year terms in succession. The terms are scheduled to expire on 12/31/2026.

***COMMISSION ACTION**: Dr. Meier (Chairman) appointed Bryant Foriest and Dr. David Mayer to serve on the Executive Committee for a two year term beginning January 1, 2025 and ending December 31, 2026.*

XII. Election of Vice-Chairman (Action Item)……..….....……..Dr. John Meier

In accordance with N.C.G.S. § 143B-168, the NCMCC shall elect from the members a Vice Chairman to serve for a term of two years (ending 12/31/2026) or until the expiration of his/her regularly appointed term.

***COMMISSION ACTION**: The Commission unanimously elected Joseph Crocker to serve a two year term as the Vice Chairman beginning January 1, 2025 and ending December 31, 2026.*

XIII. 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 February 7, 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 February 7, 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 Joseph Crocker, seconded by Dr. Robert Schaaf, and unanimously approved.*

XIV. Meeting Adjournment

There being no further business the meeting was adjourned at 11:35 a.m.

Respectfully submitted,

Geary W. Knapp, JD, CPA
Assistant Secretary

STATE ETHICS COMMISSION

POST OFFICE BOX 27685
RALEIGH, NC 27611
PHONE: 919-814-3600

Via Email

January 3, 2025

The Honorable Joshua H. Stein
Governor of North Carolina
20301 Mail Service Center
Raleigh, North Carolina 27699-0301

Re: Evaluation of Statement of Economic Interest Filed by Dr. Michelle F. Jones
Prospective Appointee to the Medical Care Commission

Dear Governor Stein:

Our office has received **Dr. Michelle F. Jones's** 2025 Statement of Economic Interest as a prospective appointee to the **Medical Care Commission (the "Commission")**. We have reviewed it for actual and potential conflicts of interest pursuant to Chapter 138A of the North Carolina General Statutes ("N.C.G.S."), also known as the State Government Ethics Act (the "Act").

Compliance with the Act and avoidance of conflicts of interest in the performance of public duties are the responsibilities of every covered person, regardless of this letter's contents. This letter, meanwhile, is not meant to impugn the integrity of the covered person in any way. This letter is required by N.C.G.S. § 138A-28(a) and is designed to educate the covered person as to potential issues that could merit particular attention. Advice on compliance with the Act is available to certain public servants and legislative employees under N.C.G.S. § 138A-13.

We did not find an actual conflict of interest but found the potential for a conflict of interest. The potential conflict identified does not prohibit service on this entity.

The North Carolina Medical Care Commission was created to adopt statewide plans for the construction and maintenance of public and private hospitals, medical centers, and related facilities, including the approval of projects in the amounts of grants-in-aid from funds by both federal and state governments. The Commission is charged with administering the Health Care Facilities Finance Act (N.C.G.S. Chapter 131A) and issues bonds pursuant thereto. In addition, the Commission has the authority to adopt rules, regulations and standards for the different types of hospitals to be licensed, the operation of nursing homes, the inspection, licensure and operation of adult care homes, including personnel requirements of staff employed in adult care homes. The Commission also adopts rules providing for the accreditation of facilities that perform mammography and other procedures.

The Act establishes ethical standards for certain public servants and prohibits public servants from: (1) using their positions for their financial benefit or for the benefit of their extended family or business, N.C.G.S. § 138A-31; and (2) participating in official actions from which they or certain associated persons might receive a reasonably foreseeable financial benefit, N.C.G.S. § 138A-36(a). The Act also requires public servants to take appropriate steps to remove themselves from proceedings in which their

impartiality might reasonably be questioned due to a familial, personal, or financial relationship with a participant in those proceedings. N.C.G.S. § 138A-36(c).

Dr. Jones would fill the role of an at-large member on the Commission. She is a family physician with Wilmington Health Associates and is also employed at Community Care of the Lowel Cape Fear. As such, Dr. Jones has the potential for a conflict of interest and should exercise appropriate caution in the performance of her public duties should the business of Wilmington Health Associates, Community Care of the Lowel Cape Fear come before the Commission for official action.

In addition to the conflicts standards noted above, the Act prohibits public servants from accepting gifts from (1) a lobbyist or lobbyist principal, (2) a person or entity that is seeking to do business with the public servant's agency, is regulated or controlled by that agency, or has financial interests that might be affected by their official actions, or (3) anyone in return for being influenced in the discharge of their official responsibilities. N.C.G.S. § 138A-32. Exceptions to the gifts restrictions are set out in N.C.G.S. § 138A-32(e).

When this letter cites an actual or potential conflict of interest under N.C.G.S. § 138A-24(e), the conflict must be recorded in the minutes of the applicable board and brought to the membership's attention by the board's chair as often as necessary to remind all members of the conflict and to help ensure compliance with the Act. N.C.G.S. § 138A-15(c).

Finally, the Act mandates that all public servants attend an ethics and lobbying education presentation. N.C.G.S. § 138A-14. Please review the attached document for additional information concerning this requirement.

Please contact our office if you have any questions concerning our evaluation or the ethical standards governing public servants under the Act.

Sincerely,

Jane Steffens, SEI Unit
State Ethics Commission

cc: Michelle F. Jones
Attachment: Ethics Education Guide

NC Medical Care Commission

Quarterly Report on **Outstanding Debt** (End: 1st Quarter FYE 2025)

Program Measures	FYE 2024 Ending: 6/30/2024	FYE 2025 Ending: 12/31/2024
Outstanding Debt	**$4,677,104,694**	**$4,745,068,046**
Outstanding Series	**114**[1]	**116**[1]

Detail of Program Measures	Ending: 6/30/2024	Ending: 12/31/2024
Outstanding Debt per Hospitals and Healthcare Systems	$3,088,410,639	$3,022,714,993
Outstanding Debt per CCRCs	$1,588,694,055	$1,722,353,053
Outstanding Debt per Other Healthcare Service Providers	$0	$0
Outstanding Debt Total	**$4,677,104,694**	**$4,745,068,046**
Outstanding Series per Hospitals and Healthcare Systems	50	50
Outstanding Series per CCRCs	64	66
Outstanding Series per Other Healthcare Service Providers	0	0
Series Total	**114**	**116**
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

Exhibit B (Outstanding Balance)

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: 1st Quarter FYE 2025)

