STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEDICAL CARE COMMISSION QUARTERLY MEETING
DIVISION OF HEALTH SERVICE REGULATION
MOBILE DISASTER HOSPITAL
315 BETHEL CHURCH ROAD
MOCKSVILLE, NC 27028

OR

TEAMS Video Conference: Click here to join the meeting

OR

Dial-IN: 1-984-204-1487 / Passcode: 445 807 125#

FEBRUARY 2, 2024 (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. Approval of Minutes (Action Items)……Dr. John Meier

- **October 27, 2023** (NCMCC Special Rules Meeting) **(See Exhibit A**)
- **November 3, 2023** (NCMCC Quarterly Meeting) (**See Exhibit A/1**)
- **November 8, 2023** (Executive Committee) **(See Exhibit B/1)**
- **December 18, 2023** (NCMCC Special Rules Meeting) **(See Exhibit B/2)**
- **January 23, 2024** (NCMCC Special Rules Meeting) **(See Exhibit B/3)**

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

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

VII. Old Business (Discuss Rules, Fiscal Note, & Comments Submitted) (Action Items)

A. Rules for Adoption

1. **Emergency Medical Services and Trauma Rules**..T. Corpening & W. Ainsworth

   Amendment of 25 Rules

   - Rules: 10A NCAC 13P .0101, .0102, .0201, .0207, .0216 - .0218, .0221, .0224, .0301, .0401 - .0404, .0407, .0410, .0502, .0503, .0512, .0601, .0602, .0904, .0905, .1505, .1507.

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

2. **Nursing Pool Licensure Rules**……..……Taylor Corpening & Azzie Conley

   Amendments in response to rulemaking petition granted by MCC

   - Rules: 10A NCAC 13L .0301, .0302

     (See Exhibits D thru D/3)

3. **Acute & Home Care Licensure Rules**…...…..Taylor Corpening & Azzie Conley

   Discussion of text of rules.

   - **Rules:** 10A NCAC 13S .0101, .0104, .0111, .0112, .0114, .0201, .0202, .0207, .0209, .0210, .0211, .0212, .0315, .0318, .0319, .0320, .0321, .0322, .0323, .0324, .0325, .0326, .0327, .0328, .0329, .0330, & .0331. (27 Rules)

     (See Exhibits F thru F/1)

VIII. New Business (Discuss Rules & Fiscal Note) (<u>Action Items</u>)

A. **Periodic Review of Existing Rules** (150B-21.3A) **–** Initial Category Determination

1. **Executive Committee**…….....Taylor Corpening & Geary Knapp

   - 10A NCAC 13A .0101, .0201, .0202, & .0203 (4 Rules)

     (See Exhibits E thru E/2)

IX. 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 10, 2024 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 10, 2024. Refunding projects may include non-Commission debt, and non-material, routine capital improvement expenditures.

X. Tour of the Mobile Disaster Hospital……Geary W. Knapp & Kimberly Clement

XI. Meeting Adjournment

STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEDICAL CARE COMMISSION QUARTERLY MEETING
DIVISION OF HEALTH SERVICE REGULATION
809 RUGGLES DRIVE, RALEIGH NC 27603
EDGERTON BUILDING
CONFERENCE ROOM – 026A
OR
TEAMS Video Conference: Click here to join the meeting
OR
Dial-IN: 1-984-204-1487 / Passcode: 546 736 422#

October 27, 2023 (Friday)
11:30 a.m.

Minutes

MEMBERS PRESENT	MEMBERS ABSENT
John J. Meier, IV, M.D., Chairman Joseph D. Crocker, Vice-Chairman Kathy G. Barger Sally B. Cone Paul R.G. Cunningham, M.D. Bryant C. Foriest Linwood B. Hollowell, III Eileen C. Kugler, RN, MSN, MPH, FNP Ashley H. Lloyd, D.D.S. David C. Mayer, M.D. Neel G. Thomas, M.D. Pascal O. Udekwu, M.D. Timothy D. Weber, RPh **DIVISION OF HEALTH SERVICE REGULATION STAFF** S. Mark Payne, Director, DHSR/Secretary, MCC Emery E. Milliken, DHSR Deputy Director Geary W. Knapp, JD, CPA, Assistant Secretary, MCC Eric Hunt, Attorney General's Office Jeff Harms, Acting Construction Chief, DHSR	Karen E. Moriarty Robert E. Schaaf, M.D. Lisa A. Tolnitch, M.D. Jeffrey S. Wilson

Taylor Corpening, Rules Review Coordinator, DHSR Azzie Conley, Chief, Acute & Home Care Licensure Crystal Abbott, Auditor, MCC Kathy Larrison, Auditor, MCC Alice Creech, Executive Assistant, MCC	
OTHERS PRESENT Mark Benton, DHHS Secretary's Office Susanna Birdsong, Planned Parenthood Bethany Burgon, Attorney General's Office Julie Cronin, DHHS Office of General Counsel Makeda Harris, NC Hospital Association Terry Sallas Merritt, A Woman's Choice Rajeev Premakumar, DHHS Office of General Counsel	

I. Meeting Opens – Roll Call

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

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

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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. New Business

A. Rules for Adoption (Discuss rules)

1. Acute & Home Care Licensure Rules……...Taylor Corpening & Azzie Conley

Emergency rulemaking to replace the current Emergency abortion rules before they expire. (Adoption of 30 rules)

- **Rules:** 10A NCAC 13S .0101, .0104, .0106, .0107, .0109, .0111, .0112, .0114, .0201, .0202, .0207, .0209, .0210, .0211, .0212, .0315, .0318, .0319, .0320, .0321, .0322, .0323, .0324, .0325, .0326, .0327, .0328, .0329, .0330 & .0331.

(See Exhibit A)

COMMISION ACTION: The Commission voted unanimously to approve the Emergency Abortion rules before they were due to expire.

VII. Meeting Adjournment

There being no further business the meeting was adjourned at 12:10 p.m.

Respectfully submitted,

Geary W. Knapp, JD, CPA
Assistant Secretary

STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Dial-IN: 1-984-204-1487 / Passcode: 566 714 070#

NOVEMBER 3, 2023

MINUTES

I. Meeting Attendance

MEMBERS PRESENT	MEMBERS ABSENT
John J. Meier, IV, M.D., Chairman Joseph D. Crocker, Vice-Chairman Kathy G. Barger Sally B. Cone Paul R.G. Cunningham, M.D. Bryant C. Foriest Eileen C. Kugler, RN, MSN, MPH, FNP David C. Mayer, M.D. Neel G. Thomas, M.D. Lisa A. Tolnitch, M.D. Pascal O. Udekwu, M.D. Timothy D. Weber, RPH Jeffrey S. Wilson **DIVISION OF HEALTH SERVICE REGULATION STAFF** Mark Payne, Director, DHSR/Secretary, MCC Emery Milliken, Deputy Director, DHSR Geary W. Knapp, JD, CPA, Assistant Secretary, MCC Eric Hunt, Attorney General's Office	Linwood B. Hollowell, III Ashley H. Lloyd, D.D.S. Karen E. Moriarty Robert E. Schaaf, M.D.

Bethany Burgon, Attorney General's Office Jeff Harms, Acting Construction Chief, DHSR Taylor Corpening, Rules Review Coordinator, DHSR Azzie Conley, Chief, Acute & Home Care Licensure Greta Hill, Asst. Chief, Acute & Home Care Licensure Megan Lamphere, Chief, ACLS Libby Kinsey, Assistant Chief, ACLS Shalisa Jones, Policy Coordinator, ACLS Crystal Abbott, Auditor, MCC Kathy Larrison, Auditor, MCC Alice Creech, Executive Assistant, MCC **OTHERS PRESENT** Tommy Brewer, Ziegler Adam Garcia, Ziegler Jonathan Erickson, URMH Laurie Stallings, UMRH Stacy Dobson, UMRH Dan Novelli, LCS Development Reed Vanderslik, Thrivemore Matthew Lux, Thrivemore Tom Bowden, HJ Sims David Saustad, HJ Sims Nadine Pfeiffer	

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

III. Public Meeting Statement……Dr. John Meier

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V. Resolution of Appreciation for Retiring DHSR Staff Member……Dr. John Meier

- Nadine Pfeiffer **(See Exhibit A/1)**

VI. Introduction of New Rules Review Coordinator……..…….Geary Knapp

- Taylor Corpening

VII. Approval of Minutes (Action Item)……...…….……...……..Dr. John Meier

- **August 11, 2023** (Medical Care Commission Quarterly Meeting) (**See Exhibit A**)

COMMISSION ACTION: *A motion was made to approve the minutes by Mr. Joe Crocker, seconded by Mr. Bryant Foriest, and unanimously approved.*

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

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

IX. Bond Projects (Action Items)

A. Thrivemore (Concord)……..…….…….Geary W. Knapp

Resolution: The Commission grants preliminary approval for a Baptist Retirement Homes of NC (dba Thrivemore) project to provide funds to be used, together with other available funds, to 1) *refund* a taxable loan that was used to fund the purchase of Ardenwoods (CCRC in Asheville), 2) *purchase* land in New Bern for future development, and 3) *construct* the following:

- Taylor Glen (Concord) expansion
  - 50 Independent Living Units (Cottages and Villas)
  - 12 Assisted Living Units as a Green House
  - Refurbish existing dementia beds to assisted living after transfer to Green House
  - Dining renovations

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	$	81,148,101.00
Total Sources	**$**	**81,148,101.00**
ESTIMATED USE OF FUNDS		
Bridge Loan (Purchase of Ardenwoods)	$	13,325,000.00
New Bern Land Purchase	$	5,100,000.00
Construction Cost	$	52,890,486.49
Land Costs	$	62,884.36
Utility Development Costs	$	703,000.00
Architect Fees	$	1,946,742.24
Architect Reimbursables	$	25,950.00
Contingency	$	594,991.96
Surveys	$	107,104.94
Title/Survey Fees	$	121,723.48
Phase I Environment Fees	$	15,000.00
Consultant Fees (Wetlands, Legal, Marketing, etc.)	$	668,840.00
Bond Interest During Construction	$	4,842,295.10
Underwriter Placement Fee	$	112,962.17
Feasibility Study	$	120,000.00
Corporate Counsel	$	80,000.00
Bond Counsel	$	120,000.00
Trustee Fee	$	4,500.00
Trustee Counsel	$	10,000.00
Local Government Commission Fee	$	8,750.00
Bank Counsel	$	65,000.00
Bank Fee	$	202,870.26
Appraisal Fee	$	20,000.00
Total Uses	**$**	**81,148,101.00**

Tentative approval is given with the understanding that the governing board of Thrivemore 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
Construction & Related Costs are Reasonable: YES

(See Exhibit E & I for selected application information, fee schedule, Bond Sale Approval Form, and presentation**)**

COMMISSION ACTION: *A motion to approve the project for Thrivemore was made by Mrs. Kathy Barger, seconded by Mr. Joe Crocker, and unanimously approved.*

B. United Methodist Retirement Homes (Greenville)……..……..Geary W. Knapp

Resolution: The Commission grants preliminary approval for a United Methodist Retirement Homes project to provide funds to be used, together with other available funds, to *construct* the following:

- Cypress Glen (Greenville) expansion
  - 57 Independent Units
  - New Dining Facility
  - Kitchen upgrade

- New Auditorium
- Community Amenities & Administrative Area improvements
- Flood Control Levee

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	$	113,800,000.00
Total Sources	**$**	**113,800,000.00**
ESTIMATED USE OF FUNDS		
Construction Cost	$	67,198,699.00
Architect Fees	$	2,953,183.00
Architect Reimbursables	$	35,000.00
Contingency	$	549,309.00
Moveable Equipmet	$	2,654,306.00
Surveys	$	230,000.00
Consultant Fees (Wetlands, Legal, Marketing, etc.)	$	5,208,372.00
Bond Interest During Construction	$	23,898,000.00
Debt Service Reserve Fund	$	9,172,881.00
Underwriter Placement Fee	$	1,055,250.00
Placement Agent Fee	$	95,000.00
Feasibility Study	$	120,000.00
Accountant Fee	$	45,000.00
Corporate Counsel	$	85,000.00
Bond Counsel	$	150,000.00
Trustee Fee	$	11,250.00
Underwriter Counsel	$	70,000.00
Local Government Commission Fee	$	8,750.00
Bank Counsel	$	50,000.00
Bank Fee	$	50,000.00
Rating Agencies Fee	$	100,000.00
Printing Costs	$	5,000.00
Blue Sky Filings	$	5,000.00
Real Estate/Title/Recording	$	50,000.00
Total Uses	**$**	**113,800,000.00**

Tentative approval is given with the understanding that the governing board of United Methodist Retirement Homes 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
Construction & Related Costs are Reasonable: YES

(See Exhibit F & H for selected application information, fee schedule, Bond Sale Approval Form, and presentation**)**

COMMISSION ACTION: *A motion was made to approve the project for United Methodist Retirement Homes by Mrs. Eileen Kugler, seconded by Dr. David Mayer, and unanimously approved with the recusal of Dr. Paul Cunningham.*

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

A. Rules for Adoption

1. **Adult Care Home/Family Care Home Rules**……...T. Corpening & M. Lamphere

   Readoption of 9 rules following Periodic Review of rules (Phase 5), Amendment of 2 rules (Total of 11 rules)

   - Rules: 10A NCAC 13F .0703, .0704, .1103, .1104, .1106
     10A NCAC 13G .0702, .0703, .0704, .1102, .1103, .1106

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

COMMISSION ACTION: *A motion was made to approve the Adult Care Home/Family Care Home Rules by Dr. Paul Cunningham, seconded by Dr. David Mayer, and unanimously approved.*

XI. New Business (Discuss Rules & Fiscal Note) (Action Item)

A. Rules for Initiating Rulemaking Approval

1. **Adult Care Home/Family Care Home Rules**.....T. Corpening & M. Lamphere

   Readoption of 8 rules following Periodic Review (Phase 5.5), 6 adoptions, and 2 amendments (Total of 16 rules)

   - Rules: 10A NCAC 13F .0102, .0402, .0404, .0408, .0601-.0609
     10A NCAC 13G .0102, .0404, .0601

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

COMMISSION ACTION: *A motion was made to approve the Adult Care Home/Family Care Home Rules by Dr. Paul Cunningham, seconded by Dr. David Mayer, and unanimously approved.*

2. Acute & Home Care Licensure Rules…….....…T. Corpening & M. Lamphere

Rules for licensure of suitable facilities for the performance of surgical abortion / Adoption of 30 Rules pursuant to G.S. 150B-21.1A(b)

- Rules: 10A NCAC 13S .0101, .0104, .0106-.0107, .0109, .0111-.0112, .0114, .0201-.0202, .0207, .0209-.0212, .0315, .0318-.0331

(**See Exhibit G**)

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

XII. Appointment of Three Executive Committee Members (Action Item)...Dr. John Meier

In accordance with 10A NCAC 13A.0101, three members of the Executive Committee shall be appointed by a vote of the Commission of each odd year at its meeting in November. No member of the Executive Committee, except the Chairman and Vice-Chairman, shall serve more than two two-year terms in succession. The terms of the three elected/appointed Executive Committee Members will expire 12/31/2025.