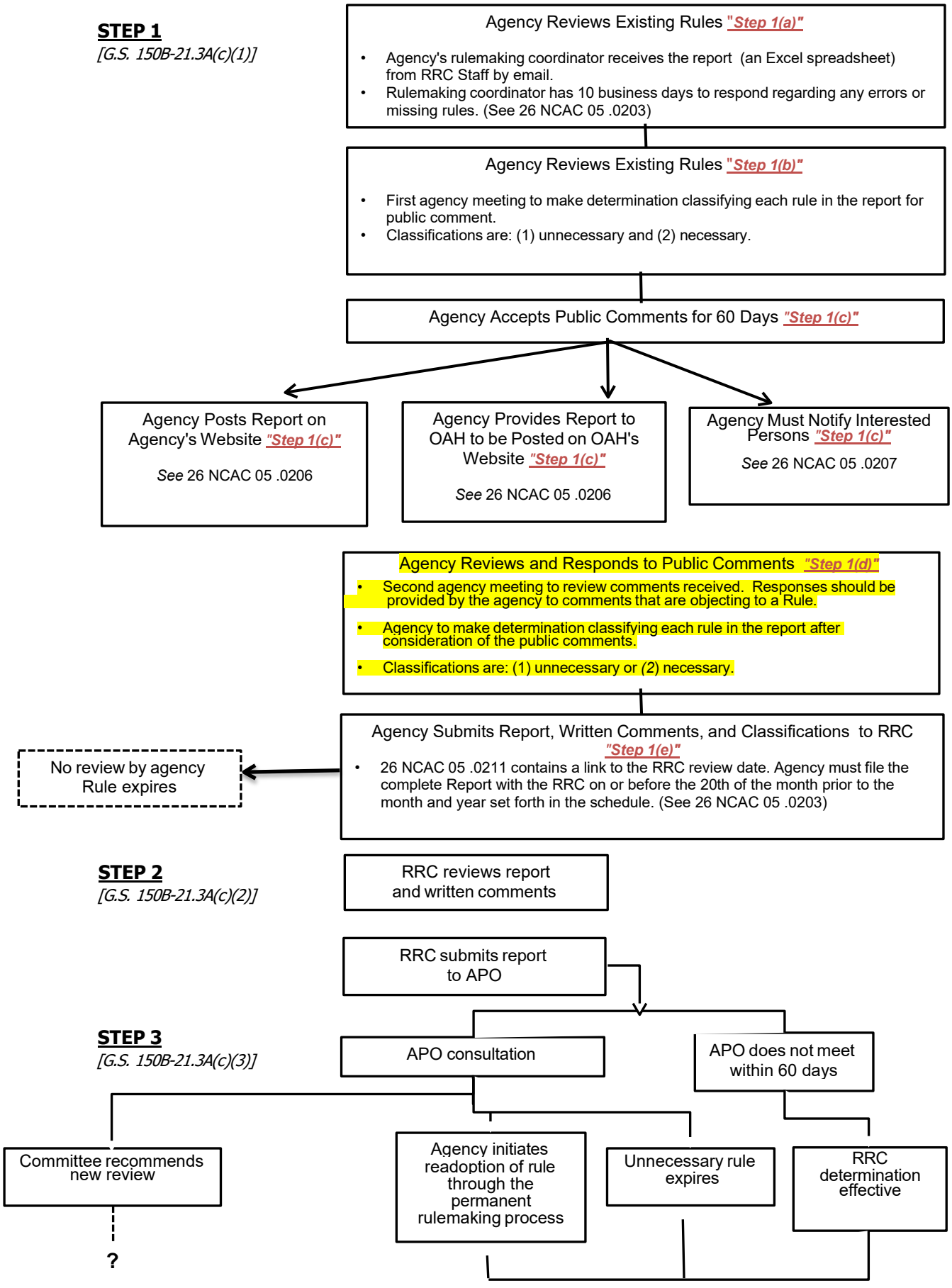
Program Measures	FYE 2024 Ending: 6/30/2024	FYE 2025 Ending: 12/31/2024
Total PAR Amount of Debt Issued	**$29,378,557,997**	**$29,688,247,997**
Total Project Debt Issued (excludes refunding/conversion proceeds)[1]	**$13,828,615,223**	**$14,003,390,223**
Total Series Issued	**715**	**726**

Detail of Program Measures	Ending: 6/30/2024	Ending: 12/31/2024
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	$6,080,777,913
PAR Amount of Debt per Other Healthcare Service Providers	$374,295,230	$374,295,230
Par Amount Total	**$29,378,557,997**	**$29,688,247,998**
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.

Periodic Review and Final Determinations



SUBCHAPTER 13L - NURSING POOL LICENSURE

SECTION .0100 - GENERAL INFORMATION

10A NCAC 13L .0101 DEFINITIONS

The following definitions apply throughout this Subchapter:

(1) "Division" means the Division of Health Service Regulation within the Department of Health and Human Services.

(2) "Premises" means a building and the tract of land upon which it sits.

History Note: *Authority G.S. 131E-154.4;*
Eff. January 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0200 - LICENSING

10A NCAC 13L .0201 APPLICATION FOR LICENSE

(a) Requests for a nursing pool license shall be submitted on application forms made available by the Division. Each application shall include the following information:

(1) Business identification consisting of the following:
  (A) The business name or names under which the licensed services will be offered in brochures, yellow pages, and other advertisements.
  (B) The full street address location of the office premises which the public will contact to obtain the offered nursing pool services.
  (C) The postal address of the office for which licensing is requested.
  (D) A listing or description of any state issued licenses applicable to the premises for which the application is submitted.

(2) Ownership disclosure consisting of the following:
  (A) The name of the legal person, corporation, partnership, or proprietor, with ownership liability and authority applying for a license.
  (B) The name, business title, address, and telephone number of the proprietor, managing partner, or chief executive officer.
  (C) The name of other corporations, trusts, or holding companies involved when the applying entity is a wholly owned subsidiary corporation.

(3) Names, title and telephone number of the on-site manager for the location to be licensed.

(4) General information on all health care related services expected to be offered to the public from the premises on the effective date of licensure.

(b) Nursing pools subject to this Subchapter, but exempt from separate licensure, shall submit an application in accordance with this Rule and an addendum to their existing license shall be issued.

(c) A copy of this Subchapter together with the governing statutes shall be maintained on the licensed premises for use by on-site personnel.

History Note: *Authority G.S. 131E-154.4;*
Eff. January 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 13L .0202 ISSUANCE OF LICENSE

(a) Each site shall be individually licensed when it has been determined by the Division that the site involved is substantially in compliance with this Subchapter. Business sites using the same public business name already licensed by the Division pursuant to G.S. 131E, Articles 5 or 6 shall have "nursing pool" added to their existing license.

(b) Nursing pools administered by health care facilities as defined in G.S. 131E-154.2 of the Nursing Pool Licensure Act, and agencies licensed under Article 5 or 6 of Chapter 131E of the General Statutes and not required to be separately licensed may request the issuance of a license as a more visible means of demonstrating their compliance with the provisions of this Subchapter.

(c) All licenses shall be renewed every two years.

History Note: *Authority G.S. 131E-154.3; 131E-154.4; 131E-154.5;*
Eff. January 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 13L .0203 PROGRAM COMPLIANCE

(a) The Division shall employ a system of initial and renewal applications, complaint investigation and on-site inspections for nursing pools with sites in the state as a means for monitoring and determining program compliance. This system shall be applied uniformly to all licensed and license-exempt nursing pool premises. Routine licensing renewal activities may be conducted by mail. Licensing of nursing pools with sites outside the state, but which provide personnel to health care facilities within the state, shall be conducted by mail.

(b) In the event of non-compliance with any rule or rules in this Subchapter or the Nursing Pool Licensure Act, the business shall be given no more than thirty days, the specific time period to be determined by the Division, to correct the non-compliance.

(c) The Division may suspend, revoke, annul, withdraw, recall, cancel, or amend a license in accordance with G.S. 131E-154.6 for any nursing pool that substantially fails to comply with the rules contained in this Subchapter or that fails to implement an approved plan of correction for violations of rules cited by the Division. A nursing pool may appeal any adverse decision made by the Division 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. As provided for in G.S. 131E-154.7, the Division may seek injunctive relief to prevent a person from establishing or operating a nursing pool without a license.

History Note: *Authority G.S. 131E-154.4;*
Eff. January 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 13L .0204 PUBLIC DISPLAY

(a) The nursing pool's license shall be valid only for the premises on which displayed and specified on the license.

(b) The public use of the pool's license status shall not be included in any advertisement which involves any unlicensed services offered by the licensee and has the potential for misleading the public into believing that both covered and non-covered services are represented by the license.

History Note: *Authority G.S. 131E-154.3; 131E-154.4;*
Eff. January 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 13L .0302 PERSONNEL RECORDS

(a) A nursing pool shall maintain a personnel record on each individual.

(b) Each individual's personnel record shall include:

(1) A legible copy of an unexpired license verification to practice nursing as a registered nurse or a licensed practical nurse or an unexpired Nurse Aide I or Nurse Aide II listing verification.

(2) A completed job application with employment history, training, education, continuing education, and identification data including name, address, and telephone number.

(3) Results of reference checks.

(4) Performance evaluations annually. The annual performance evaluation shall include feedback from the health care facility of the on-site performance of contracted nursing personnel.

(c) Personnel records shall be maintained for one year after termination from agency employment.

History Note: *Authority G.S. 131E-154.4;*
Eff. January 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015;
Amended Eff. April 1, 2024.

SECTION .0300 - ADMINISTRATION

10A NCAC 13L .0301 WRITTEN POLICIES AND PROCEDURES

(a) The nursing pool shall have written administrative and personnel policies to govern the services that it provides. These policies shall include those concerning patient care, personnel, training and orientation, supervision, employee evaluation, and organizational structure.

(b) At the option of the licensee, written policies and procedures may address other services not subject to the Nursing Pool Licensure Act. The Division shall not require separate policies and procedures if the premises from which nursing pool services are offered also offers additional temporary nursing services not subject to licensure.

(c) Policies shall provide that no reprisal action shall be taken against any employee who reports instances of patient rights violations or patient abuse, neglect, or exploitation to the appropriate governmental authority.

(d) The nursing pool shall retain all administrative records for five years and shall make these records available to the Division upon request. Administrative records shall include:

(1) documents evidencing control and ownerships, such as corporation or partnership papers;
(2) policies and procedures governing the operation of the agency;
(3) minutes of the agency's professional and administrative staff meetings;
(4) reports of complaints, inspections, reviews, and corrective actions taken related to licensure; and
(5) contracts and agreements to which the agency is a party.

History Note: *Authority G.S. 131E-154.4;*
Eff. January 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015;
Amended Eff. April 1, 2024.

10A NCAC 13L .0303 INSURANCE REQUIRED

The nursing pool shall carry general and professional liability insurance written by an insurer approved by the North Carolina Department of Insurance. The terms of such insurance shall be disclosed to clients receiving services from the licensee.

History Note: *Authority G.S. 131E-154.4;*
Eff. February 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

Exhibit C/2

G.S. 150B-21.3A Report for 10A NCAC 13L, NURSING POOL LICENSURE

Agency - Medical Care Commission

Comment Period - November 27, 2024 - January 26, 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 13L - NURSING POOL LICENSURE	**SECTION .0100 - GENERAL INFORMATION**	10A NCAC 13L .0101	DEFINITIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .0200 - LICENSING	10A NCAC 13L .0201	APPLICATION FOR LICENSE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13L .0202	ISSUANCE OF LICENSE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13L .0203	PROGRAM COMPLIANCE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13L .0204	PUBLIC DISPLAY	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .0300 - ADMINISTRATION	10A NCAC 13L .0301	WRITTEN POLICIES AND PROCEDURES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13L .0302	PERSONNEL RECORDS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13L .0303	INSURANCE REQUIRED	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	No		No	Necessary	Select One	Select One	Select One

SUBCHAPTER 13M - MAMMOGRAM AND PAP SMEAR CERTIFICATION

SECTION .0100 - PAP SMEAR CERTIFICATION

10A NCAC 13M .0101 STATE CERTIFICATION FOR LABORATORIES CONDUCTING PAP SMEARS

(a) All laboratories evaluating Pap smears shall be state certified by the Division of Health Service Regulation, Department of Health and Human Services, in accordance with this Rule.
(b) To be state certified, all laboratories shall be licensed under the federal Clinical Laboratory Improvement Act as amended or certified by the Centers for Medicare and Medicaid Services for the specialty of cytology.
(c) To be state certified, laboratories shall perform Pap smear examinations only on specimens submitted by a health care provider whose scope of practice includes the function of taking Pap smears.
(d) An application for state certification shall be submitted to the Division of Health Service Regulation listing the name and location of the laboratory requesting certification, the name of the laboratory director and evidence that the laboratory meets the requirements listed in Paragraphs (b) and (c) of this Rule. Laboratories will be notified in writing within 45 days of the receipt of the application that they have been certified or, if certification has been denied, of the reasons for denial.
(e) State certification must be renewed by a facility when licensing or certification renewal is required by the program that established state certification eligibility pursuant to Paragraph (b) of this Rule.
(f) If a laboratory's license or certification for one of these programs is suspended or revoked, the laboratory director shall immediately notify the Division of Health Service Regulation and the laboratory's state certification under this Rule shall be revoked. The laboratory may apply for recertification when it can provide evidence that it meets the requirements listed in Paragraphs (a) - (e) of this Rule.
(g) Appeals of the Division's decisions regarding state certification shall be in accordance with the Administrative Procedures Act, G.S. 150B.

History Note: *Authority G.S. 143B-165;*
Temporary Adoption Eff. October 11, 1991 For a Period of 141 Days to Expire on February 29, 1992;
Eff. March 1, 1992;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0200 - MAMMOGRAPHY CERTIFICATION

10A NCAC 13M .0201 STATE CERTIFICATION OF SCREENING MAMMOGRAPHY SERVICES

(a) All facilities performing screening mammograms shall be state certified by the Division of Health Service Regulation, Department of Health and Human Services in accordance with this Rule.

(b) To be state certified, all equipment used in the performance of screening mammography shall be dedicated to such use by manufacturer's design. Each piece of mammography X-ray equipment, whether located in a fixed or mobile facility, shall be maintained in a safe operating condition and shall be registered and used in accordance with the Rules in 15A NCAC 11.

(c) To be state certified, all facilities shall be certified by the Centers for Medicare and Medicaid Services or shall be accredited by the American College of Radiology for the performance of mammography screening.

(d) An application for state certification shall be submitted to the Division of Health Service Regulation listing the name and location of the facility requesting certification, the name of the owner, and evidence that the facility meets the requirements listed in Paragraphs (b) and (c) of this Rule. Facilities shall be notified in writing within 45 days of the receipt of the application that they have been certified or, if certification has been denied, of the reasons for denial.

(e) State certification must be renewed by a facility when certification or accreditation renewal is required by the program that established state certification eligibility pursuant to Paragraph (c) of this Rule.

(f) If a facility's certification or accreditation for one of these programs is suspended or revoked, the facility operator shall immediately notify the Division of Health Service Regulation and the facility's state certification under this Rule shall be revoked. The facility may apply for recertification when it can provide evidence that it meets the requirements listed in Paragraphs (a) - (e) of this Rule.

(g) The North Carolina Medical Care Commission delegates the authority to grant waivers of this Rule to the Division of Health Service Regulation. The Commission, however, shall review all waivers granted at its next regularly scheduled meeting and shall make any revisions to waivers deemed necessary at that time.

(h) In order to be granted a waiver of this Rule, a facility shall make a request for a waiver in writing to the Division of Health Service Regulation providing the following:

(1) justification that the rule should not be applied as written, because strict application would cause undue hardship;

(2) justification that adequate standards assuring early detection of breast cancer and affording protection of health and safety exist and will be met in lieu of the exact requirements;

(3) justification that the purpose of this Rule is met through equivalent standards affording equivalent protection of health and safety;

(4) information on the number of screening mammograms performed monthly for the previous six months;

(5) information proving that there is no state certified facility nearby by identifying the nearest state certified facility and providing information regarding the accessibility of mobile units in the area; and

(6) a plan for meeting standards necessary for certification, including the time required to meet standards.

(i) The Division of Health Service Regulation may grant a waiver to the extent that the factors listed in Paragraph (h) of this Rule are satisfied.

(j) Appeals of the Division's decisions regarding state certification shall be in accordance with the Administrative Procedures Act, G.S. 150B.