COMMISSION ACTION: *Dr. Paul Cunningham, Mrs. Eileen Kugler, and Dr. Neel Thomas were unanimously appointed to serve a two-year term on the Executive Committee, which will expire on 12/31/ 2025.*

XIII. Schedule of 2024 Quarterly Meetings for Adoption (Action Item)…...….Dr. John Meier

February 1-2, 2024
May 9-10, 2024
August 8-9, 2024
November 7-8, 2024

COMMISSION ACTION: *The Commission unanimously approved the quarterly meeting dates for 2024.*

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

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 2, 2024 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 2, 2024. 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 February 2, 2024 by Dr. David Mayer, seconded by Mr. Bryant Foriest, and unanimously approved.*

XV. 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

NC Medical Care Commission

Quarterly Report on **Outstanding Debt** (End: 2nd Quarter FYE 2024)

Program Measures	FYE 2023 Ending: 6/30/2023	FYE 2024 Ending: 12/31/2023
Outstanding Debt	**$4,676,200,334**	**$4,662,306,804**
Outstanding Series	**114**[1]	**111**[1]

Detail of Program Measures	Ending: 6/30/2023	Ending: 12/31/2023
Outstanding Debt per Hospitals and Healthcare Systems	$3,212,486,549	$3,146,917,432
Outstanding Debt per CCRCs	$1,463,713,786	$1,515,389,372
Outstanding Debt per Other Healthcare Service Providers	$0	$0
Outstanding Debt Total	**$4,676,200,334**	**$4,662,306,804**
Outstanding Series per Hospitals and Healthcare Systems	51	51
Outstanding Series per CCRCs	63	60
Outstanding Series per Other Healthcare Service Providers	0	0
Series Total	**114**	**111**
Number of Hospitals and Healthcare Systems with Outstanding Debt	10	10
Number of CCRCs with Outstanding Debt	19	19
Number of Other Healthcare Service Providers with Outstanding Debt	0	0
Facility Total	29	29

Exhibit B (Outstanding Balance)

Note 1: For FYE 2024, NCMCC has closed 1 **Bond Series**. Out of the closed Bond Series: 0 conversions, 0 were new money projects, 0 combination of new money project and refunding, and 1 refunding. The Bond Series outstanding from FYE 2023 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: 2nd Quarter FYE 2024)

Program Measures	FYE 2023 Ending: 6/30/2023	FYE 2024 Ending: 12/31/2023
Total PAR Amount of Debt Issued	**$28,995,305,288**	**$29,203,083,260**
Total Project Debt Issued (excludes refunding/conversion proceeds) [1]	**$13,523,822,513**	**$13,653,140,486**
Total Series Issued	**708**	**709**

Detail of Program Measures		Ending: 6/30/2023	Ending: 12/31/2023
PAR Amount of Debt per Hospitals and Healthcare Systems		$23,116,044,855	$23,116,044,855
PAR Amount of Debt per CCRCs		$5,504,965,203	$5,712,743,175
PAR Amount of Debt per Other Healthcare Service Providers		$374,295,230	$374,295,230
	Par Amount Total	**$28,995,305,288**	**$29,203,083,260**
Project Debt per Hospitals and Healthcare Systems		$10,273,019,674	$10,273,019,674
Project Debt per CCRCs		$3,003,788,925	$3,133,106,897
Project Debt per Other Healthcare Service Providers		$247,013,915	$247,013,915
	Project Debt Total	**$13,523,822,513**	**$13,653,140,486**
Series per Hospitals and Healthcare Systems		433	433
Series per CCRCs		236	237
Series per Other Healthcare Service Providers		39	39
	Series Total	**708**	**709**
Number of Hospitals and Healthcare Systems issuing debt		99	99
Number of CCRCs issuing debt		41	41
Number of Other Healthcare Service Providers issuing debt		46	46
	Facility Total	186	186

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.

STATE OF NORTH CAROLINA
NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

MINUTES

CALLED MEETING OF THE EXECUTIVE COMMITTEE OF THE COMMISSION
CONFERENCE TELEPHONE MEETING ORIGINATING
FROM THE OFFICES OF THE COMMISSION
November 8, 2023
11:30 a.m.

Members of the Commission Present:

John J. Meier, IV, M.D., Chairman
Joseph D. Crocker, Vice-Chairman
Kathy G. Barger
Sally B. Cone
Bryant C. Foriest
Linwood B. Hollowell, III

Members of the Commission Absent:

Jeffrey S. Wilson

Members of Staff Present:

Emery E. Milliken, Deputy Director, DHSR
Geary W. Knapp, Assistant Secretary, MCC
Kathy Larrison, Auditor, MCC
Crystal Watson-Abbott, Auditor, MCC

Others Present:

Paul Billow, Womble Bond Dickinson (US) LLP
Andy Zukowski, ECU Health
Brian Dunn, ECU Health

1. Purpose of Meeting

To consider a resolution providing consent to the execution and delivery of a First Amendment to Master Trust Indenture between the University Health Systems of Eastern Carolina, Inc. d/b/a ECU Health and U.S. Bank Trust Company, National Association.

2. Resolution of the North Carolina Medical Care Commission Consenting to the Execution and Delivery of a First Amendment to Master Trust Indenture between the University Health Systems of Eastern Carolina, Inc. d/b/a ECU Health and U.S. Bank Trust Company, National Association

Executive Committee Action: A motion was made to approve the resolution by Mrs. Sally Cone, seconded by Mr. Bryant Foriest, and unanimously approved with the recusal of Mrs. Kathy Barger.

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

WHEREAS, the Commission has heretofore issued various series of bonds on behalf of the University Health Systems of Eastern Carolina, Inc. d/b/a ECU Health (the "Parent Corporation") and its various affiliates, including, without limitation, Pitt County Memorial Hospital, Incorporated d/b/a ECU Health Medical Center (the "Corporation");

WHEREAS, such series of bonds that remain outstanding are secured by Master Obligations issued by the Parent Corporation and the Corporation (collectively, the "Members of the Obligated Group") under a Master Trust Indenture (Amended and Restated), dated as of February 1, 2006 (as supplemented and amended, the "Master Indenture"), between the Parent Corporation, the Corporation and First-Citizens Bank & Trust Company (succeeded by U.S. Bank Trust Company, National Association), as master trustee (the "Master Trustee");

WHEREAS, Section 902 of the Master Indenture allows for the Members of the Obligated Group and the Master Trustee to enter indentures supplemental to the Master Indenture for the purpose of adding any provisions to or changing in any manner or eliminating any of the provision of the Master Indenture or of modifying in any manner the rights of the Holders (subject to certain limitations set forth in the Master Indenture), subject to the consent of the Local Government Commission and the Commission and the Holders of not less than a majority in aggregate principal amount of the Master Obligations then Outstanding affected by such supplemental indenture;

WHEREAS, subject to the receipt of the requisite consents as provided above, the Members of the Obligated Group and the Master Trustee have determined to enter into a First Amendment to Master Trust Indenture, to be dated as of the date of delivery thereof (the "First Amendment"), to modify certain definitions contained in the Master Indenture necessitated by accounting and operational changes that resulted in a need for clarification of how to calculate

the Coverage Ratio for purposes of the various financial covenants contained in the Master Indenture; and

WHEREAS, the Members of the Obligated Group have presented to the members of the Executive Committee a proposed form of the First Amendment and has requested the Commission to approve and consent to the same;

NOW THEREFORE, BE IT RESOLVED by the Executive Committee of the North Carolina Medical Care Commission as follows:

Section 1. Capitalized terms used in this resolution and not defined herein shall have the meanings given such terms in the Master Indenture.

Section 2. The form, terms and provisions of the First Amendment are hereby approved and consented to in all respects. The Chairman, the Vice Chairman or any member of the Commission designated in writing by the Chairman for such purpose and the Secretary or any Assistant Secretary of the Commission are hereby authorized and directed to execute and deliver such documents as are necessary or appropriate to evidence the consent of the Commission to the First Amendment, and such execution and delivery shall be conclusive evidence of the approval and consent thereto by the Commission.

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

3. Adjournment

There being no further business, the meeting was adjourned at 11:38 a.m.

Respectfully submitted,

Geary W. Knapp, JD, CPA
Assistant Secretary

Date: November 8, 2023

STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEDICAL CARE COMMISSION QUARTERLY MEETING
DIVISION OF HEALTH SERVICE REGULATION
809 RUGGLES DRIVE, RALEIGH NC 27603
EDGERTON BUILDING
CONFERENCE ROOM – 026A
OR
TEAMS Video Conference: Click here to join the meeting
OR
Dial-IN: 1-984-204-1487 / Passcode: 675 543 670#

December 18, 2023 (Monday)
11:30 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 Sally B. Cone Paul R.G. Cunningham, M.D. Bryant C. Foriest Linwood B. Hollowell, III Eileen C. Kugler, RN, MSN, MPH, FNP David C. Mayer, M.D. Neel G. Thomas, M.D. Jeffrey S. Wilson **DIVISION OF HEALTH SERVICE REGULATION STAFF** Mark Payne, Director, DHSR/Secretary, MCC Emery Milliken, Deputy Director, DHSR Geary W. Knapp, JD, CPA, Assistant Secretary, MCC Rajeev Premakumar, DHHS General Counsel's Office Eric Hunt, Attorney General's Office Bethany Burgon, Attorney General's Office Jeff Harms, Acting Construction Chief, DHSR Taylor Corpening, Rules Review Coordinator, DHSR Azzie Conley, Chief, Acute & Home Care Licensure Greta Hill, Asst. Chief, Acute & Home Care Licensure Crystal Abbott, Auditor, MCC Kathy Larrison, Auditor, MCC Alice Creech, Executive Assistant, MCC	Ashley H. Lloyd, D.D.S. Karen E. Moriarty Robert E. Schaaf, M.D. Lisa A. Tolnitch, M.D. Pascal O. Udekwu, M.D. Timothy D. Weber, RPH

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. New Business

A. Rules for Adoption (Discuss rules)

1. Acute & Home Care Licensure Rules ..... Taylor Corpening & A. Conley

Emergency rulemaking to withdraw three emergency abortion rules, which are rendered unnecessary. (Withdrawal of 3 rules) (For comparison we have attached the Department's Rules 14E).

- **Rules:** 10A NCAC 13S .0106, .0107, & .0109.
  See (Exhibit A)

COMMISSION ACTION: *A motion was made to approve the withdrawal of the three emergency abortion rules by Mrs. Kathy Barger, seconded by Dr. Paul Cunningham, and unanimously approved.*

VI. Meeting Adjournment

There being no further business the meeting was adjourned at 11:42 a.m.

Respectfully submitted,

Geary W. Knapp, JD, CPA
Assistant Secretary

STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEDICAL CARE COMMISSION QUARTERLY MEETING
DIVISION OF HEALTH SERVICE REGULATION
809 RUGGLES DRIVE, RALEIGH NC 27603
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OR
TEAMS Video Conference: Click here to join the meeting
OR
Dial-IN: 1-984-204-1487 / Passcode: 675 543 670#

January 23, 2024 (Tuesday)
11:30 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 Sally B. Cone Paul R.G. Cunningham, M.D. Bryant C. Foriest Linwood B. Hollowell, III Eileen C. Kugler, RN, MSN, MPH, FNP David C. Mayer, M.D. Robert E. Schaaf, M.D. Neel G. Thomas, M.D. Pascal O. Udekwu, M.D. Jeffrey S. Wilson **DIVISION OF HEALTH SERVICE REGULATION STAFF** Mark Payne, Director, DHSR/Secretary, MCC Emery Milliken, Deputy Director, DHSR Geary W. Knapp, JD, CPA, Assistant Secretary, MCC Rajeev Premakumar, DHHS General Counsel's Office	Ashley H. Lloyd, D.D.S. Karen E. Moriarty Lisa A. Tolnitch, M.D. Timothy D. Weber, RPH

Eric Hunt, Attorney General's Office Jeff Harms, Acting Construction Chief, DHSR Taylor Corpening, Rules Review Coordinator, DHSR Azzie Conley, Chief, Acute & Home Care Licensure Greta Hill, Asst. Chief, Acute & Home Care Licensure Gwen Gillis, Acute & Home Care Licensure Crystal Abbott, Auditor, MCC Kathy Larrison, Auditor, MCC Alice Creech, Executive Assistant, MCC	

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. New Business

A. Rules for Adoption (Discuss rules)

1. Acute & Home Care Licensure Rule…….Taylor Corpening & A. Conley

Emergency rulemaking to consider adopting the emergency abortion rules as temporary abortion rules (13S) before they expire on January 30, 2024.

- **Rules:** 10A NCAC 13S .0101, .0104, .0111, .0112, .0114, .0201, .0202, .0207, .0209, .0210, .0211, .0212, .0315, .0318, .0319, .0320, .0321, .0322, .0323, .0324, .0325, .0326, .0327, .0328, .0329, .0330, & .0331.

  (27 Rules)

  (See Exhibits A thru G)

COMMISSION ACTION: *A motion was made to approve the emergency abortion rules as temporary abortion rules before the expire on January 30 2024, by Mrs. Eileen Kugler, seconded by Dr. Paul Cunningham, and unanimously approved.*

VI. Meeting Adjournment

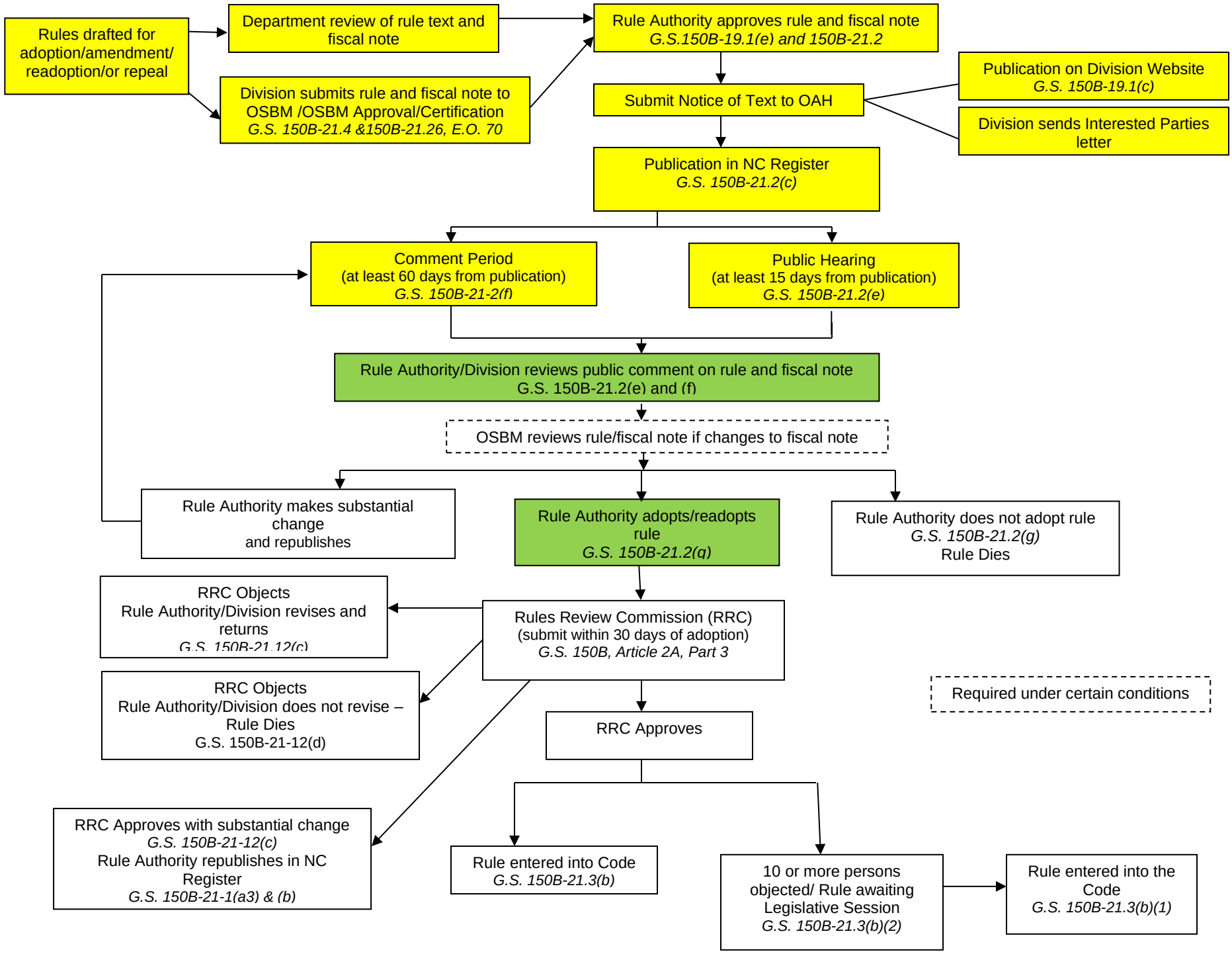
There being no further business the meeting was adjourned at 12:15 p.m.