History Note: *Authority G.S. 143B-165;*
Temporary Adoption Eff. October 11, 1991 For a Period of 141 Days to Expire on February 29, 1992;
Eff. March 1, 1992;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

Exhibit D/1

G.S. 150B-21.3A Report for 10A NCAC 13M, MAMMOGRAM AND PAP SMEAR CERTIFICATION

Agency - Medical Care Commission

Comment Period - November 27, 2024 - January 26, 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 13M MAMMOGRAM AND PAP SMEAR CERTIFICATION	**SECTION .0100 PAP SMEAR CERTIFICATION**	10A NCAC 13M .0101	STATE CERTIFICATION FOR LABORATORIES CONDUCTING PAP SMEARS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	Yes If yes, include the citation to the federal law	CFR 493.1274: cytology	No	Necessary	Select One	Select One	Select One
	SECTION .0200 MAMMOGRAPHY CERTIFICATION	10A NCAC 13M .0201	STATE CERTIFICATION OF SCREENING MAMMOGRAPHY SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	No		No	Necessary	Select One	Select One	Select One

SUBCHAPTER 13O – HEALTHCARE PERSONNEL REGISTRY

SECTION .0100 - HEALTH CARE PERSONNEL REGISTRY

10A NCAC 13O .0101 DEFINITIONS

The following definitions shall apply throughout this Subchapter:

(1) "Abuse" is defined by 42 CFR Part 488 Subpart E which is incorporated by reference, including subsequent amendments. Copies of the Code of Federal Regulations may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington D.C. 20402.

(2) "Diversion of drugs" means the unauthorized taking or use of any drug.

(3) "Drug" means any chemical compound that may be used on or administered to humans or animals as an aid in the diagnosis, treatment or prevention of disease or other condition or for the relief of pain or suffering or to control or improve any physiological pathologic condition.

(4) "Finding" (when used in conjunction with the Health Care Personnel Registry) means a determination by the Department that an allegation of resident abuse or neglect, misappropriation of resident or health care facility property, diversion of drugs belonging to a resident or health care facility, and fraud against a resident or health care facility has been substantiated.

(5) "Fraud" means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State Law.

(6) "Health Care Facility" means all the facilities and agencies as defined in G.S. 131E-256(b).

(7) "Health Care Personnel" means all the persons as defined in G.S. 131E-256(c).

(8) "Misappropriation of resident property" is defined by 42 CFR Part 488 Subpart E which is incorporated by reference, including subsequent amendments. Copies of the Code of Federal Regulations may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington D.C. 20402.

(9) "Misappropriation of the property of a health care facility" means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a health care facility's property without the facility's consent.

(10) "Neglect" is defined by 42 CFR Part 488 Subpart E which is incorporated by reference, including subsequent amendments. Copies of the Code of Federal Regulations may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington D.C. 20402.

(11) "Resident" means all the individuals residing in or being served by a health care facility as defined in G.S. 131E-256(b).

History Note: *Authority G.S. 131E-256; 42 U.S.C. 1395; 42 U.S.C. 1396;*
Temporary Adoption Eff. December 20, 1996;
Eff. August 1, 1998;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 13O .0102 INVESTIGATING AND REPORTING HEALTH CARE PERSONNEL

The reporting by health care facilities to the Department of all allegations against health care personnel as defined in G.S. 131E-256 (a)(1), including injuries of unknown source, shall be done within 24 hours of the health care facility becoming aware of the allegation. The results of the health care facility's investigation shall be submitted to the Department in accordance with G.S. 131E-256(g).

History Note: *Authority G.S. 131E-256;*
Temporary Adoption Eff. December 20, 1996;
Eff. August 1, 1998;
Amended Eff. April 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0200 – MEDICATION AIDE REGISTRY

10A NCAC 13O .0201 MEDICATION AIDE COMPETENCY EVALUATION

(a) A competency evaluation candidate shall be advised by the Department after successful completion of a North Carolina Board of Nursing approved medication aide training program and prior to the competency exam that upon successful completion of the competency exam the individual will be listed on the State's medication aide registry.

(b) The competency exam shall include each course requirement specified in the North Carolina Board of Nursing's approved training program as provided for in 21 NCAC 36 .0403 and 21 NCAC 36 .0406.

(c) The competency examination shall be administered and evaluated only by the Department or its agent.

(d) A record of successful completion of the competency exam shall be included in the medication aide registry within 30 business days of successful completion of the evaluation.

(e) If the competency exam candidate does not satisfactorily complete the exam, the candidate shall be advised by the Department of the areas which the individual did not pass.

(f) Every competency exam candidate shall have the opportunity to take the exam three times before being required to retake and successfully complete the Medication Aide training program.

History Note: *Authority G.S. 131E-114.2(b); 131E-270;*
Eff. October 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 13O .0202 REGISTRY OF MEDICATION AIDES

(a) Prior to assigning medication aide duties to a Medication Aide, pursuant to G.S. 131E-114.2, the facility shall conduct a clinical skills validation for those medication administration tasks to be performed in the facility. This validation shall be conducted by a registered nurse consistent with his/her occupational licensing law and who has a current unencumbered license to practice in North Carolina. A record of this validation shall be retained in the Medication Aide's file.

(b) The Department shall provide information on the registry within one business day of the request for information.

(c) The medication aide listing on the Medication Aide Registry shall be renewed every two years provided the individual has worked for a minimum of eight hours as a Medication Aide in each consecutive 24 month period following their initial listing.

(d) The registry shall contain the following information for each individual who is listed on the Medication Aide Registry:

(1) the individual's full name;
(2) the date the individual became eligible for placement on the registry;
(3) the training program and competency exam completed; and
(4) the date of listing renewal and expiration.

(e) The Medication Aide Registry shall remove entries for individuals who have not been employed as a medication aide for a minimum of eight hours in each consecutive 24 month period following initial listing.

(f) An individual who gains or attempts to gain registry listing by providing false or misleading information on listing or re-listing applications shall not be listed on the registry.

History Note: *Authority G.S. 131E-114.2(b); 131E-270;*
Eff. October 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0300 - NURSE AIDE I REGISTRY

10A NCAC 13O .0301 NURSE AIDE I TRAINING AND COMPETENCY EVALUATION

(a) To be eligible to be listed on the NC Nurse Aide I Registry by the Health Care Personnel Education and Credentialing Section, a person shall:

(1) pass a Nurse Aide I training program approved by the Department in accordance with 42 CFR 483.151 through 42 CFR 483.152 and the State of North Carolina's Nurse Aide I competency exam; or
(2) apply to the Department for approval to be listed on the NC Nurse Aide I Registry by reciprocity of a nurse aide certification or registration from another State to North Carolina.

(b) In applying for reciprocity of a nurse aide certification or registration to be listed on the NC Nurse Aide I Registry pursuant to Subparagraph (a)(2) of this Rule, the applicant shall:

(1) submit a completed application to the Department that includes the following:
  (A) first, middle, and last name;
  (B) the applicant's prior name(s), if any;
  (C) mother's maiden name;
  (D) gender;
  (E) social security number;
  (F) date of birth;
  (G) mailing address;
  (H) email address;
  (I) home telephone number;
  (J) any other State registries of nurse aides upon which the applicant is listed;
  (K) certification or registration numbers for any State nurse aide registries identified in Part (b)(1)(J) of this Rule;
  (L) original issue dates for any certifications or registrations identified in Part (b)(1)(K) of this Rule;
  (M) expiration dates for any certifications or registrations identified in Part (b)(1)(K) of this Rule; and
  (N) employment history;

(2) provide documentation verifying that his or her registry listing is active and in good standing in the State(s) of reciprocity, dated no older than 30 calendar days prior to the date the application is received by the Department; and

(3) provide a copy of his or her Social Security card and an unexpired government-issued identification containing a photograph and signature.