Respectfully Submitted,

Geary W. Knapp, JD, CPA
Assistant Secretary

Process for Medical Care Commission to Adopt/Readopt Rule

Exhibit C



10A NCAC 13P .0101 is amended with changes as published in 38:06 NCR 308-332 as follows:

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;
~~(9)~~(10) EMR: Emergency Medical Responder;
~~(10)~~(11) EMS: Emergency Medical Services;
~~(11)~~(12) EMS-NP: EMS Nurse Practitioner;
~~(12)~~(13) EMS-PA: EMS Physician Assistant;
~~(13)~~(14) EMT: Emergency Medical Technician;
~~(14)~~(15) FAA: Federal Aviation Administration;
~~(15)~~(16) FCC: Federal Communications Commission;
~~(16)~~(17) ICD: International Classification of Diseases;
~~(17)~~(18) ISS: Injury Severity Score;
~~(18) MICN: Mobile Intensive Care Nurse;~~
(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) SMARTT: State Medical Asset and Resource Tracking Tool;~~
~~(27)~~(26) STEMI: ST Elevation Myocardial Infarction; and
~~(28)~~(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 is amended as published in 38:06 NCR 308-332 as follows:

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 there is~~ 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, ~~or~~ by a hospital of its own volition ~~reroutes~~ 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~~ 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~~ 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 Performance Improvement Self-Tracking and Assessment of Targeted Statistics" means one or more reports generated from the State EMS data system analyzing the EMS service delivery, personnel performance, and patient care provided by an EMS system and its associated EMS agencies and personnel. Each EMS Performance Improvement Self-Tracking and Assessment of Targeted Statistics focuses on a topic of care such as trauma, cardiac arrest, EMS response times, stroke, STEMI (heart attack), and pediatric care.~~

~~(21)~~(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.

~~(22)~~(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.

~~(23)~~(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.

~~(24)~~(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.

~~(25)~~(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.

~~(26)~~(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.

~~(27)~~(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.

~~(28)~~(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.

~~(29)~~(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.

~~(30)~~(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.

~~(31)~~(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.

~~(32)~~(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.

~~(33)~~(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.

~~(34)~~(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.

~~(35)~~(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.

~~(36)~~(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.

~~(37)~~(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.

~~(38)~~(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.

~~(39)~~(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.

~~(40)~~(39) "Physician" means a medical or osteopathic doctor licensed by the North Carolina Medical Board to practice medicine in the state of North Carolina.

~~(41)~~(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.

~~(42)~~(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) "State Medical Asset and Resource Tracking Tool" means the Internet web-based program used by the OEMS both in its daily operations and during times of disaster to identify, record, and monitor EMS, hospital, health care, and sheltering resources statewide, including facilities, personnel, vehicles, equipment, and pharmaceutical and supply caches.~~

~~(45)~~(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.

~~(46)~~(45) "Specialty Care Transport Program Continuing Education Coordinator" means a ~~Level II~~ Level I EMS Instructor within a SCTP who is responsible for the coordination of EMS continuing education programs for EMS personnel within the program.

~~(47)~~(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.

~~(48)~~(47) "Stroke" means an acute cerebrovascular hemorrhage or occlusion resulting in a neurologic deficit.

~~(49)~~(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.

~~(50)~~(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, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost and online at www.ncems.org~~ OEMS at https://oems.nc.gov at no cost.

~~(51)~~(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.

~~(52)~~(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, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost and~~ OEMS online at ~~https://info.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html~~ https://oems.nc.gov/wp-content/uploads/2022/10/datadictionary.pdf at no cost.

~~(53)~~(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.

~~(54)~~(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 ~~at https://info.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html~~ online at https://oems.nc.gov/wp-content/uploads/2022/10/datadictionary.pdf at no cost.

~~(55)~~(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.

~~(56)~~(55) "Triage" means the assessment and categorization of a patient to determine the level of EMS and healthcare facility based care required.

~~(57)~~(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 .0201 is amended as published in 38:06 NCR 308-332 as follows:

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) weekly updating of the SMARTT EMS Provider information;~~

~~(F)~~(E) a disaster plan;

~~(G)~~(F) a mass-gathering plan that includes how the provision of EMS standby coverage for the public-at-large will be provided;

~~(H)~~(G) a mass-casualty plan;

~~(I)~~(H) a weapons plan for any weapon as set forth in Rule .0216 of this Section;

~~(J)~~(I) a plan on how EMS personnel shall report suspected child abuse pursuant to G.S. 7B-301;

~~(K)~~(J) a plan on how EMS personnel shall report suspected abuse of the disabled pursuant to G.S. 108A-102; ~~and~~

~~(L)~~(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~~ 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.~~ 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.

10A NCAC 13P .0207 is amended as published in 38:06 NCR 308-332 as follows:

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," 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.~~ 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 in addition to those required by Federal Motor Vehicle Safety Standards.~~ 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 ~~sufficient~~ 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 ~~mounted~~ 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 ~~shall not use a radiotelephone device such as a cellular telephone as the only source of two-way radio voice communication.~~ 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 (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.~~ 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0216 is amended as published in 38:06 NCR 308-332 as follows:

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 ~~or not~~ 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(a)(13)(I)~~ 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(a)(13)(I)~~ 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 ~~so as~~ 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.~~ 2017;
Amended Eff. April 1, 2024.

10A NCAC 13P .0217 is amended as published in 38:06 NCR 308-332 as follows:

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," which is incorporated by reference, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost.~~ Collection." The equipment and supplies shall be clean, in working order, and secured in the vehicle;

(3) ~~five pound~~ 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 in addition to those required by Federal Motor Vehicle Safety Standards.~~ 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 ~~sufficient~~ 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 ~~mounted~~ 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~~ the Department imposes an administrative sanction which specifies permit expiration;

(2) ~~The~~ the EMS Provider closes or goes out of business;

(3) ~~The~~ the EMS Provider changes name or ownership; or

(4) ~~Failure~~ 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.~~ 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0218 is amended as published in 38:06 NCR 308-332 as follows:

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," which is incorporated by reference, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost.~~ 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 in addition to those required by Federal Motor Vehicle Safety Standards.~~ 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 ~~sufficient~~ 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 ~~mounted~~ 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~~ the Department imposes an administrative sanction which specifies permit expiration;

(2) ~~The~~ the EMS Provider closes or goes out of business;

(3) ~~The~~ the EMS Provider changes name or ownership; or

(4) ~~Failure~~ 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.~~ 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0221 is amended as published in 38:06 NCR 308-332 as follows:

10A NCAC 13P .0221 PATIENT TRANSPORTATION BETWEEN HOSPITALS

(a) For the purpose of this Rule, hospital means those facilities as defined in ~~Rule .0102(25)~~ 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(a)(3)~~ Rule .0204 of this Section; and

(2) showing authorization pursuant to ~~Rule .0204(a)(4)~~ 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 ~~www.nccems.org.~~ 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 .0224 is amended as published in 38:06 NCR 308-332 as follows:

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,~~ 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" (GVS v.1.0),~~ 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 ~~fifty-two dollars ($52.00).~~ 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;

~~(3)~~(4) "convalescent ambulances" as defined in Rule .0102 of this Subchapter;

~~(4)~~(5) ~~remounted or~~ refurbished ambulances; or

~~(5)~~(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.~~ 2018;
Amended Eff. April 1, 2024.

10A NCAC 13P .0301 is amended as published in 38:06 NCR 308-332 as follows:

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 a period to coincide with the EMS Provider License that is issued by OEMS and 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 .0401 is amended as published in 38:06 NCR 308-332 as follows:

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," 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;~~ 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, ~~MICN,~~ 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.~~ 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0402 is amended as published in 38:06 NCR 308-332 as follows:

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," 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.~~ 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, ~~MICN,~~ 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.~~ 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0403 is amended as published in 38:06 NCR 308-332 as follows:

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;~~ protocols as set forth in Rule .0405 of this Section;

(3) EMD programs, the establishment, approval, and annual updating of the ~~Emergency Medical Dispatch Priority Reference System;~~ 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; and~~ practice.

~~(10) developing and implementing an orientation plan for all hospitals within the EMS system that use MICN, EMS-NP, or EMS-PA personnel to provide on-line medical direction to EMS personnel. This plan shall include:~~

~~(A) a discussion of all EMS System treatment protocols and procedures;~~

~~(B) an explanation of the specific scope of practice for credentialed EMS personnel, as authorized by the approved EMS System treatment protocols required by Rule .0405 of this Section;~~

~~(C) a discussion of all practice settings within the EMS System and how scope of practice may vary in each setting;~~

~~(D) a mechanism to assess the ability to use EMS System communications equipment, including hospital and prehospital devices, EMS communication protocols, and communications contingency plans as related to on-line medical direction; and~~

~~(E) the completion of a scope of practice performance evaluation that verifies competency in Parts (A) through (D) of this Subparagraph and that is administered under the direction of the Medical Director.~~

(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.~~ 2017;
Amended Eff. April 1, 2024.

10A NCAC 13P .0404 is amended as published in 38:06 NCR 308-332 as follows:

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~~ the establishment, approval, and updating of adult and pediatric treatment ~~protocols;~~ protocols as set forth in Rule .0406 of this Section;

(2) ~~Medical~~ medical supervision of the selection, program orientation, continuing education, and performance of medical crew members;

(3) ~~Medical~~ 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~~ the medical review of the care provided to patients;

(5) ~~Keeping~~ keeping the care provided up to date with current medical practice; ~~and~~

(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

~~(6)~~(7) ~~In~~ in air medical programs, determination and specification of the medical equipment required in ~~Item (2) of~~ 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.~~ 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0407 is amended as published in 38:06 NCR 308-332 as follows:

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," 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~~ Collection;"

(2) not exceed the EMD scope of practice defined by the North Carolina Medical Board pursuant to G.S. ~~143-514.~~ 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.~~ 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0410 is amended with changes as published in 38:06 NCR 308-332 as follows:

10A NCAC 13P .0410 COMPONENTS OF MEDICAL OVERSIGHT FOR AIR MEDICAL PROGRAMS

~~(a) In addition to the terms defined in Rule .0102 of this Subchapter, the following definition applies to this Rule: "Specialized Ambulance Protocol Summary (SAPS) form" means a document completed by the Medical Director of the Air Medical Program that contains a listing of all medications, equipment, and supplies.~~

~~(b)~~(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.

~~(c)~~(b) Licensed EMS providers seeking to offer multiple air medical programs under separate medical oversight processes as set forth in Paragraph ~~(d)~~ (c) of this Rule shall make application for each program and receive approval from the OEMS as set forth in Paragraph ~~(b)~~ (a) of this Rule.

~~(d)~~(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 ~~appropriate~~ 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 ~~into the PreHospital Medical Information System (PreMIS)~~ 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 ~~arrange~~ arranging for the receiving hospital to prepare for the incoming patient.

~~(e)~~(d) In addition to the requirements set forth in Paragraph ~~(d)~~ (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 ~~(d)(2)~~ (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;

~~(d)~~(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: *G.S. 131E-155.1; 131E-156; 131E-157(a); 131E-161; 143-508(d)(8);*
Eff. January 1, ~~2018.~~ 2018;
Amended Eff. April 1, 2024.

10A NCAC 13P .0502 is amended with changes as published in 38:06 NCR 308-332 as follows:

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~~ director to qualify for an extension of the 90-day requirement set forth in this Paragraph. If the EMS Educational Institution's program ~~coordinator~~ director 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) Individuals applying to OEMS for legal recognition, who completed initial educational courses through an OEMS approved North Carolina educational institution, shall complete a written examination administered by the OEMS.~~

(5)[~~(6)~~] Submit to a criminal background history check as set forth in Rule .0511 of this Section.

(6)[~~(7)~~] 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. Individuals applying to OEMS for legal recognition, who completed initial educational courses through an OEMS approved North Carolina educational institution, shall complete a written examination administered by the OEMS.

(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;~~ possess a valid CPR card;

(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. April 1, 2024; July 1, 2021.*

10A NCAC 13P .0503 is amended with changes as published in 38:06 NCR 308-332 as as follows:

10A NCAC 13P .0503 TERM OF CREDENTIALS FOR EMS PERSONNEL

~~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(f)~~ 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 .0512 is amended as published in 38:06 NCR 308-332 as follows:

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 ~~36 months,~~ 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;~~ 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; and~~ 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 ~~36 months,~~ 12 months shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c); ~~and~~

~~(2) meet the provisions for initial credentialing set forth in Rule .0502 of this Section.~~

(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 .0601 is amended with changes as published in 38:06 NCR 308-332 as follows:

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 ~~coordinator~~ 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 ~~Coordinator~~ 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 ~~coordinators~~ directors shall attend an OEMS Program Coordinator workshop annually. A listing of scheduled OEMS Program ~~Coordinator~~ Director Workshops is available at https://emspic.org. Newly appointed program [~~coordinators~~] directors who have not attended an OEMS Program [~~Coordinator~~] Director Workshop within the past year shall attend a workshop within one year of appointment as the program [~~coordinator~~] 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 ~~must~~ 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 is amended with changes as published in 38:06 NCR 308-332 as follows:

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) ~~at least~~ 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 ~~under Standard III~~ of the CAAHEP Standards and Guidelines for the Accreditation of Educational Programs in the Emergency Medical Services ~~Professions.~~ 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 ~~coordinator.~~ director. This individual shall be a Level II EMS Instructor credentialed at or above the highest level of course offered by the ~~institution,~~ institution. Newly appointed program [~~coordinators~~] 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 [~~coordinator;~~] 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 ~~Section;~~ Subchapter;

(3) a lead EMS educational program ~~coordinator~~ 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; ~~and~~

(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 [~~coordinator~~] 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.

~~(d)~~(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 .0904 is amended as published in 38:06 NCR 308-332 as follows:

10A NCAC 13P .0904 INITIAL DESIGNATION PROCESS

(a) For initial Trauma Center ~~designation,~~ 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 ~~at least~~ 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 ~~weekly a minimum~~ 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 ~~at least~~ 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 and the site visit shall be conducted within six months of the recommendation.~~ days. The hospital and the OEMS shall agree on the date of the site visit.

(k) Except for OEMS representatives, ~~any in-state reviewer~~ 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 ~~state~~ site survey team shall be as follows:

(1) one ~~out-of-state~~ trauma surgeon who is a Fellow of the ACS, experienced as a site surveyor, who shall be the primary reviewer;

(2) one ~~in-state~~ 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 ~~in-state~~ trauma ~~surgeon who is a member of the North Carolina Committee on Trauma;~~ surgeon;

(4) ~~for Level I designation, one out-of-state~~ one trauma program ~~manager with an equivalent license from another state;~~ manager; and

~~(5) for Level II designation, one in-state program manager who is licensed to practice nursing in North Carolina in accordance with the Nursing Practice Act, Article 9A, Chapter 90 of the North Carolina General Statutes; and~~

~~(6)~~(5) OEMS Staff.

(l) All site team members for a Level III ~~visit shall be from in-state, and,~~ 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, who is a member of the North Carolina Committee on Trauma~~ ACS and shall be the primary reviewer;

(2) one emergency physician who currently works in a designated trauma ~~center, is a member of the North Carolina College of Emergency Physicians or American Academy of Emergency Medicine,~~ 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 who is licensed to practice nursing in North Carolina in accordance with the Nursing Practice Act, Article 9A, Chapter 90 of the North Carolina General Statutes;~~ manager; and

(4) OEMS Staff.

(m) ~~On the day of the site visit, the~~ 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 is amended as published in 38:06 NCR 308-332 as follows:

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(k)~~ 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(l)~~ 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 ~~out-of-state~~ trauma surgeon who is a Fellow of the ACS, experienced as a site surveyor, who shall be the primary reviewer;

(B) one ~~out-of-state~~ 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 ~~out-of-state~~ trauma program ~~manager with an equivalent license from another state;~~ 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 .1505 is amended as published in 38:06 NCR 308-332 as follows:

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 for any of the following reasons:~~ 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 .1507 is amended with changes as published in 38:06 NCR 308-332 as follows:

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, ~~student,~~ ~~bystander,~~ EMS personnel, other allied healthcare personnel, student, educational institution staff, members of the public, or OEMS staff, either physically, verbally, or in writing;

(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; ~~or~~

(32) filing a knowingly false complaint against an individual, EMS Agency, or educational ~~institution.~~ 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.~~ 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.

DHHS
Fiscal Impact Analysis of Permanent Rule Amendment without Substantial Economic Impact

Agencies Proposing Rule Change
North Carolina Medical Care Commission
Division of Health Service Regulation
Office of Emergency Medical Services

Contact Persons
Nadine Pfeiffer, DHSR Rule Making Manager – (919) 855-3811
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Impact Summary

State Government:	**Yes**
Local Government:	**Yes**
Private Entities:	**Yes**
Substantial Impact:	**No**

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Appendix A: EMS and Trauma Rules 10A NCAC 13P proposed for revision

Authorizing Statutes
The following statutes are cited in the statutory authority of the rules under revision by the MCC.

G.S. 131E-155	Definitions
G.S. 131E-156	Permit Required to Operate Ambulance
G.S. 131E-157	Standards for Equipment; Inspection of Equipment and Supplies Required for Ambulances
G.S. 131E-158	Credentialed Personnel Required; Temporary Waiver of Requirements During an Emergency
G.S. 131E-159	Credentialing Requirements
G.S. 131E-162	Statewide Trauma System
G.S. 143-508	Department of Health and Human Services to Establish Program; Rules and Regulations of North Carolina Medical Care Commission
G.S. 143-509	Powers and Duties of Secretary
G.S. 143-517	Ambulance Support; Free Enterprise

G.S. 143-518	Confidentiality of Patient Information
G.S. 143-519	Emergency Medical Services Disciplinary Committee
G.S. 143B-952	Criminal Records Checks of EMS Personnel

Titles of Rule Changes and Related Statutory Citations affected by amendment to the General Statues of the State of North Carolina.

To support the proposed revisions to the 10A NCAC 13P EMS and Trauma rules, the Office of Emergency Medical Services (OEMS) is recommending §131E-155 be changed to remove "mobile intensive care nurse" from the definitions. This reference is obsolete. The rules being updated to reflect the proposed change to the statutory language directly related to this change are as follows:

10A NCAC 13P

Section .0100 – Definitions

- .0101- Abbreviations

Section .400 Medical Oversight

- .0401 – Components of Medical Oversight for EMS Systems
- .0402 – Components of Medical Oversight for Specialty Care Transport Programs

Titles of Rule Changes Proposed for Amendment

The following rules reflect the changes needed to update obsolete or unnecessary standards, clarify ambiguous language, incorporate changes in the healthcare delivery models, recognize new technologies, and to provide all regulated entities and the public the most efficient and effective structure for services regulated for emergency medical and trauma systems. The Medical Care Commission meeting for initial approval of the proposed rules is scheduled for August 11, 2023. These Rules are identified as follows:

10A NCAC 13P *(See proposed text of these rules in Appendix A)*

Section .0100 – Definitions

- .0101– Abbreviations (Amend)
- .0102 – Definitions (Amend)

Section .0200 – EMS Systems

- .0201 – EMS System Requirements (Amend)
- .0207 – Ground Ambulance: Vehicle and Equipment Requirements (Amend)
- .0216 – Weapons and Explosives Forbidden (Amend)
- .0217 – Medical Ambulance/Evacuation Bus: Vehicle and Equipment Requirements (Amend)
- .0218 – Pediatric Specialty Care Ground Ambulance: Vehicle and Equipment Requirements (Amend)
- .0221 – Patient Transportation Between Hospitals (Amend)
- .0224 – Ground Ambulance Manufacturing Standards (Amend)

Section .0300 – Specialty Care Transport Programs

- .0301 – Specialty Care Transport Program Criteria (Amend)

Section .0400 – Medical Oversight

- .0401 – Components of Medical Oversight for EMS Systems (Amend)
- .0402 – Components of Medial Oversight for Specialty Care Transport Programs (Amend)
- .0403 – Responsibilities of the Medical Director for EMS Systems (Amend)
- .0404 – Responsibilities of the Medical Director for Specialty Care Transport Programs (Amend)
- .0407 – Requirements for Emergency Medical Dispatch Priority Reference System (Amend)
- .0410 – Components of Medical Oversight for Air Medical Programs (Amend)

Section .0500 – EMS Personnel

- .0502 – Initial Credentialing Requirements for EMR, EMT, AEMT, Paramedic, and EMD (Amend)
- .0503 – Term of Credentials for EMS Personnel (Amend)
- .0512 – Reinstatement of Lapsed Credential (Amend)

Section .0600 – EMS Educational Institutions and Programs

- .0601 – Continuing Education EMS Educational Program Requirements (Amend)
- .0602 – Basic and Advanced EMS Educational Institution Requirements (Amend)

Section .0900 Trauma Center Standards and Approval

- .0904 – Initial Designation Process (Amend)
- .0905 – Renewal Designation Process (Amend)

Section .1500 Denial, Suspension, Amendment, or Revocation

- .1505 – EMS Educational Institutions (Amend)
- .1507 – EMS Personnel Credentials (Amend)

Summary of Revisions and Anticipated Impacts

Rules .0101 – Abbreviations and .0102 Definitions

Rules .0101 and .0102 are being amended to update terminology that is used throughout the rules. There is no impact associated with these amendments other than improved clarity.

Rule .0201 – EMS System Requirements

The proposed amendments to Rule .0201 and associated impacts are as follows:

Delete outdated reference to updating of SMARTT EMS provider information that is no longer a part of the OEMS database. The change also moves the documentation of how each hospital will

use and maintain two-way radio communications for incoming EMS providers from Rule .0403 – Responsibilities of the Medical Director for EMS System into this Rule. The OEMS staff review for approving and auditing of the EMS System Plan require all documents be available for review. This will streamline the development, update, and review of the respective EMS System Plan. The amendment also adds language for strengthening EMS System oversight of the EMD agency, particularly the agency roster in the OEMS database. This will address a common issue of rosters not being updated in a timely manner to reflect the current roster of credentialed EMD personnel. Adding this requirement to EMS System Plan, not just at the agency level, should strengthen compliance.

The primary impact associated with this rule is the potential for incremental improvements to compliance from the increased clarity of the requirements for document review and maintaining EMD personnel rosters.

Rules .0207 – Ground Ambulance: Vehicle and Equipment Requirements, .0217 – Medical Ambulance/Evacuation Bus: Vehicle and Equipment Requirements, and **.0218 – Pediatric Specialty Care Ground Ambulance: Vehicle and Equipment Requirements**

The proposed amendments to Rules .0207, .0217, and .0218 and associated impacts are as follows:

Remove Radio Mounting Requirement

Remove the requirement for a "mounted" radio device in the patient compartment of a ground ambulance. Since these rules were last updated, portable two-way communication technology has improved and is now considered sufficient for EMS personnel to communicate with the hospital from the ambulance. This change would apply to both 911 Emergency ambulances and Non-Emergency transport vehicles. 911 Emergency ambulances would still be required to have a radio control device in the rear patient compartment, but it would not need to be mounted (i.e., it could be portable). 911 Emergency ambulances would still be required to have a mounted two-way radio in the cab.

The potential future cost savings to agencies from this change will be in the form of avoided costs from not having to purchase and reinstall the radios as they replace existing radios, or not having to purchase a new radio or pay for reinstallation of an existing radio in a new ambulance. The potential savings will be available to state, county government. and private licensed EMS agencies.

EMS agencies may choose to phase out the ambulance mounted rear radios as they age out or the ambulances are replaced. The majority of new ambulances and virtually all remounts are purchased to replace vehicles that have either reached the end of the project life cycle, or a very few replacing those involved in accidents which repair costs exceed the value of the vehicle. Although the OEMS does not have a means to predict how many agencies will choose to replace mounted radios with portable technology, we expect it is likely to occur more frequently as portable technology continues to improve and become more affordable.

As far as installation costs, OEMS reached out to a Raleigh area communications company for an estimate. They estimated the cost for installation (labor only) of the radio component at $450 in the front cab and patient compartment and $350 for installation in the cab only. Cost for cables,

antenna, faceplates, and connects were not included. Not including the costs for the radio itself and other related equipment costs, OEMS estimates the minimum potential cost savings (avoided costs) for non-emergency ambulances is $450 per vehicle. For the EMS 911 ambulances, the savings would be $100 per vehicle as the rear mounted radio is not required. Avoided costs will be greater if purchase of new cables and other related equipment would have been required for installation. Potential minimum avoided costs associated with the proposed rule change are summarized for non-emergency agencies (Table 1) and 911 emergency agencies (Table 2).

Table 1: Potential Minimum Cost Savings (Avoided Costs) to Non-Emergency Agencies from Revisions to Radio Mounting Requirement

Non-Emergency Agency Type	Number of Ambulances currently in operation*	Estimated Minimum Cost Savings per Vehicle	Sub-Total Potential Cost Savings by Agency Type
State owned and operated	6	$450	$2,700
Local Government Owned	0	$450	$0
Privately owned and operated (Hospitals, For-Profit Non-Hospital Agencies, Volunteer agencies)	160	$450	$72,000
Total Potential Minimum Cost Savings†			$74,700

** The non-emergency (medical transport/convalescent) ambulance numbers were obtained from the OEMS Continuum database. These ambulances are permitted at the EMT level.*

† Savings would occur over an unknown number of years.

Table 2: Potential Minimum Cost Savings (Avoided Costs) to 911 Emergency Agencies from Revisions to Radio Mounting Requirement

911 Emergency and SCTP Agency Type	Number of Ambulances currently in operation*	Estimated Minimum Cost Savings per Vehicle	Sub-Total Potential Cost Savings by Agency Type
State owned and operated	0	$100	$0
Local Government Owned	624	$100	$62,400
Privately owned and operated (Hospitals, For-Profit Non-Hospital Agencies, Volunteer agencies)	570	$100	$57,000
Total Potential Minimum Cost Savings†			$119,400

**The 911 and Specialty Care Transport (SCTP) ambulance numbers include only vehicles in-service, ready for frontline use at various levels (EMT, AEMT, Paramedic, Specialty Care).*
† Savings would occur over an unknown number of years.

Remove Two-way Radio Requirement – non-emergency transport only

Remove the requirement for two-way radios on ambulances of agencies that only provide "convalescent" or non-emergency transport that do not back up the 911 EMS System. In place of the requirement for a two-way radio, the change will allow either a two-way radio or a radiotelephone device be available. The reason for having one of these devices is for ambulance personnel to have a reliable way to request emergency assistance if needed.

Based on manufacturer recommendations (Motorola), two-way radios generally have a long lifespan and do not need replacement frequently. Although the rules do not require replacement of radios on a fixed schedule, most agencies have a budget plan to replace their radios on a fixed schedule (8 to 10 years is a common schedule). Any cost savings from the proposed rule change will be spread out over many years as existing radios gradually age out. It is possible some agencies will elect to replace existing radios with new radios or install existing radios into new ambulances even when it is no longer required. OEMS has no way of projecting this number.

If an agency providing non-emergency transport chooses not to install new or used two-way radios and instead relies on radiotelephone devices, it is reasonable to assume they would do so as a means to save on costs. There are too many unknown variables to estimate the likely cost savings in this scenario. In any case, cost savings (in the form of avoided costs) would occur over an unknown number of years.

Rules .0216 – Weapons and Explosives Forbidden and .0221 – Patient Transportation Between Hospitals

Rules .0216 and .0221 are being amended with minor technical changes only. There is no impact associated with these changes other than improved clarity.

Rule .0224 Ground Ambulance Vehicle Manufacturing Standards

The proposed amendments to Rule .0224 and associated impacts are as follows:

Rule .0224 was first adopted on January 1, 2018 to establish a minimum manufacturing standard for all ground ambulances for the transport of emergent and non-emergent patients in North Carolina. In order to ensure ambulances operating in North Carolina are safe and reliable, the Office of Emergency Medical Services (OEMS) determined that the minimum manufacturing standard for North Carolina must be either the Commission on Accreditation of Ambulance Services (CAAS) Ground Vehicle Manufacturing Standard, CAAS GVS v.1.0[1] or the National Fire Protection Association (NFPA) 1917-2016 Standard for Automotive Ambulances.[2] In 2018 those were the only two American National Standards Institute (ANSI) accredited "standards developers" issuing new ambulance manufacturing standards in the United States. Since the original adoption of this rule, both accrediting agencies have implemented subsequent standards to include ambulance "remounts."

In the proposed rule amendment, the addition of the "remount" standards is to align the rule with updates to the CAAS and NFPA standards and provide a reasonable timeframe for agencies to comply. Due to recent supply chain challenges for ambulance vehicle chassis, EMS agencies may currently have contractual agreements with vendors that may extend well over a year or 18 months before the unit is ready for delivery.

Any costs or benefits associated with the remount standards would occur as a result of the change to the CAAS and NFPA standards themselves, and not to the proposed rule amendments. These standards already apply to the regulated community as the current rule includes "all subsequent amendments and editions" for both accrediting agencies.