(c) For the applicant to be approved for reciprocity of a nurse aide certification or registration and be listed on the NC Nurse Aide I Registry, the Department shall verify the following:

(1) the applicant has completed an application in accordance with Subparagraph (b)(1) of this Rule;

(2) the applicant is listed on another State's registry of nurse aides as active and in good standing;

(3) the applicant has no pending or substantiated findings of abuse, neglect, exploitation, or misappropriation of resident or patient property recorded on other State registries of nurse aides;

(4) if the applicant has been employed as a nurse aide for monetary compensation consisting of at least a total of eight hours of time worked performing nursing or nursing-related tasks delegated and supervised by a Registered Nurse, then the applicant shall provide the employer name, employer address, and dates of employment for the previous 24 consecutive months;

(5) the name listed on the Social Security card and government-issued identification containing a photograph and signature submitted with the application matches the name listed on another State's registry of nurse aides or that the applicant has submitted additional documentation verifying any name changes; and

(6) the applicant completed a State-approved nurse aide training and competency evaluation program that meets the requirements of 42 CFR 483.152 or a State-approved competency evaluation program that meets the requirements of 42 CFR 483.154.

(d) The Department shall within 10 business days of receipt of an application for reciprocity of a nurse aide certification or registration or receipt of additional information from the applicant:

(1) inform the applicant by letter whether he or she has been approved; or

(2) request additional information from the applicant.

The applicant shall be added to the NC Nurse Aide I Registry within three business days of Department approval.

(e) This Rule incorporates 42 CFR Part 483 Subpart D by reference, including all subsequent amendments and editions. Copies of the Code of Federal Regulations may be accessed electronically free of charge from www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

(f) The State of North Carolina's Nurse Aide I competency exam shall include each course requirement specified in the Department-approved Nurse Aide I training program as provided for in 42 CFR 483.152.

(g) The State of North Carolina's Nurse Aide I competency exam shall be administered and evaluated only by the Department or its contracted testing agent as provided for in 42 CFR 483.154.

(h) The Department shall include a record of completion of the State of North Carolina's Nurse Aide I competency exam in the NC Nurse Aide I Registry within 30 days of passing the written or oral exam and the skills demonstration as provided for in 42 CFR 483.154.
(i) If the State of North Carolina's Nurse Aide I competency exam candidate does not pass the written or oral exam and the skills demonstration as provided for in 42 CFR 483.154, the candidate shall be advised by the Department of the areas that the individual did not pass.
(j) Every North Carolina's Nurse Aide I competency exam candidate shall have the opportunity to take the exam at maximum three times before being required to retake and pass a Nurse Aide I training program.
(k) U.S. military personnel who have completed medical corpsman training and retired or non-practicing nurses shall not be required to take the Department-approved Nurse Aide I training program to be listed or relisted on the Nurse Aide I Registry, unless the person fails to pass the State of North Carolina's Nurse Aide I competency exam after three attempts.

History Note: *Authority G.S. 131E-255; 42 CFR 483.150; 42 CFR 483.151; 42 CFR 483.152; 42 CFR 483.154; 42 CFR 483.156; 42 CFR 483.158;*
Eff. January 1, 2016;
Emergency Amendment Eff. April 20, 2020;
Temporary Amendment Eff. June 26, 2020;
Amended Eff. April 1, 2021.

10A NCAC 13O .0102 INVESTIGATING AND REPORTING HEALTH CARE PERSONNEL

The reporting by health care facilities to the Department of all allegations against health care personnel as defined in G.S. 131E-256 (a)(1), including injuries of unknown source, shall be done within 24 hours of the health care facility becoming aware of the allegation. The results of the health care facility's investigation shall be submitted to the Department in accordance with G.S. 131E-256(g).

History Note: *Authority G.S. 131E-256;*
Temporary Adoption Eff. December 20, 1996;
Eff. August 1, 1998;
Amended Eff. April 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

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.

SECTION .0200 – MEDICATION AIDE REGISTRY

10A NCAC 13O .0201 MEDICATION AIDE COMPETENCY EVALUATION

(a) A competency evaluation candidate shall be advised by the Department after successful completion of a North Carolina Board of Nursing approved medication aide training program and prior to the competency exam that upon successful completion of the competency exam the individual will be listed on the State's medication aide registry.
(b) The competency exam shall include each course requirement specified in the North Carolina Board of Nursing's approved training program as provided for in 21 NCAC 36 .0403 and 21 NCAC 36 .0406.
(c) The competency examination shall be administered and evaluated only by the Department or its agent.
(d) A record of successful completion of the competency exam shall be included in the medication aide registry within 30 business days of successful completion of the evaluation.
(e) If the competency exam candidate does not satisfactorily complete the exam, the candidate shall be advised by the Department of the areas which the individual did not pass.
(f) Every competency exam candidate shall have the opportunity to take the exam three times before being required to retake and successfully complete the Medication Aide training program.

History Note: *Authority G.S. 131E-114.2(b); 131E-270;*
Eff. October 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0300 - NURSE AIDE I REGISTRY

10A NCAC 13O .0301 NURSE AIDE I TRAINING AND COMPETENCY EVALUATION

(a) To be eligible to be listed on the NC Nurse Aide I Registry by the Health Care Personnel Education and Credentialing Section, a person shall:

(1) pass a Nurse Aide I training program approved by the Department in accordance with 42 CFR 483.151 through 42 CFR 483.152 and the State of North Carolina's Nurse Aide I competency exam; or

(2) apply to the Department for approval to be listed on the NC Nurse Aide I Registry by reciprocity of a nurse aide certification or registration from another State to North Carolina.

(b) In applying for reciprocity of a nurse aide certification or registration to be listed on the NC Nurse Aide I Registry pursuant to Subparagraph (a)(2) of this Rule, the applicant shall:

(1) submit a completed application to the Department that includes the following:

(A) first, middle, and last name;

(B) the applicant's prior name(s), if any;

(C) mother's maiden name;

(D) gender;

(E) social security number;

(F) date of birth;

(G) mailing address;

(H) email address;

(I) home telephone number;

(J) any other State registries of nurse aides upon which the applicant is listed;

(K) certification or registration numbers for any State nurse aide registries identified in Part (b)(1)(J) of this Rule;

(L) original issue dates for any certifications or registrations identified in Part (b)(1)(K) of this Rule;

(M) expiration dates for any certifications or registrations identified in Part (b)(1)(K) of this Rule; and

(N) employment history;

(2) provide documentation verifying that his or her registry listing is active and in good standing in the State(s) of reciprocity, dated no older than 30 calendar days prior to the date the application is received by the Department; and

(3) provide a copy of his or her Social Security card and an unexpired government-issued identification containing a photograph and signature.

(c) For the applicant to be approved for reciprocity of a nurse aide certification or registration and be listed on the NC Nurse Aide I Registry, the Department shall verify the following:

(1) the applicant has completed an application in accordance with Subparagraph (b)(1) of this Rule;

(2) the applicant is listed on another State's registry of nurse aides as active and in good standing;

(3) the applicant has no pending or substantiated findings of abuse, neglect, exploitation, or misappropriation of resident or patient property recorded on other State registries of nurse aides;

(4) if the applicant has been employed as a nurse aide for monetary compensation consisting of at least a total of eight hours of time worked performing nursing or nursing-related tasks delegated and supervised by a Registered Nurse, then the applicant shall provide the employer name, employer address, and dates of employment for the previous 24 consecutive months;

(5) the name listed on the Social Security card and government-issued identification containing a photograph and signature submitted with the application matches the name listed on another State's registry of nurse aides or that the applicant has submitted additional documentation verifying any name changes; and

(6) the applicant completed a State-approved nurse aide training and competency evaluation program that meets the requirements of 42 CFR 483.152 or a State-approved competency evaluation program that meets the requirements of 42 CFR 483.154.