Rule .0301 – Specialty Care Transport Program Criteria

The proposed amendments to Rule .0301 and associated impacts are as follows:

Clarify that the listing of all required equipment, supplies, and medications approved by the medical director must be documented on a "Specialized Ambulance Protocol Summary" form provided by the OEMS. The document specifies OEMS required equipment, supplies, and

[1] A copy of the updated CAAS GVS v.3.0 *"Ground Vehicle Standard for Ambulances"* may be obtained online without cost at www.groundvehiclestandard.org/.
[2] A copy of the NFPA 1917-2016 *"Automotive Ambulance Standard"* may be obtained online at www.nfpa.org for a cost of $78.00.

medications and the optional equipment, supplies, and medications approved by the program medical director. The "SAPS" document is used by OEMS staff to inspect the vehicle or aircraft to issue a permit as required by NC G.S. 131E-156. "Aircraft" was added to clarify the aircraft is under the SCTP and must meet the requirements listed on the respective agency SCTP "SAPS" document. The OEMS has been utilizing the "SAPS" document for several years and the regulated programs are already in compliance. As such, there will no be no impact associated with the proposed amendments.

Rules .0401 – Components of Medical Oversight for EMS Systems and .0402 – Components of Medical Oversight for Specialty Care Transport Programs

The proposed amendments to Rules .0401 and .0402 and associated impacts are as follows:

Delete obsolete language regarding MICN (Mobile Intensive Care Nurse) and a minor technical change. EMS systems and Specialty Care Transport Programs no longer use Registered Nurses in the MICN role. There is no impact associated with these changes other than improved clarity.

Rule .0403 – Responsibilities of the Medical Director for EMS Systems

The proposed amendments to Rule .0403 and associated impacts are as follows:

Clarify that EMDPRS updates include subsequent editions as published used by the respective EMS System. The current rule requires that the Medical Director for the EMS System update the EMDPRS on an annual basis. This proposed change simply clarifies that the most current version of the EMDPRS must be utilized. As compared to the regulatory baseline, this change will not impose any new requirements or result in any additional workload. The increased rule clarity could result in better compliance with the protocol update requirements which could ultimately lead to incremental improvements in delivery of emergency services to the public.

Due to protocol advancement during recent years, standing orders have been expanded. On-line medical control is far less frequent. On-line medical control is provided by system designated hospital Emergency Department physician, EMS-PA, EMS NP, or by contacting the System Medical Director, or Assistant Medical Director.

Add an option for the EMS System Medical Director to delegate Medical Oversight of a licensed non-emergency EMS agency to the agency medical director. These agencies are franchised to provide "non-emergency" ambulance transport within the EMS System. This would be an option only for those agencies that do not back up the emergency 911 EMS System. The rule also proposes requirements regarding qualifications of the delegated medical director, treatment protocols, and a peer review process. It should be noted that the delegation option will not supersede local franchise requirements for Medical Oversight.

Many "non-emergency" ambulance transport agencies provide services in multiple counties. Each of the counties have protocols specific to their respective EMS system which require EMS personnel employed by these agencies to be familiar with each EMS system's protocols and Medical Director. The option to delegate medical oversight to non-emergency EMC providers

will allow an EMC System to focus more of their staff resources on the more urgent 911 EMS components rather than on providing non-emergency transportation. OEMS cannot predict how many EMS Systems will elect to delegate medical oversight at the agency level. Presumably, an EMC System would only choose to delegate if they believe it will be beneficial to them as far as cost or time savings or improved delivery of services. OEMS believes that companies that have multiple EMS Systems across counties are likely to derive the most benefit from this option.

OEMS cannot estimate the cost associated with delegation of medical oversight. Contracts for services vary for accessibility and an agreed upon number of hours per week or month. The vast majority of the "non-emergency" transport agencies are private entities whose funding is based on fee for transport services. Franchise requirements in some county EMS systems include agency level medical oversight for the non-emergency services. Other EMS systems may appoint the agency Medical Director as an Assistant Medical Director for the EMS system with the sole responsibility for medical oversight of that agency.

Requiring the non-emergency agencies to conduct peer review and report information to the EMS System peer review committee will provide feedback back to the EMS System to validate the agencies are maintaining OEMS compliance as well as local franchise requirements. As compared to the regulatory baseline, this change will result in minimal additional costs to the agencies in the form of time spent conducting the focused peer review and preparing reports. Rule .0408 already requires a peer review committee, a quarterly review, and reporting, so the addition of the focused peer review specific to Rule .0403 will not require agencies to form a new peer review committee or to change the frequency of ongoing reviews. Rather, the inclusion of this requirement in Rule .0403 will serve as a prompt for the System committee to focus on particular elements related to delegated medical oversight.

The agency medical director will determine agency staff required for the peer review committee and criteria for focused review. The focused review will provide opportunities to improve criteria specific to the level of care and services provided by the non-emergency agency. Examples of focused review may include patient suctioning, management of patients transported in home ventilators, patient encounters resulting in request for 911 EMS response, areas of documentation, and safe patient transfer to mention a few. The impact should be minimal as reports should be available through agency data and quarterly meetings are projected to be an hour or less.

Rule .0404 - Responsibilities of the Medical Director for Specialty Care Transport Programs

The proposed amendments to Rule .0404 and associated impacts are as follows:

Clarify specific responsibilities of the SCTP Medical Director and minor technical changes. Clarification includes specific reference for compliance to Rule .0406 Requirements for Adult and Pediatric Treatment Protocols for Specialty Care Transport Programs and the addition of the SAPS document to detail medications, equipment, and supplies on the vehicles and aircraft. The SAPS document is the tool OEMS personnel use to conduct permitting and compliance inspections. Disciplinary action by the medical director has been added to mirror language in Rule .0403 Responsibilities of the Medical Director for EMS Systems. There is no impact associated with these changes other than improved clarity.

Rule .0407 – Requirements for Emergency Medical Dispatch Priority Reference System

The proposed amendments to Rule .0407 and associated impacts are as follows:

Clarify that certain components of the existing performance measure requirements be incorporated into a written plan, including how the agency will maintain a current roster of EMD personnel and how the dispatching agency will comply with updates to compliance standards defined by EMDPRS. EMD personnel credentialed by the OEMS are required to be entered into the OEMS credentialing and information database. Agencies providing EMDPRS must also be listed in the database and maintain a "current" roster all credentialed personnel. OEMS audits of EMS systems and EMD agencies have identified concerns regarding failure to keep rosters and credential staff information up to date. EMD agencies consistently have a high turnover rate of EMD personnel and often administrative staff. Documenting the roster requirement under Rule .0201 - EMS System Requirements, in this Rule should enhance oversight at the EMS system level and the EMD agency level.

EMD participation in the EMS system peer review has been defined in the "North Carolina College of Emergency Physicians: Standard for Medical Oversight and Data Collection Performance Improvement" document. The addition of the proposed language to this rule clarifies and strengthens peer review compliance requirements for EMD centers.

The primary impact associated with changes to this rule is the potential for incremental improvements to compliance as a result of the increased clarity of the requirements for maintaining rosters and staying up to date with EMSPRS program requirements, including peer review requirements.

Rule .0410 Components of Medical Oversight for Air Medical Programs

The proposed amendments to Rule .0410 and associated impacts are as follows:

Paragraph (a) is proposed to be deleted since the Specialized Ambulance Protocol Summary was moved to Rule .0102 Definitions.

Paragraph (c)(9) referenced the PreHospital Medical Information System (PreMIS) which is outdated. Language added clarifies the electronic submission requirements as defined in Rule .0204 EMS Licensed Provider Requirements. Agencies are already compliant with the updated data system.

There is no impact associated with these changes other than improved clarity.

Rule .0502 – Initial Paramedic Credentialing Requirements for EMR, EMT, AEMT, Paramedic and EMD

The proposed amendments to Rule .0502 and associated impacts are as follows:

Streamlines and updates terminology regarding qualifications for being credentialed to provide CPR instructions to 911 callers. The change in paragraph (c)(3) is based on updates to CPR training for the public, which are already required in practice. EMD personnel provide CPR instructions to 911 callers, which for the public is "hands only" and no mouth-to-mouth breaths. As compared to the regulatory baseline, the change to the term "valid CPR card" will not result in any changes to existing procedures. EMD personnel will continue to comply with EMDPRS recommended CPR training.

Add a requirement that individuals seeking legal recognition (the OEMS internal process for applying for reciprocity) for an EMR, EMT, AEMT, or Paramedic credential and who completed initial courses through an approved NC educational institution must complete a written examination administered by the OEMS. The OEMS written examination is online and available at designated centers throughout the United States.

Under the current rule, applicants for initial credentialing who have completed an initial education course in North Carolina and fail the OEMS written examination may currently take the National Registry examination and apply for legal recognition for an initial OEMS credential. This proposed change would not apply to individuals who are seeking reciprocity but have not taken coursework at a NC institution. Those individuals would continue to have the option to take either the NC exam or the national exam.

The OEMS strongly believes maintaining an accredited credentialing examination allows more efficient cost of credentialing at all levels. The process also allows credential term of EMS credentials of four years versus two years for National Registry. Maintaining a state examination allows better oversight of the educational curriculum to focus skills within the scope of practice for EMS personnel in North Carolina. Maintaining the state exam also allows the OEMS to better assist students/applicants by approving accommodation requests locally rather than being determined by the National Registry.

The proposed change related to reciprocity could result in some modest cost savings for applicants who would have otherwise chosen to take the national exam. The total cost savings to an applicant would vary due to 1) how many attempts taken to pass the OEMS exam versus how many attempts it would have taken to pass the National Registry exam and 2) which credential they are seeking. OEMS written examinations (all levels) cost $68. National Registry cost is EMT $104, AEMT $144, Paramedic $160. Those applicants seeking credentialing as a Paramedic would potentially see the largest cost savings ($160 for national exam versus $68 for OEMS exam). The OEMS examination may be taken at any Meazured Learning approved testing site nationwide, so there would not be a cost difference as far as location. In 2022, a total of 1,394 applicants were approved for legal recognition. OEMS does not have data on how many of those had completed their coursework in NC and then taken the National Registry rather than the OEMS exam.

Table 3: Calendar Year 2022 OEMS Legal Recognition Applicants Approved

Advanced EMT	36
Emergency Medical Responder	7
EMT	555
Paramedic	253
Emergency Medical Dispatcher	543
Total	1,394

While the OEMS cannot predict the number of students that will apply for the National Registry examination and then seek reciprocity, there is likely to be some cost savings to students due to the lower cost of the OEMS examination. The OEMS does not receive any funds from the examination fees. The fees go to Meazured Learning.

Table 4: Calendar Year 2022 OEMS Written Examinations

Totals Examinations	5,863	Includes carry over initial testers completing courses in late 2021, and 2nd and 3rd time testers who initially tested in 2021
Students from qualified through OEMS approved teaching institutions in 2022	4,319	Passed 1st Attempt 3,128 Passed 2nd or 3rd Attempt 494

Rule .0503 - Terms of Credentials for EMS Personnel

The proposed amendments to Rule .0503 and associated impacts are as follows:

Revise the state EMD credential renewal period from four years to two years to align with the National EMD credential renewal period. NCOEMS credentials will continue to be valid for four years. Changing the NC EMD credential to two years to coincide with national credentials should streamline the process and avoid confusion for EMD personnel and respective EMD agency administration. The OEMS administrative staff will be processing EMD reciprocity application every two years versus the current four-year time frame. Considerable time is spent to swiftly process expired credentials routinely.

Table 5 compares the OEMS cost to process EMD applicants for a North Carolina credential. Based on the Continuum database, 2,039 EMD personnel are on an agency roster. The general assumption is an average percentage number of credentialed EMD personnel would be renewed per year (e.g., 50% of 2,039 personnel renewed each year under proposed 2-year certification period). Most EMD centers have a significant amount of turnover, therefore based on "roster" numbers, the figure should remain consistent even with new applicants. The estimated total time to process an EMD application by OEMS staff is approximately ten minutes. The total compensation for an Administrative Officer 2 was estimated at $37.34 per hour.[3] Once the

[3] Total compensation was estimated using NC OSHR Total Compensation Calculator and was based on the salary + benefits of an Administrative Officer 2 with 8 years of experience.

background check is completed by the North Carolina SBI, the credential is approved. As a result of the proposed change to the certification period from four years to two years, OEMS is likely to spend about twice as much time processing applications, with an increased opportunity cost of about $3,174 per year. This workload will be absorbed into existing staff's regular duties and will not require additional expenditures other than time.

Table 5: Estimated Annual Opportunity Cost to OEMS to Process EMD Applicants

Certification Period	Applicants per year	Time to Process One Application *(Minutes)*	Time to Process All Applications per year *(Hours)*	Total Employee Hourly Compensation Estimate	Total Annual Processing Cost*
4 year (current)	510	10 Min	85 Hrs	$37.34	$3,174
2 year (proposed)	1020	10 Min	170 Hrs	$37.34	$6,348

**Total Annual Processing Cost is an opportunity cost rather than a direct cost.*

Rule .0512 – Reinstatement of Lapsed EMS Credential

The proposed amendments to Rule .0512 and associated impacts are as follows:

Clarify that EMS personnel affiliated with an alternative practice setting, as defined in Rule .0102 of this Subchapter, in North Carolina are also eligible for reinstatement. This aligns with current practice; as such, there should not be an impact from this change other than from improved rule clarity.

Replace the requirement for repeating initial credentialing course with a requirement to complete a refresher course and pass an OEMS written exam. This change is in response to public feedback that questioned the benefit of repeating initial educational requirements. OEMS agrees that a refresher course and examination is sufficient to help ensure the quality of applicants' preparation. However, this relaxation of the educational requirement needs to be accompanied by shortening the duration of the allowable lapse. OEMS believes changing the timeframe to 12 months for previously meeting all continuing education requirements for renewal prior to expiring would be more appropriate to validate compliance with up-to-date medical care.

Under the proposed rule, the refresher course and written exam would apply to those whose credentials have lapsed more than 12 months. For applicants whose credentials have lapsed for less than 12 months, they would retain the opportunity to present other evidence that continuing education requirements were met prior to the expiration date or complete a refresher course and complete a written exam. In 2022, 58 individuals with expired credentials completed a refresher course/examination. OEMS assumes that the number of individuals completing refresher courses may increase as a result of the proposed rule changes, but there is no way to predict by how much.

Given the current staffing challenges facing EMS providers and considering that multiple other licenses/certifications issued by the State require the appropriate fee and educations updates to be reinstated, the OEMS feels this change may encourage EMS personnel to re-enter the profession by providing a more reasonable opportunity than repeating the entire education program. The hiring processes and orientation programs, performance improvement, and Medical Oversight of EMS providers provide additional educational guidance to target specific needs for successful integration back into the agency work force.

The criminal history check is required for reinstatement of credentials for those with lapses of greater than 12 months. As compared to the regulatory baseline, this is not a new requirement as it was already part of the coursework process to get reinstatement. As such, this change will not impact the regulated community as compared to the baseline.

Rule .0601 – Continuing Education EMS Educational Program Requirements

The proposed amendments to Rule .0601 and associated impacts are as follows:

Clarify the time frame for newly appointed program coordinators requirements to attend an OEMS Program Coordinator Workshop. The current rule already requires program coordinators to attend a workshop annually. The proposed change simply clarifies that this requirement applies to newly appointed coordinators as well. There will be no impact associated with the proposed amendments other than improved clarity and incremental improvements to compliance.

Rule .0602 - Basic and Advanced EMS Educational Institution Requirements

The proposed amendments to Rule .0602 and associated impacts are as follows:
Clarify the time frame for newly appointed program coordinators requirements to attend an OEMS Program Coordinator Workshop. The current rule already requires program coordinators to attend a workshop annually. The proposed change simply clarifies that this requirement applies to newly appointed coordinators as well.

Language has also been added to the written educational policies and procedures requirements to align the educational program evaluation and community needs with accreditation requirements.

Paragraph (d) was added to clarify required timelines for reporting changes of the program coordinator or medical advisor to the OEMS.

Impacts associated with these changes include improved clarity which could result in incremental improvements to compliance with accreditation requirements.

Rule .0904 – Initial Designation Process

The proposed amendments to Rule .0904 and associated impacts are as follows:

Proposed amendments include technical changes, clarification, and specific changes to survey team members. Language was added to clarify a designated trauma center applying to change

levels is considered an "initial designation." Survey team member requirements have been changed to delete any references to in or out of state, which clarifies ACS verification. Individual surveyor team members descriptions have been amended to be less restrictive but still maintain the integrity of the team and provide better consistency for Level II survey team members.

These changes may potentially have a small future impact on the reimbursement costs for out-of-state team members. However, the estimate is unquantifiable due to there have not be any new trauma centers since 2019. OEMS is aware of one potential trauma center that may upgrade, but no timeline has been established at this time.

Rule .0905 – Renewal Designation Process

The proposed amendments to Rule .0905 and associated impacts are as follows:

Proposed amendments include technical changes and removing out-of-state requirements for survey team members. The OEMS feels there are qualified individuals throughout the state who can fill the surveyor requirements for renewal site visits. Amending the OEMS site visit team requirements will provide a more efficient pool of surveyors and eliminate scheduling challenges posed by out-of-state surveyors. The option of the OEMS site visit offers a four-year renewal designation versus a three-year with the ACS verification.

Rule .1505 - EMS Educational Institutions

The proposed amendments to Rule .1505 and associated impacts are as follows:

Prohibit an Educational Institution from reapplying for designation for two years after being denied initial designation. This change addresses an issue OEMS staff has encountered with the lack of quality of some EMS Educational Institution applications. OEMS receives applications that are incomplete or from startup educational institutions that do not have the equipment, resources, or clinical affiliations to qualify. The addition of a two-year prohibition on reapplying should result in a time savings for OEMS staff. Staff estimate that a typical well-documented application review takes about 8 to 16 hours to thoroughly review. The time processing the application depends on the level of the institution (continuing education, basic, or advanced) and the quality of the application. Poor quality and incomplete applications often require more time spent communicating about the shortcomings with the applicant. Reducing the number of poor-quality applications is estimated to save OEMS staff as much as an additional 16 to 24 hours per application. Some applicants may not complete the application process for approval even after numerous reviews that required either returning the application or consistently requesting additional information or supporting documents. The added language added will enhance the OEMS ability to consistently approve and reinforce high quality educational institutions for the benefit of potential students and our regulated public.

Rule .1507 EMS Personnel Credentials

The proposed amendments to Rule .1507 and associated impacts are as follows:

Clarify that the Department can amend, deny, suspend, or revoke credentials of an EMC personnel for harassing, abusing, or intimidating EMS personnel, other allied healthcare personnel, students, educational institution staff, and members of the public. Currently, the rule uses the more general terms "bystanders" and "OEMS staff." These changes are proposed because of recommendations from the EMS Disciplinary Committee, OEMS Compliance staff, EMS System administrators, and medical directors. Ongoing complaints, investigations, and interviews identified a need to list more specifically the persons that could be considered "bystanders" or "OEMS staff."

Another challenge has been clarity for acting on EMS instructor credentials for credentialed instructors who have consistently failed to comply with educational requirements that potentially impact the institution. The addition of (b)(33) provides the avenue to take appropriate action on the individual instructor that failed to comply with requirements and not the institution. Investigations from the OEMS regarding instructor failure to comply with course requirements result in action on the institution and do not hold the instructor accountable. This addition will allow action on the specific instructor's credential for failure to comply with course requirements without unnecessarily penalizing the institution itself.

Lastly, a reporting timeline for violations is proposed to be added at the request of numerous EMS System administrators and agency leaders. The reason for this is that many county or employer management, legal, and human resources staff require a timeline. The OEMS compliance personnel have been challenged by organizational legal and administrative personnel failing to provide documents to staff conducting complaint investigations. Without a required timeline to report violations some agencies/organizations have stated they do not feel obligated to provide personnel or other internal documents for the investigation process.

Impacts associated with these changes include improved clarity which could result in incremental improvements to compliance with accreditation requirements.

Conclusion

The proposed revisions to the EMS and trauma rules will delete obsolete elements, align the rules with current national and state standards, increase clarity, increase flexibility in key areas of management and credentialing, and strengthen documentation and peer review processes. Overall, the proposed changes should result in improved compliance, additional recruitment potential, higher quality EMS credential applications, and ultimately, a higher quality of care for the citizens of North Carolina. As proposed, the revisions could result in opportunity costs to OEMS of approximately $3,174 per year from additional time spent processing EMS credential applications. There is also likely to be cost savings in the form of avoided costs of at least $74,700 to non-emergency agencies and $119,400 to 911 emergency agencies from revisions to radio mounting requirements. These savings would be spread across all agencies and an unknown number of years.

APPENDIX A

10A NCAC 13P .0101 is proposed for amendment as follows:

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

~~(9)~~(10) EMR: Emergency Medical Responder;

~~(10)~~(11) EMS: Emergency Medical Services;

~~(11)~~(12) EMS-NP: EMS Nurse Practitioner;

~~(12)~~(13) EMS-PA: EMS Physician Assistant;

~~(13)~~(14) EMT: Emergency Medical Technician;

~~(14)~~(15) FAA: Federal Aviation Administration;

~~(15)~~(16) FCC: Federal Communications Commission;

~~(16)~~(17) ICD: International Classification of Diseases;

~~(17)~~(18) ISS: Injury Severity Score;

~~(18) MICN: Mobile Intensive Care Nurse;~~

(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) SMARTT: State Medical Asset and Resource Tracking Tool;

(27) STEMI: ST Elevation Myocardial Infarction; and

(28) 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 is proposed for amendment as follows:

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 there is~~ 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, ~~or~~ by a hospital of its own volition ~~reroutes~~ 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~~ 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~~ 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 Performance Improvement Self-Tracking and Assessment of Targeted Statistics" means one or more reports generated from the State EMS data system analyzing the EMS service delivery, personnel performance, and patient care provided by an EMS system and its associated EMS agencies and personnel. Each EMS Performance Improvement Self-Tracking and Assessment of Targeted Statistics focuses on a topic of care such as trauma, cardiac arrest, EMS response times, stroke, STEMI (heart attack), and pediatric care.~~

~~(21)~~(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.

~~(22)~~(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.

~~(23)~~(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.

~~(24)~~(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.

~~(25)~~(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.

~~(26)~~(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.

~~(27)~~(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.

~~(28)~~(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.

~~(29)~~(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.

~~(30)~~(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.

~~(31)~~(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.

~~(32)~~(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.

~~(33)~~(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.

~~(34)~~(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.

~~(35)~~(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.

~~(36)~~(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.

~~(37)~~(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.

~~(38)~~(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.

~~(39)~~(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.

~~(40)~~(39) "Physician" means a medical or osteopathic doctor licensed by the North Carolina Medical Board to practice medicine in the state of North Carolina.

~~(41)~~(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.

~~(42)~~(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) "State Medical Asset and Resource Tracking Tool" means the Internet web-based program used by the OEMS both in its daily operations and during times of disaster to identify, record, and monitor EMS, hospital, health care, and sheltering resources statewide, including facilities, personnel, vehicles, equipment, and pharmaceutical and supply caches.~~

~~(45)~~(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.

~~(46)~~(45) "Specialty Care Transport Program Continuing Education Coordinator" means a ~~Level II~~ Level I EMS Instructor within a SCTP who is responsible for the coordination of EMS continuing education programs for EMS personnel within the program.

~~(47)~~(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.

~~(48)~~(47) "Stroke" means an acute cerebrovascular hemorrhage or occlusion resulting in a neurologic deficit.

~~(49)~~(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.

~~(50)~~(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, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost and online at www.ncems.org~~ OEMS at https://oems.nc.gov at no cost.

~~(51)~~(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.

~~(52)~~(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, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost and~~ OEMS online at ~~https://info.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html~~ https://oems.nc.gov/wp-content/uploads/2022/10/datadictionary.pdf at no cost.

~~(53)~~(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.

~~(54)~~(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 ~~at https://info.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html~~ online at https://oems.nc.gov/wp-content/uploads/2022/10/datadictionary.pdf at no cost.

~~(55)~~(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.

~~(56)~~(55) "Triage" means the assessment and categorization of a patient to determine the level of EMS and healthcare facility based care required.

~~(57)~~(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 .0201 is proposed for amendment as follows:

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) weekly updating of the SMARTT EMS Provider information;~~

~~(F)~~(E) a disaster plan;

~~(G)~~(F) a mass-gathering plan that includes how the provision of EMS standby coverage for the public-at-large will be provided;

~~(H)~~(G) a mass-casualty plan;

~~(I)~~(H) a weapons plan for any weapon as set forth in Rule .0216 of this Section;

~~(J)~~(I) a plan on how EMS personnel shall report suspected child abuse pursuant to G.S. 7B-301;

~~(K)~~(J) a plan on how EMS personnel shall report suspected abuse of the disabled pursuant to G.S. 108A-102; ~~and~~

~~(L)~~(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~~ 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.~~ 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.

10A NCAC 13P .0207 is proposed for amendment as follows:

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," 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.~~ 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 in addition to those required by Federal Motor Vehicle Safety Standards.~~ G.S. 20-25. 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 ~~sufficient~~ 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 ~~mounted~~ 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 ~~shall not use a radiotelephone device such as a cellular telephone as the only source of two-way radio voice communication.~~ 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 (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.~~ 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0216 is proposed for amendment as follows:

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 ~~or not~~ 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(a)(13)(I)~~ 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(a)(13)(I)~~ 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 ~~so as~~ 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.~~ 2017;
Amended Eff. April 1, 2024.

10A NCAC 13P .0217 is proposed for amendment as follows:

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," which is incorporated by reference, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost.~~ Collection." The equipment and supplies shall be clean, in working order, and secured in the vehicle;

(3) ~~five-pound~~ 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 in addition to those required by Federal Motor Vehicle Safety Standards.~~ 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 ~~sufficient~~ 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 ~~mounted~~ 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~~ the Department imposes an administrative sanction which specifies permit expiration;

(2) ~~The~~ the EMS Provider closes or goes out of business;

(3) ~~The~~ the EMS Provider changes name or ownership; or

(4) ~~Failure~~ 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.~~ 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0218 is proposed for amendment as follows:

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," which is incorporated by reference, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost.~~ 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 in addition to those required by Federal Motor Vehicle Safety Standards.~~ 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 ~~sufficient~~ 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 ~~mounted~~ 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~~ the Department imposes an administrative sanction which specifies permit expiration;

(2) ~~The~~ the EMS Provider closes or goes out of business;

(3) ~~The~~ the EMS Provider changes name or ownership; or

(4) ~~Failure~~ 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.~~ 2016;

Amended Eff. April 1, 2024.

10A NCAC 13P .0221 is proposed for amendment as follows:

10A NCAC 13P .0221 PATIENT TRANSPORTATION BETWEEN HOSPITALS

(a) For the purpose of this Rule, hospital means those facilities as defined in ~~Rule .0102(25)~~ 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(a)(3)~~ Rule .0204 of this Section; and

(2) showing authorization pursuant to ~~Rule .0204(a)(4)~~ 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 ~~www.ncems.org.~~ 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 .0224 is proposed for amendment as follows:

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,~~ 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" (GVS v.1.0),~~ 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 ~~fifty-two dollars ($52.00).~~ 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;

~~(3)~~(4) "convalescent ambulances" as defined in Rule .0102 of this Subchapter;

~~(4)~~(5) ~~remounted or~~ refurbished ambulances; or

~~(5)~~(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.~~ 2018;

Amended Eff. April 1, 2024.

10A NCAC 13P .0301 is proposed for amendment as follows:

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 a period to coincide with the EMS Provider License that is issued by OEMS and 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 .0401 is proposed for amendment as follows:

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," 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;~~ 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, ~~MICN,~~ 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.~~ 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0402 is proposed for amendment as follows:

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," 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.~~ 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, ~~MICN,~~ 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.~~ 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0403 is proposed for amendment as follows:

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;~~ protocols as set forth in Rule .0405 of this Section;

(3) EMD programs, the establishment, approval, and annual updating of the ~~Emergency Medical Dispatch Priority Reference System;~~ 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; and~~ practice.

~~(10) developing and implementing an orientation plan for all hospitals within the EMS system that use MICN, EMS-NP, or EMS-PA personnel to provide on-line medical direction to EMS personnel. This plan shall include:~~

~~(A) a discussion of all EMS System treatment protocols and procedures;~~

~~(B) an explanation of the specific scope of practice for credentialed EMS personnel, as authorized by the approved EMS System treatment protocols required by Rule .0405 of this Section;~~

~~(C) a discussion of all practice settings within the EMS System and how scope of practice may vary in each setting;~~

~~(D) a mechanism to assess the ability to use EMS System communications equipment, including hospital and prehospital devices, EMS communication protocols, and communications contingency plans as related to on-line medical direction; and~~

~~(E) the completion of a scope of practice performance evaluation that verifies competency in Parts (A) through (D) of this Subparagraph and that is administered under the direction of the Medical Director.~~

(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.~~ 2017;
Amended Eff. April 1, 2024.

10A NCAC 13P .0404 is proposed for amendment as follows:

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~~ the establishment, approval, and updating of adult and pediatric treatment ~~protocols;~~ protocols as set forth in Rule .0406 of this Section;

(2) ~~Medical~~ medical supervision of the selection, program orientation, continuing education, and performance of medical crew members;

(3) ~~Medical~~ 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~~ the medical review of the care provided to patients;

(5) ~~Keeping~~ keeping the care provided up to date with current medical practice; and

(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;

~~(6)~~(7) ~~In~~ in air medical programs, determination and specification of the medical equipment required in ~~Item (2) of~~ 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.~~ 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0407 is proposed for amendment as follows:

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," 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~~ Collection;"

(2) not exceed the EMD scope of practice defined by the North Carolina Medical Board pursuant to G.S. ~~143-514.~~ 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.

(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.~~ 2016;
Amended Eff. April 1, 2024.

10A NCAC 13P .0410 is proposed for amendment as follows:

10A NCAC 13P .0410 COMPONENTS OF MEDICAL OVERSIGHT FOR AIR MEDICAL PROGRAMS

~~(a) In addition to the terms defined in Rule .0102 of this Subchapter, the following definition applies to this Rule: "Specialized Ambulance Protocol Summary (SAPS) form" means a document completed by the Medical Director of the Air Medical Program that contains a listing of all medications, equipment, and supplies.~~

~~(b)~~(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.