(d) The Department shall within 10 business days of receipt of an application for reciprocity of a nurse aide certification or registration or receipt of additional information from the applicant:

(1) inform the applicant by letter whether he or she has been approved; or

(2) request additional information from the applicant.

The applicant shall be added to the NC Nurse Aide I Registry within three business days of Department approval.
(e) This Rule incorporates 42 CFR Part 483 Subpart D by reference, including all subsequent amendments and editions. Copies of the Code of Federal Regulations may be accessed electronically free of charge from www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.
(f) The State of North Carolina's Nurse Aide I competency exam shall include each course requirement specified in the Department-approved Nurse Aide I training program as provided for in 42 CFR 483.152.
(g) The State of North Carolina's Nurse Aide I competency exam shall be administered and evaluated only by the Department or its contracted testing agent as provided for in 42 CFR 483.154.
(h) The Department shall include a record of completion of the State of North Carolina's Nurse Aide I competency exam in the NC Nurse Aide I Registry within 30 days of passing the written or oral exam and the skills demonstration as provided for in 42 CFR 483.154.
(i) If the State of North Carolina's Nurse Aide I competency exam candidate does not pass the written or oral exam and the skills demonstration as provided for in 42 CFR 483.154, the candidate shall be advised by the Department of the areas that the individual did not pass.
(j) Every North Carolina's Nurse Aide I competency exam candidate shall have the opportunity to take the exam at maximum three times before being required to retake and pass a Nurse Aide I training program.
(k) U.S. military personnel who have completed medical corpsman training and retired or non-practicing nurses shall not be required to take the Department-approved Nurse Aide I training program to be listed or relisted on the Nurse Aide I Registry, unless the person fails to pass the State of North Carolina's Nurse Aide I competency exam after three attempts.

History Note: *Authority G.S. 131E-255; 42 CFR 483.150; 42 CFR 483.151; 42 CFR 483.152; 42 CFR 483.154; 42 CFR 483.156; 42 CFR 483.158;*
Eff. January 1, 2016;
Emergency Amendment Eff. April 20, 2020;
Temporary Amendment Eff. June 26, 2020;
Amended Eff. April 1, 2021.

Exhibit E/1

G.S. 150B-21.3A Report for 10A NCAC 13O, HEALTHCARE PERSONNEL REGISTRY

Agency - Medical Care Commission

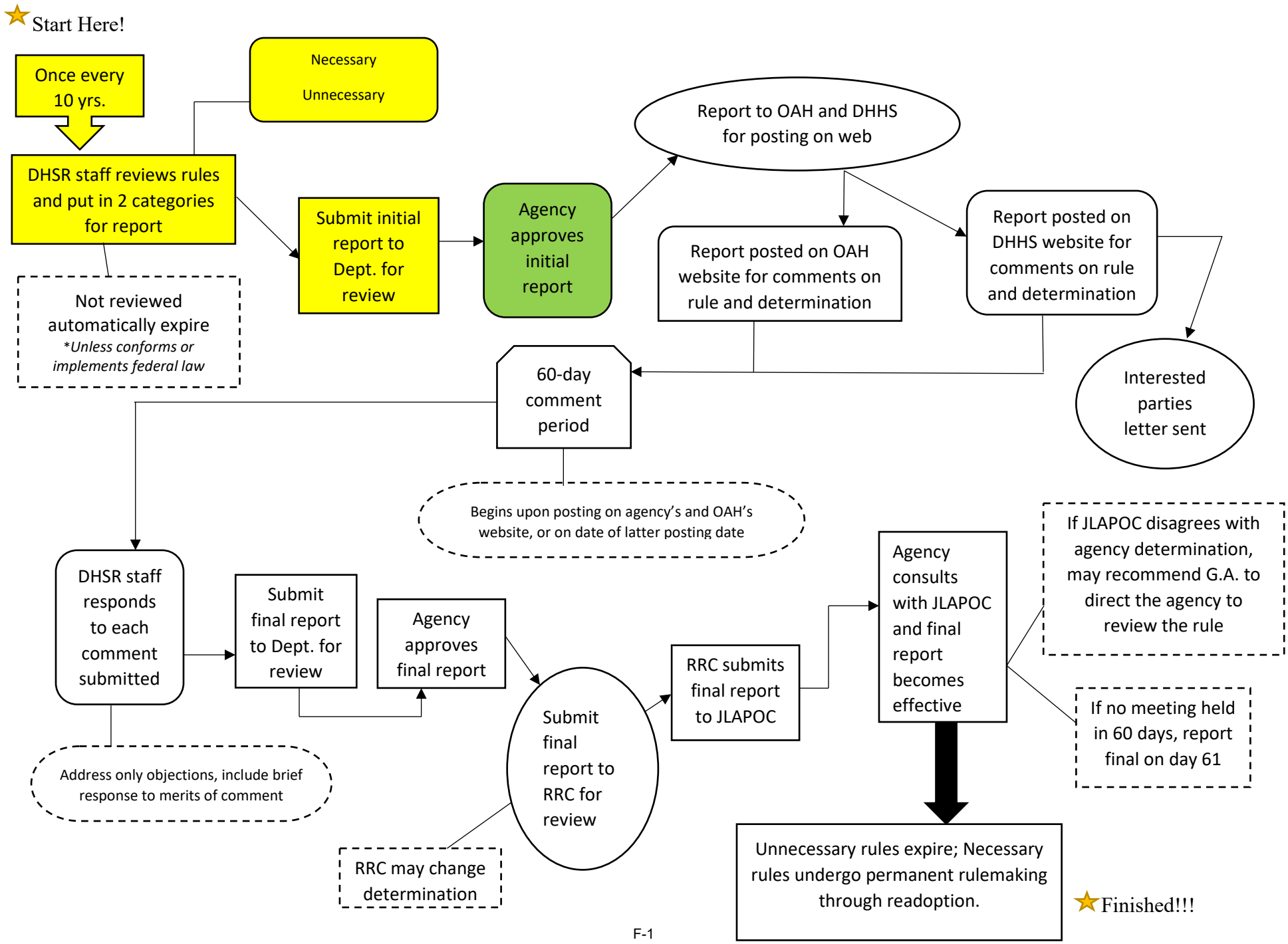
Comment Period - November 27, 2024 - January 26, 2025

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 13O – HEALTHCARE PERSONNEL REGISTRY	**SECTION .0100 - HEALTH CARE PERSONNEL REGISTRY**	10A NCAC 13O .0101	DEFINITIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	Yes If yes, include the citation to the federal law	§483.12	No	Necessary	Select One	Select One	Select One
		10A NCAC 13O .0102	INVESTIGATING AND REPORTING HEALTH CARE PERSONNEL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	Yes If yes, include the citation to the federal law	§418.52; §482.13; §483.12; §483.420; §484.50	No	Necessary	Select One	Select One	Select One
	SECTION .0200 – MEDICATION AIDE REGISTRY	10A NCAC 13O .0201	MEDICATION AIDE COMPETENCY EVALUATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	No		No	Necessary	Select One	Select One	Select One
		10A NCAC 13O .0202	REGISTRY OF MEDICATION AIDES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015	Necessary	No		No	Necessary	Select One	Select One	Select One
	SECTION .0300 - NURSE AIDE I REGISTRY	10A NCAC 13O .0301	NURSE AIDE I TRAINING AND COMPETENCY EVALUATION	Amended Eff. April 1, 2021	Necessary	Yes If yes, include the citation to the federal law	42 CFR 483.150; 42 CFR 483.151; 42 CFR 483.152; 42 CFR 483.154; 42 CFR 483.156; 42 CFR 483.158	No	Necessary	Select One	Select One	Select One

Periodic Rules Review Process for DHSR

Exhibit F



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.