~~(c)~~(b) Licensed EMS providers seeking to offer multiple air medical programs under separate medical oversight processes as set forth in Paragraph ~~(d)~~ (c) of this Rule shall make application for each program and receive approval from the OEMS as set forth in Paragraph ~~(b)~~ (a) of this Rule.

~~(d)~~(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 ~~appropriate~~ 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 ~~into the PreHospital Medical Information System (PreMIS)~~ 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 ~~arrange~~ arranging for the receiving hospital to prepare for the incoming patient.

~~(e)~~(d) In addition to the requirements set forth in Paragraph ~~(d)~~ (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 ~~(d)(2)~~ (c)(2) of this Rule;

(2) all aircrafts used within North Carolina shall comply with Rule .0209 of this Subchapter, 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;

~~(d)~~(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: *G.S. 131E-155.1; 131E-156; 131E-157(a); 131E-161; 143-508(d)(8);*
Eff. January 1, ~~2018.~~ 2018;

Amended Eff. April 1, 2024.

10A NCAC 13P .0502 is proposed for amendment as follows:

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) Individuals applying to OEMS for legal recognition, who completed initial educational courses through an OEMS approved North Carolina educational institution, shall complete a written examination administered by the OEMS.

~~(5)~~(6) Submit to a criminal background history check as set forth in Rule .0511 of this Section.

~~(6)~~(7) 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;~~ possess a valid CPR card;

(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. April 1, 2024; July 1, 2021.

10A NCAC 13P .0503 is proposed for amendment as follows:

10A NCAC 13P .0503 TERM OF CREDENTIALS FOR EMS PERSONNEL

~~Credentials for EMS Personnel~~ EMR, 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(f)~~ 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 .0512 is proposed for amendment as follows:

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 ~~36 months,~~ 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;~~ 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; and~~ 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 ~~36 months,~~ 12 months shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c); ~~and~~

~~(2) meet the provisions for initial credentialing set forth in Rule .0502 of this Section.~~

(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 .0601 is proposed for amendment as follows:

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 coordinator 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 Coordinator 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 coordinators shall attend an OEMS Program Coordinator workshop annually. A listing of scheduled OEMS Program Coordinator Workshops is available at https://emspic.org. Newly appointed program coordinators who have not attended an OEMS Program Coordinator Workshop within the past year shall attend a workshop within one year of appointment as the program coordinator.

(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 ~~must~~ 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 is proposed for amendment as follows:

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) ~~at least~~ 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 ~~under Standard III~~ of the CAAHEP Standards and Guidelines for the Accreditation of Educational Programs in the Emergency Medical Services ~~Professions.~~ 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 coordinator. This individual shall be a Level II EMS Instructor credentialed at or above the highest level of course offered by the ~~institution,~~ institution. Newly appointed program coordinators 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 coordinator; 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 ~~Section;~~ Subchapter;

(3) a lead EMS educational program coordinator 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; ~~and~~

(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 coordinator 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.

~~(d)~~(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 .0904 is proposed for amendment as follows:

10A NCAC 13P .0904 INITIAL DESIGNATION PROCESS

(a) For initial Trauma Center ~~designation,~~ 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 ~~at least~~ 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 ~~weekly a minimum~~ 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 ~~at least~~ 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 and the site visit shall be conducted within six months of the recommendation.~~ days. The hospital and the OEMS shall agree on the date of the site visit.

(k) Except for OEMS representatives, ~~any in-state reviewer~~ 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 ~~state~~ site survey team shall be as follows:

(1) one ~~out-of-state~~ trauma surgeon who is a Fellow of the ACS, experienced as a site surveyor, who shall be the primary reviewer;

(2) one ~~in-state~~ 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 ~~in-state~~ trauma ~~surgeon who is a member of the North Carolina Committee on Trauma;~~ surgeon;

(4) ~~for Level I designation, one out-of-state~~ one trauma program ~~manager with an equivalent license from another state;~~ manager; and

~~(5) for Level II designation, one in-state program manager who is licensed to practice nursing in North Carolina in accordance with the Nursing Practice Act, Article 9A, Chapter 90 of the North Carolina General Statutes; and~~

~~(6)~~(5) OEMS Staff.

(l) All site team members for a Level III ~~visit shall be from in-state, and,~~ 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, who is a member of the North Carolina Committee on Trauma~~ ACS and shall be the primary reviewer;

(2) one emergency physician who currently works in a designated trauma ~~center, is a member of the North Carolina College of Emergency Physicians or American Academy of Emergency Medicine,~~ 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 who is licensed to practice nursing in North Carolina in accordance with the Nursing Practice Act, Article 9A, Chapter 90 of the North Carolina General Statutes;~~ manager; and

(4) OEMS Staff.

(m) ~~On the day of the site visit, the~~ 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 is proposed for amendment as follows:

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(k)~~ 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(l)~~ 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 ~~out-of-state~~ trauma surgeon who is a Fellow of the ACS, experienced as a site surveyor, who shall be the primary reviewer;

(B) one ~~out-of-state~~ 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 ~~out-of-state~~ trauma program ~~manager with an equivalent license from another state;~~ 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 .1505 is proposed for amendment as follows:

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 for any of the following reasons:~~ 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 .1507 is proposed for amendment as follows:

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, student, ~~bystander,~~ EMS personnel, other allied healthcare personnel, student, educational institution staff, members of the public, or OEMS staff, either physically, verbally, or in writing;

(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; ~~or~~

(32) filing a knowingly false complaint against an individual, EMS Agency, or educational ~~institution.~~ 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.~~ 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.

Emergency Medical Services and Trauma Rules Amendments - Public Comments

10A NCAC 13P .0101, .0102, .0201, .0207, .0216 - .0218, .0221, .0224, .0301, .0401 - .0404, .0407, .0410, .0502, .0503, .0512, .0601, .0602, .0904, .0905, .1505, and .1507

Comment Period 9/15/23 – 11/14/23

Introduction:

4 individuals submitted comments during the public comment period on the amendment of rules 10A NCAC 13P .0101, .0102, .0201, .0207, .0216 - .0218, .0221, .0224, .0301, .0401 - .0404, .0407, .0410, .0502, .0503, .0512, .0601, .0602, .0904, .0905, .1505, and .1507. Of these comments, none were statements made during the public hearing conducted on November 8, 2023. The comments were submitted by representatives from the following: Surry Community College and Education Staff of North Carolina Office of EMS, and Atrium Health.

1) Listing of Comments Received and Agency's Consideration of Comments for Amendment Rules 10A NCAC 13P .0101, .0102, .0201, .0207, .0216 - .0218, .0221, .0224, .0301, .0401 - .0404, .0407, .0410, .0502, .0503, .0512, .0601, .0602, .0904, .0905, .1505, and .1507:

Commenter	Comment Summary
1) Surry Community College	The proposal creates issues for border state students such as out of NC students having to pay to 2 exam fees instead of the national registry credential being enough, non-NC residents might decide to work in NC after the 90 days allowed by the rule, and non-NC residents who want to work in NC but decide to do so after the 6 months for 3 attempts required in (a)(4). Recommendations: - Add verbiage that provides a time limit on rule (5) allowing a year delay: "Individuals applying to OEMS for legal recognition, who completed initial educational courses through an OEMS approved North Carolina educational institution within the past year." - Work the rule so it is not applicable to non-NC residents who have made no attempts at the NC state exam and are seeking to work for a NC agency or facility. - Require all those seeking reciprocity must take the NC state exam.
2) Education Staff of the North Carolina Office of EMS	The Education Staff of the North Carolina Office of EMS would like to request the following change in .0502, .0601 and .0602. Under the stated rules, program coordinator should be changed to reflect program director. While the North Carolina Office of EMS uses program coordinator and program director interchangeably, the Committee on Accreditation of Educational Programs for Emergency Medical Services Professions (CoAEMSP) and the Committee on Accreditation of Allied Health and Emergency Personnel (CAAHEP) utilize program director. We feel this requested change will provide consistency in titles, while alleviating confusion for our EMS program directors and EMS institutions.
3) Education Staff of the North Carolina Office of EMS	After further review and internal comments from OEMS staff the following technical changes are recommend: .0101 Delete (26) SMARTT, the same was deleted from the .0102 Definitions selection since it is outdated. .0410 Add "inspections" after Subchapter, in line 13 of (d)(2) to clarify. .0503 Add "EMT," which was inadvertently left out. .1507 "Student" is listed twice in (b)(22), remove one.

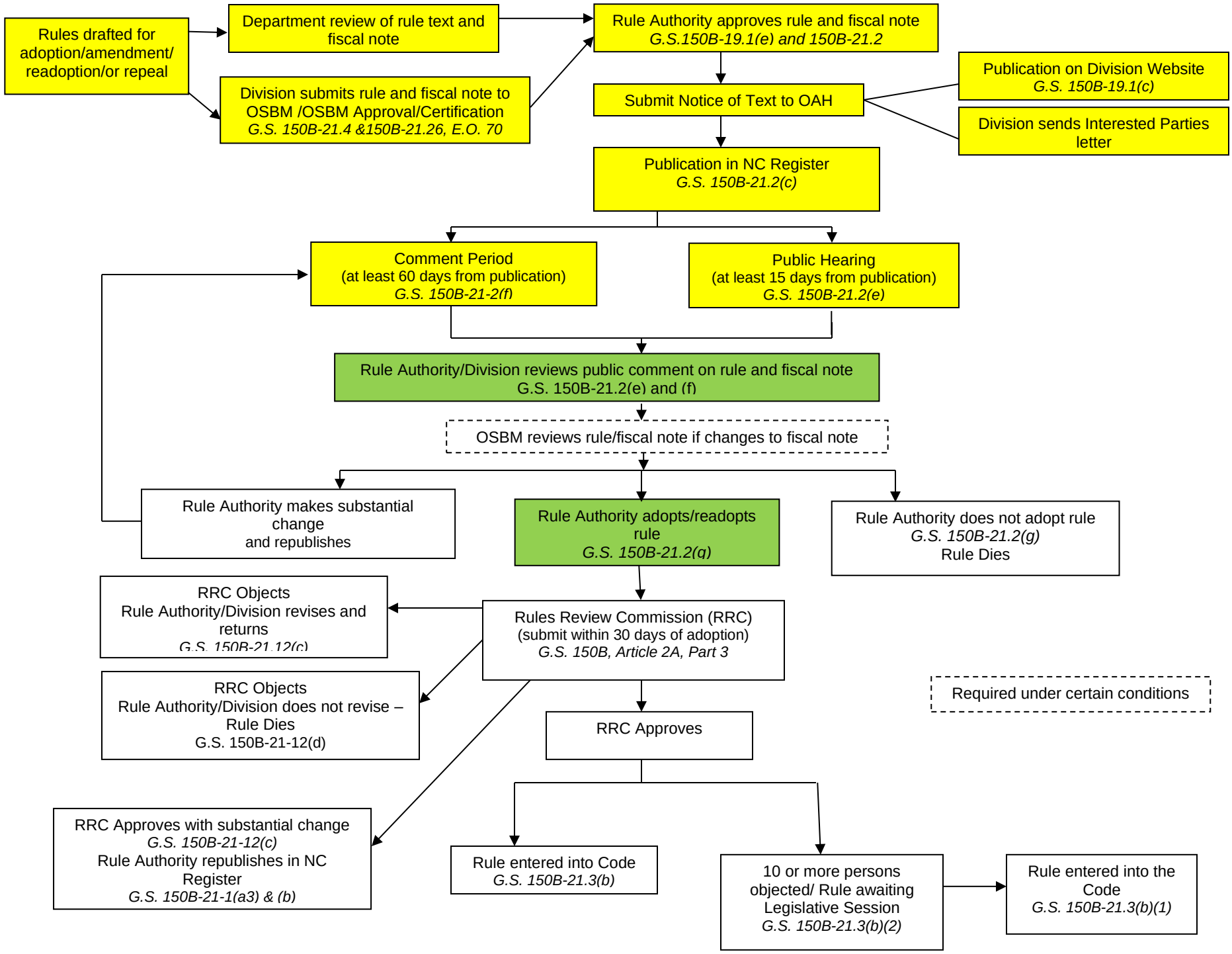
Commenter	Comment Summary
4) Atrium Health	Ambulance Manufacturing Standards: - Concerns regarding an increase in remount costs caused by the rules. - Recommendation: allowing EMS agencies one remount before requiring CAAS standards. Electronic Patient Care Data Submission: - The 24 hour standard is challenging for record completion over weekends/holidays, as well as for more complex/involved patients. - Recommendation: increase exception rate to 10% or allow for exceptions for quality reviews prior to locking charts.

Agency Response to Comments Above:

Commenter	Agency Response	Action Taken? (Y/N)
1) Surry CC	The addition of (a)(5) to Rule .0502 created confusion with the process of initial NC credentialing and reciprocity. To clarify OEMS moved the proposed language to paragraph (b) of the Rule.	Y
2) OEMS Ed Staff	Accept recommendation to change language in .0502, .0601, and .0602 to "program director."	Y
3) OEMS Staff	Accept technical changes to .0101, .0410, .0503, and .1507.	Y
4) Atrium Health	.0224(b)(1) already included language to include "all subsequent amendments and editions" for CAAS requirements. This change was to clarify and establish a timeframe for agencies who have a contract and plan for a compliance date of July 1, 2025 (c)(3). Data submission requirements are detailed in .0204 EMS PROVIDER LICENSE REQUIREMENTS. The proposed change to .0410 was to remove outdated language/system and clarify requirements already defined in .0204. Air Medical Program must be a Licensed Provider. The expectation is submission within 24 hours, OEMS does understand there will be exceptions.	N

Process for Medical Care Commission to Adopt/Readopt Rule

Exhibit D



10A NCAC 13L .0301 is amended as published in 38:06 NCR 306-308 as follows:

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~~ 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.~~ 2015;
Amended Eff. April 1, 2024.

10A NCAC 13L .0302 is amended as published in 38:06 NCR 306-308 as follows:

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 ~~a current~~ an unexpired license verification to practice nursing as a registered nurse or a licensed practical nurse or ~~a current~~ an unexpired Nurse Aide I or Nurse Aide II ~~Listing Card issued by the North Carolina Board of Nursing.~~ listing verification.

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

(3) Results of reference checks.

(4) Performance evaluations ~~at least~~ 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.~~ 2015;
Amended Eff. April 1, 2024.

Fiscal Impact Analysis of Permanent Rule Amendment without Substantial Economic Impact

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Agency:	North Carolina Medical Care Commission Division of Health Service Regulation Acute Care Licensure and Certification Section	
Rule Citation(s):	10A NCAC 13L .0301 Written Policies and Procedures 10A NCAC 13L .0302 Personnel Records (see rule text in Appendix A)	
Agency Contact:	Nadine Pfeiffer, DHSR Rules Review Manager – 919-855-3811 Azzie Conley, Section Chief, Acute and Home Care Licensure & Certification – 919-855-4646 Greta Hill, Assistant Section Chief, Acute and Home Care Licensure & Certification – 919-855-4635	
Rulemaking Authority:	G.S. 131E-154.4	
Impact Summary:	State Government:	No Impact
	Local Government:	No Impact
	Private Entities:	Yes
	Substantial Impact:	No Impact

Introduction and Purpose

In response to a Petition for Rulemaking regarding North Carolina Nursing Pool agencies and pursuant to N.C. General Statute150B-20(c), N.C. General Statute section 131E-154.1 to 154.8 the Department of Health and Human Services proposes to amend existing rules set forth at 10A NCAC 13L Rules Governing the Licensure of Nursing Pools.