G.S. 150B-21.3A Report for 10A NCAC 14A, DIRECTOR, DIVISION OF HEALTH SERVICE REGULATION

Agency - DHHS - Secretary & 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 14A – RULEMAKING	**SECTION .0100 RULEMAKING**	10A NCAC 14A .0101	PETITIONS	Readopted Eff. July 1, 2019	Necessary	No						
		10A NCAC 14A .0103	DECLARATORY RULINGS	Readopted Eff. July 1, 2019	Necessary	No						
	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					
		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					
		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					

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.

Report for 10A NCAC 13P, Emergency Medical Services and Trauma Rules Initial Determinations

Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]
10A NCAC 13P .0101	ABBREVIATIONS	Amended Eff. April 1, 2024	Necessary
10A NCAC 13P .0102	DEFINITIONS	Amended Eff. April 1, 2024	Necessary
10A NCAC 13P .0201	EMS SYSTEM REQUIREMENTS	Amended Eff. April 1, 2024	Necessary
10A NCAC 13P .0203	SPECIAL SITUATIONS	Readopted Eff. April 1, 2017	Necessary
10A NCAC 13P .0204	EMS PROVIDER LICENSE REQUIREMENTS	Readopted Eff. June 1, 2018	Necessary
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
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
10A NCAC 13P .0207	GROUND AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS	Amended Eff. April 1, 2024	Necessary
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
10A NCAC 13P .0209	AIR MEDICAL AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS	Amended Eff. January 1, 2017	Necessary
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
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

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
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
10A NCAC 13P .0214	EMS NON-TRANSPORTING VEHICLE PERMIT CONDITIONS	Amended Eff. January 1, 2017	Necessary
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
10A NCAC 13P .0216	WEAPONS AND EXPLOSIVES FORBIDDEN	Amended Eff. April 1, 2024	Necessary
10A NCAC 13P .0217	MEDICAL AMBULANCE/EVACUATION BUS: VEHICLE AND EQUIPMENT REQUIREMENTS	Amended Eff. April 1, 2024	Necessary
10A NCAC 13P .0218	PEDIATRIC SPECIALTY CARE GROUND AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS	Amended Eff. April 1, 2024	Necessary
10A NCAC 13P .0219	STAFFING FOR MEDICAL AMBULANCE/EVACUATION BUS VEHICLES	Readopted Eff. January 1, 2017	Necessary
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
10A NCAC 13P .0221	PATIENT TRANSPORTATION BETWEEN HOSPITALS	Amended Eff. April 1, 2024	Necessary
10A NCAC 13P .0222	TRANSPORT OF STRETCHER BOUND PATIENTS	Amended Eff. July 1, 2021	Necessary
10A NCAC 13P .0223	REQUIRED DISCLOSURE AND REPORTING INFORMATION	Eff. January 1, 2017	Necessary
10A NCAC 13P .0224	GROUND AMBULANCE VEHICLE MANUFACTURING STANDARDS	Amended Eff. July 1, 2024	Necessary
10A NCAC 13P .0301	SPECIALTY CARE TRANSPORT PROGRAM CRITERIA	Amended Eff. July 1, 2024	Necessary

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
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
10A NCAC 13P .0401	COMPONENTS OF MEDICAL OVERSIGHT FOR EMS SYSTEMS	Amended Eff. April 1, 2024.	Necessary
10A NCAC 13P .0402	COMPONENTS OF MEDICAL OVERSIGHT FOR SPECIALTY CARE TRANSPORT PROGRAMS	Amended Eff. April 1, 2024.	Necessary
10A NCAC 13P .0403	RESPONSIBILITIES OF THE MEDICAL DIRECTOR FOR EMS SYSTEMS	Amended Eff. April 1, 2024.	Necessary
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
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
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
10A NCAC 13P .0407	REQUIREMENTS FOR EMERGENCY MEDICAL DISPATCH PRIORITY REFERENCE SYSTEM	Amended Eff. April 1, 2024.	Necessary
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
10A NCAC 13P .0409	EMS PEER REVIEW COMMITTEE FOR SPECIALTY CARE TRANSPORT PROGRAMS	Amended Eff. January 1, 2017	Necessary
10A NCAC 13P .0410	COMPONENTS OF MEDICAL OVERSIGHT FOR AIR MEDICAL PROGRAMS	Amended Eff. April 1, 2024.	Necessary

10A NCAC 13P .0501	EDUCATIONAL PROGRAMS	Amended Eff. July 1, 2021	Necessary
10A NCAC 13P .0502	INITIAL CREDENTIALING REQUIREMENTS FOR EMR, EMT, AEMT, PARAMEDIC, AND EMD	Amended Eff. April 1, 2024.	Necessary
10A NCAC 13P .0503	TERM OF CREDENTIALS FOR EMS PERSONNEL	Amended Eff. April 1, 2024.	Necessary
10A NCAC 13P .0504	RENEWAL OF CREDENTIALS FOR EMR, EMT, AEMT, PARAMEDIC, AND EMD	Amended Eff. July 1, 2021	Necessary
10A NCAC 13P .0505	SCOPE OF PRACTICE FOR EMS PERSONNEL	Amended Eff. July 1, 2018	Necessary
10A NCAC 13P .0506	PRACTICE SETTINGS FOR EMS PERSONNEL	Amended Eff. July 1, 2018	Necessary
10A NCAC 13P .0507	INITIAL CREDENTIALING REQUIREMENTS FOR LEVEL I EMS INSTRUCTORS	Amended Eff. January 1, 2022	Necessary
10A NCAC 13P .0508	INITIAL CREDENTIALING REQUIREMENTS FOR LEVEL II EMS INSTRUCTORS	Amended Eff. January 1, 2022	Necessary
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
10A NCAC 13P .0510	RENEWAL OF CREDENTIALS FOR LEVEL I AND LEVEL II EMS INSTRUCTORS	Amended Eff. July 1, 2021	Necessary
10A NCAC 13P .0511	CRIMINAL HISTORIES	Amended Eff. January 1, 2017	Necessary
10A NCAC 13P .0512	REINSTATEMENT OF LAPSED EMS CREDENTIAL	Amended Eff. April 1, 2024.	Necessary
10A NCAC 13P .0513	REFRESHER COURSES	Eff. January 1, 2017	Necessary
10A NCAC 13P .0601	CONTINUING EDUCATION EMS EDUCATIONAL PROGRAM REQUIREMENTS	Amended Eff. April 1, 2024.	Necessary
10A NCAC 13P .0602	BASIC AND ADVANCED EMS EDUCATIONAL INSTITUTION REQUIREMENTS	Amended Eff. April 1, 2024.	Necessary

10A NCAC 13P .0605	ACCREDITED EMS EDUCATIONAL INSTITUTION REQUIREMENTS	Eff. January 1, 2017	Necessary
10A NCAC 13P .0901	TRAUMA CENTER CRITERIA	Amended Eff. September 1, 2019	Necessary
10A NCAC 13P .0904	INITIAL DESIGNATION PROCESS	Amended Eff. April 1, 2024.	Necessary
10A NCAC 13P .0905	RENEWAL DESIGNATION PROCESS	Amended Eff. April 1, 2024.	Necessary
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
10A NCAC 13P .1101	STATE TRAUMA SYSTEM	Amended Eff. July 1, 2021	Necessary
10A NCAC 13P .1102	REGIONAL TRAUMA SYSTEM PLAN	Amended Eff. January 1, 2017	Necessary
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
10A NCAC 13P .1401	CHEMICAL ADDICTION OR ABUSE RECOVERY PROGRAM REQUIREMENTS	Amended Eff. July 1, 2021	Necessary
10A NCAC 13P .1402	PROVISIONS FOR PARTICIPATION IN THE CHEMICAL ADDICTION OR ABUSE RECOVERY PROGRAM	Readopted Eff. January 1, 2017	Necessary
10A NCAC 13P .1403	CONDITIONS FOR RESTRICTED PRACTICE WITH LIMITED PRIVILEGES	Amended Eff. July 1, 2021	Necessary
10A NCAC 13P .1404	REINSTATEMENT OF AN UNENCUMBERED EMS CREDENTIAL	Amended Eff. July 1, 2021	Necessary
10A NCAC 13P .1405	FAILURE TO COMPLETE THE CHEMICAL ADDICTION OR ABUSE RECOVERY PROGRAM	Amended Eff. July 1, 2021	Necessary

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
10A NCAC 13P .1502	LICENSED EMS PROVIDERS	Amended Eff. July 1, 2018	Necessary
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
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
10A NCAC 13P .1505	EMS EDUCATIONAL INSTITUTIONS	Amended Eff. April 1, 2024.	Necessary
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
10A NCAC 13P .1507	EMS PERSONNEL CREDENTIALS	Amended Eff. April 1, 2024.	Necessary
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
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
10A NCAC 13P .1510	PROCEDURES FOR THE VOLUNTARY SURRENDER OR MODIFICATION OF THE LEVEL OF AN EMS CREDENTIAL	Eff. January 1, 2017	Necessary
10A NCAC 13P .1511	PROCEDURES FOR QUALIFYING FOR AN EMS CREDENTIAL FOLLOWING ENFORCEMENT ACTION	Amended Eff. July 1, 2021	Necessary

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.

Initial Determinations by Agency Rule 10A NCAC 13C

Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]
10A NCAC 13C .0103	DEFINITIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary
10A NCAC 13C .0201	APPLICATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary
10A NCAC 13C .0202	REQUIREMENTS FOR ISSUANCE OF LICENSE	Readopted Eff. January 1, 2021	Necessary
10A NCAC 13C .0203	SUSPENSION OR REVOCATION: AMBULATORY SURGICAL FACILITY	Amended Eff. January 1, 2021	Necessary
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
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
10A NCAC 13C .0206	REPORTING REQUIREMENTS	Amended Eff. January 31, 2017	Necessary
10A NCAC 13C .0301	GOVERNING AUTHORITY	Readopted Eff. January 1, 2021	Necessary
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
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
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
10A NCAC 13C .0305	PERSONNEL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary

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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
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
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
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
10A NCAC 13C .0501	PROVIDING ANESTHESIA SERVICES	Readopted Eff. January 1, 2021	Necessary
10A NCAC 13C .0502	EQUIPMENT	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary
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
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
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
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
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
10A NCAC 13C .0702	REGULATIONS FOR PERFORMED SERVICES	Amended Eff. January 1, 2021	Necessary

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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
10A NCAC 13C .0802	REGULATIONS FOR DISPENSING	Amended Eff. September 1, 2019	Necessary
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
10A NCAC 13C .0902	NURSING PERSONNEL	Readopted Eff. January 1, 2021	Necessary
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
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
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
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
10A NCAC 13C .1201	GENERAL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary
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
10A NCAC 13C .1301	GENERAL	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary
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

Initial Determinations by Agency Rule 10A NCAC 13C

10A NCAC 13C .1303	HOUSEKEEPING	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary
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
10A NCAC 13C .1305	SANITATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017	Necessary
10A NCAC 13C .1401	DEFINITIONS	Amended Eff. January 1, 2020	Necessary
10A NCAC 13C .1402	LIST OF REFERENCED GUIDELINES, CODES, STANDARDS, AND REGULATION	Amended Eff. January 1, 2020	Necessary
10A NCAC 13C .1403	GENERAL AND EMERGENCY PREPAREDNESS	Amended Eff. January 1, 2020	Necessary
10A NCAC 13C .1404	EQUIVALENCY AND CONFLICTS WITH REQUIREMENTS	Readopted Eff. January 1, 2020	Necessary
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

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.

10A NCAC 13K .0102	DEFINITIONS	Readopted Eff. January 1, 2021	Necessary
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
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
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
10A NCAC 13K .0208	INSPECTIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary
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
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
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
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
10A NCAC 13K .0401	PERSONNEL	Readopted Eff. January 1, 2021	Necessary
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
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

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
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
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
10A NCAC 13K .0604	PATIENT'S RIGHTS AND RESPONSIBILITIES	Readopted Eff. January 1, 2021	Necessary
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
10A NCAC 13K .0701	CARE PLAN	Readopted Eff. January 1, 2021	Necessary
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
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
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
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
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
10A NCAC 13K .1101	ADMINISTRATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary

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
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
10A NCAC 13K .1104	DIETARY SERVICES	Readopted Eff. January 1, 2021	Necessary
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
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
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
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
10A NCAC 13K .1109	RESIDENT CARE AREAS	Readopted Eff. October 1, 2021	Necessary
10A NCAC 13K .1110	FURNISHINGS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 22, 2018	Necessary
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
10A NCAC 13K .1112	DESIGN AND CONSTRUCTION	Amended Eff. October 1, 2021	Necessary
10A NCAC 13K .1113	PLANS AND SPECIFICATIONS	Readopted Eff. October 1, 2021	Necessary
10A NCAC 13K .1114	PLUMBING	Readopted Eff. October 1, 2021	Necessary
10A NCAC 13K .1115	WASTE DISPOSAL	Readopted Eff. October 1, 2021	Necessary
10A NCAC 13K .1116	APPLICATION OF PHYSICAL PLANT REQUIREMENTS	Readopted Eff. October 1, 2021	Necessary

10A NCAC 13K .1201	REQUIREMENTS FOR HOSPICE INPATIENT UNITS	Readopted Eff. October 1, 2021	Necessary
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
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
10A NCAC 13K .1204	ADDITIONAL PATIENT CARE AREA REQUIREMENTS FOR HOSPICE INPATIENT UNITS	Readopted Eff. October 1, 2021	Necessary
10A NCAC 13K .1205	FURNISHINGS FOR HOSPICE INPATIENT CARE	Readopted Eff. October 1, 2021	Necessary
10A NCAC 13K .1206	HOSPICE INPATIENT FIRE AND SAFETY REQUIREMENTS	Readopted Eff. October 1, 2021	Necessary
10A NCAC 13K .1207	HOSPICE INPATIENT REQUIREMENTS FOR HEATING/AIR CONDITIONING	Readopted Eff. October 1, 2021	Necessary
10A NCAC 13K .1208	HOSPICE INPATIENT REQUIREMENTS FOR EMERGENCY ELECTRICAL SERVICE	Amended Eff. October 1, 2021	Necessary
10A NCAC 13K .1209	HOSPICE INPATIENT REQUIREMENTS FOR GENERAL ELECTRICAL	Amended Eff. October 1, 2021	Necessary
10A NCAC 13K .1210	OTHER HOSPICE INPATIENT REQUIREMENTS	Amended Eff. October 1, 2021	Necessary
10A NCAC 13K .1211	ADDITIONAL PLUMBING REQUIREMENTS/HOSPICE INPATIENT UNITS	Readopted Eff. October 1, 2021	Necessary
10A NCAC 13K .1212	APPLICATION OF PHYSICAL PLANT REQUIREMENTS	Readopted Eff. October 1, 2021	Necessary

EXHIBIT J

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 Duke University:

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
Corporate Counsel:	Womble Bond Dickinson
Underwriter:	JP Morgan
Underwriter Counsel:	Kaufman Hall
Accountant (AUP Forecast):	Dixon Hughes Goodman LLP
Trustee:	Bank of New York Mellon
Trustee Counsel:	Moore VanAllen

6) Board Diversity:

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

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