This fiscal analysis addresses two rules proposed for amendment. The rule amendments require a retention period for records and require a policy for annually assessing the performance of nursing personnel assigned to health care facilities. In addition, technical and formatting revisions have been made and rule language has been amended to be consistent with updated terminology.

Currently, there are 436 Nursing Pool agencies that are licensed to provide nursing personnel to North Carolina facilities. A Nursing Pool is any person, firm, corporation, partnership, or association engaged for hire in the business of providing or procuring temporary employment for nursing personnel in health care facilities. It should be noted that many of these Nursing Pool agencies are headquartered outside of North Carolina but provide personnel to North Carolina healthcare facilities. All of these agencies are privately owned. Nursing personnel includes nurses, nursing assistants, nurse aides, and orderlies. Nursing personnel shortages exacerbated during the COVID-19 pandemic resulted in health care facilities relying on Nursing Pools to provide staff for the care of patients and residents. The increase in the use of nursing pools resulted in a rise in the percentage of nursing care being provided by nursing personnel from nursing pools and caused health care facilities to prioritize improvements to regulation of Nursing

Pool agencies. There are numerous states currently engaged in the process of enhancing regulation of nursing pool agencies including Connecticut, Iowa, Illinois, Louisiana, Oregon, Ohio, and Pennsylvania.

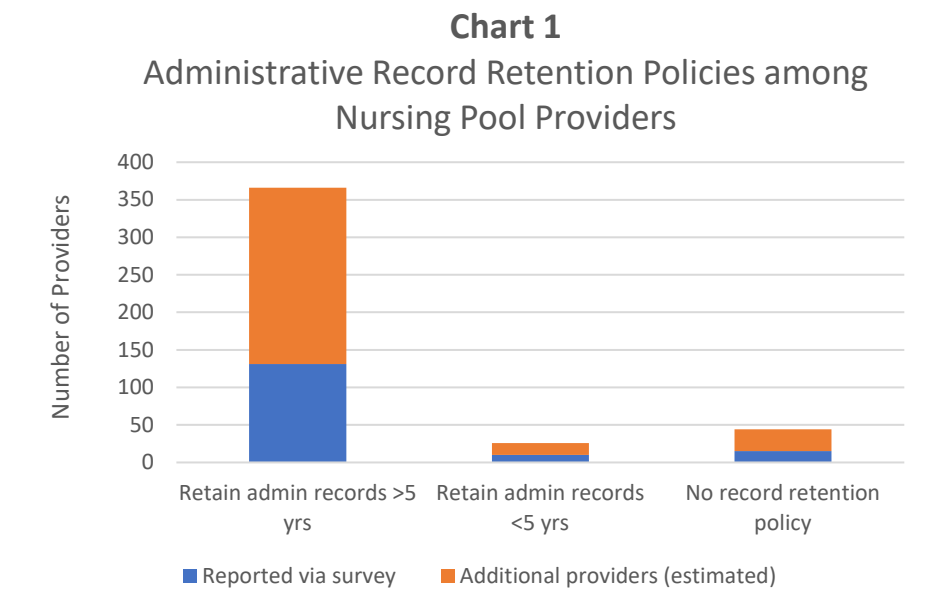
Description of Proposed Rules and Anticipated Fiscal Impact

Rule 10A NCAC 13L .0301- Written Policies and Procedures

The agency is proposing to amend this rule with substantive changes. This rule establishes the criteria for written policies and procedures. The agency is amending the rule to require the nursing pool to retain administrative records for a period of five years. The change will list the type of administrative documents the nursing pool must keep and how long they must keep them.

In September 2022, DHSR surveyed 436 Nursing Pool providers to inquire about their retention period policy for administrative documents. 156 Nursing Pool providers responded to the survey (about 36% of total providers). Of those, 141 (about 90% of respondents) reported they already have an established retention period for administrative documents that is written in the contract, policies and procedures, or both.

The vast majority of providers with an existing retention policy reported having a retention period of five to ten years. Only 10 providers (about 6% of survey respondents) reported having a retention period of less than the proposed five years. 15 providers (about 10% of survey respondents) reported that they did not have any established retention period. In the absence of survey responses from all 436 Nursing Pool providers, we assumed that the relative proportions of responding providers with and without retention policies was representative of the total population of providers. Using this assumption, we estimated that about 366 of the 436 licensed NC providers will already be compliant with the proposed retention requirement, 26 will need to increase their existing requirement to meet or exceed five years, and 44 will need to adopt a new retention policy.



A review of other states' regulations for nursing pools revealed no retention period requirement at all (as of September 2022).

For the majority of Nursing Pool providers licensed in North Carolina, adding the proposed requirement for a five-year retention period should have no additional impact on their existing record keeping practice. For the relatively small proportion of Nursing Pool providers that currently have either no retention period or a retention period of less than five years, they will be required to revise their policies and procedures to comply. There should be no fiscal impact to these providers other than a minimal one-time expenditure of time to revise their contract and policies/ procedures documentation and establish an internal process for keeping these records.

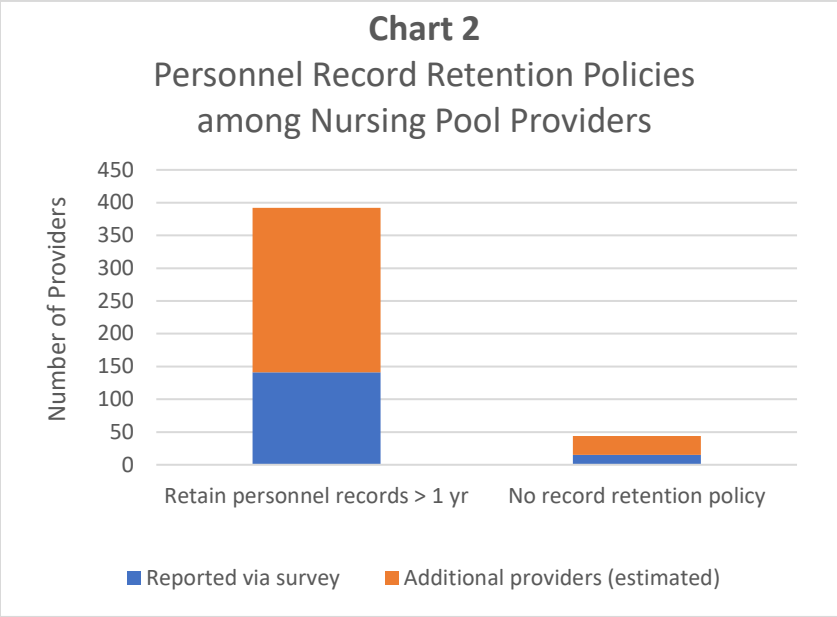
Rule 10A NCAC 13L .0302 - Personnel Records

The agency is proposing to amend this rule with substantive changes. This rule establishes the criteria for Nursing Pool personnel records and the content of personnel records. The current rule requires a completed job application and an annual performance evaluation for each individual employee. The agency is updating the rule to clarify the identification data to be included on the job application. This change will ensure the nursing pool gathers consistent data on all applicants. This change will not result in any impacts to Nursing Pool providers as this is already standard practice.

In addition, the agency is proposing a new requirement that will make it mandatory that the annual performance evaluation include feedback from the health care facility for assigned nursing personnel. This change should enable the Nursing Pool providers to better assess the satisfaction of the health care facility with each assigned nursing personnel's services, and competencies. Nursing Pool nursing personnel are evaluated after every assignment in the general areas of adaptability, communication, dependability, punctuality, documentation, overall clinical skills and job performance. Nursing Pool agencies obtain feedback from Clinical Site Managers via various methods such as periodic phone calls, emails, site visits, and customer surveys. The method used to collect feedback is determined by agency policy. Adding this requirement would improve the quality of nursing care, improve patient/customer experience, and help Nursing Pools address issues as they arise and prevent future issues that could lead to poor and unsafe care for patients.

Lastly, the agency is amending the rule to require the nursing pool to retain personnel records for a period of one year after termination. The change will establish a minimum for how long the nursing pool must keep employee files after termination. The U.S Equal Employment Opportunity Commission (EEOC) requires employers to retain personnel records for one year from the date of termination. Guidelines may vary from state to state but they complement and mirror federal requirements.

According to the 2022 survey by DHSR, about 90% of the Nursing Pool providers who responded indicated they already have a policy to retain personnel records for at least one year. Providers reported personnel record retention periods that varied from one to seven years. About 10% of survey respondents reported having no personnel record retention policy. A review by DHSR of other states' regulations for nursing pools reveals no retention period requirements for personnel records at all.



For the majority of Nursing Pool providers licensed in North Carolina, adding the proposed requirement for a one-year retention period for personnel records should have no additional impact on their existing record keeping practice. For the relatively small proportion of Nursing Pool providers that currently have no retention period for personnel records, they will be required to revise their policies and procedures to comply. There should be no fiscal impact to these providers other than a minimal one-time expenditure of time to revise their contracts and policies/procedures documentation and establish an internal process for keeping these records. The exact cost will vary and depends on the method the Nursing Pool agency chooses to retain files (manual/digital). We can assume the cost of retaining a paper document is more than a digital document.

Summary

The proposed amendments should result in minimal costs to a small number of currently licensed Nursing Pool providers in the form of time spent revising policies and procedures and implementing new internal record retention processes. Ultimately, the goal of the proposed changes is to benefit the patient community by promoting consistency in regulation among Nursing Pool providers and strengthening the existing evaluation processes for nursing personnel employed by these providers. These small, but meaningful, improvements will help to assure quality care, improve patient safety, and provide accountability for Nursing Pool agencies.

Appendix A

10A NCAC 13L .0301 is proposed for amendment as follows:

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~~ 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.~~ 2015;
Amended Eff. April 1, 2024.

10A NCAC 13L .0302 is proposed for amendment as follows:

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 ~~a current~~ an unexpired license verification to practice nursing as a registered nurse or a licensed practical nurse or ~~a current~~ an unexpired Nurse Aide I or Nurse Aide II ~~Listing Card issued by the North Carolina Board of Nursing.~~ listing verification.

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

(3) Results of reference checks.

(4) Performance evaluations ~~at least~~ 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.~~ 2015;
Amended Eff. April 1, 2024.

Exhibit D-3

Nursing Pool Licensure Amendments
10A NCAC 13L .0201, .0301, .0302 – Public Comments
Comment Period 9/15/23 – 11/14/23

Introduction:

1 individual submitted comments during the public comment period on the amendment of rules 10A NCAC 13L .0201, .0301, .0302. Of these comments, 1 person made a statement during the public hearing conducted on November 9, 2023. The comment was submitted by a representative from the North Carolina Health Care Facilities Association (NCHCFA).

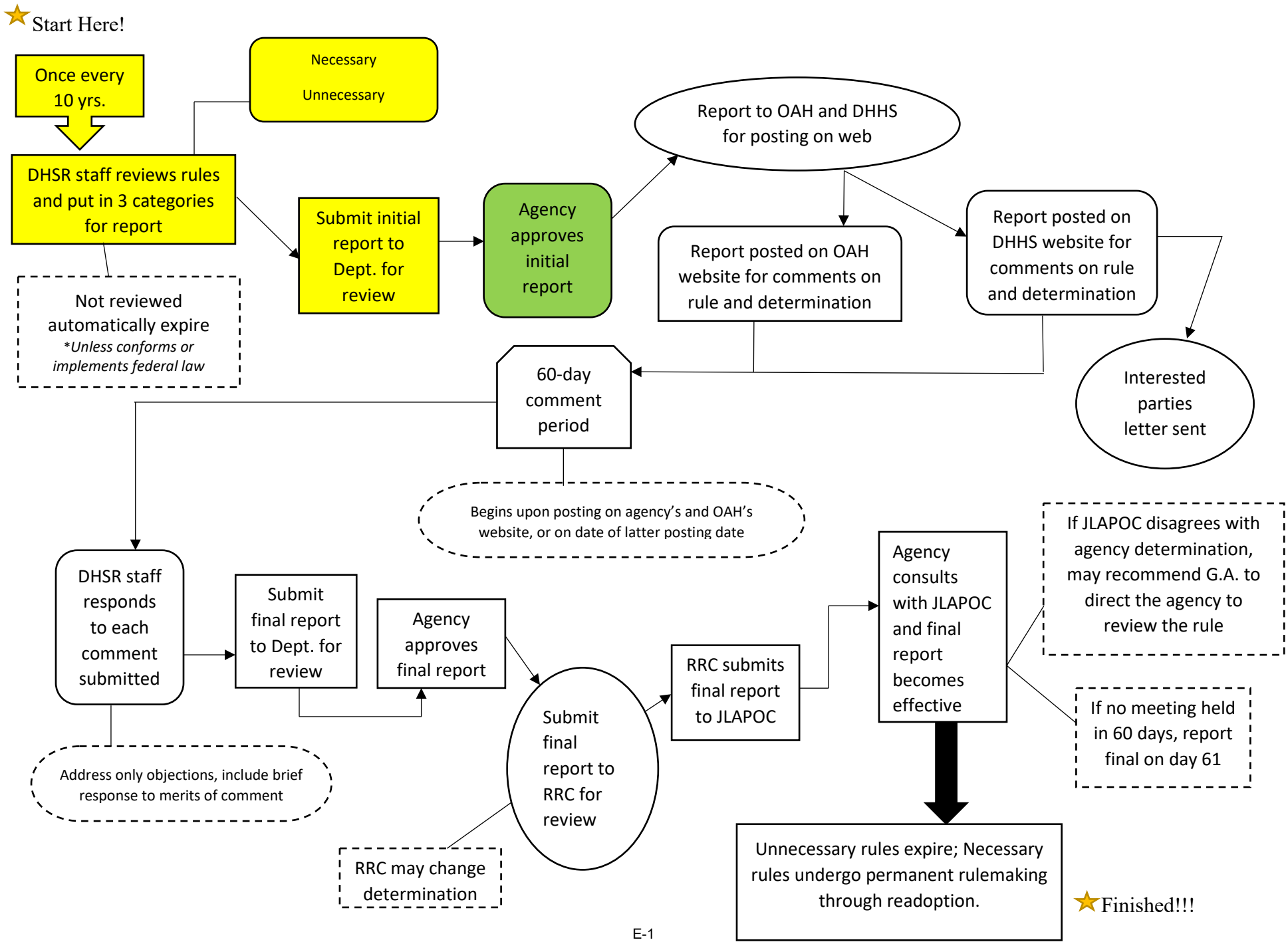
1) Listing of Comments Received and Agency's Consideration of Comments for Amendment Rule 13L .0201 – Application for License:

Commenter	Comment Summary
1) NCHCFA	The Comment was in support of the proposed rules. The NCHCFA reiterated their original petition asking for many other changes to the rules governing the licensure and operation of Nursing Pools. There were no formal recommendations.

Agency Response to Comments Above:
The Agency thanks you for your support of these rules.

Exhibit E

Periodic Rules Review Process for DHSR



CHAPTER 13 – NC MEDICAL CARE COMMISSION

SUBCHAPTER 13A – EXECUTIVE COMMITTEE

SECTION .0100 – EXECUTIVE COMMITTEE

10A NCAC 13A .0101 EXECUTIVE COMMITTEE

(a) There shall be an executive committee of the North Carolina Medical Care Commission composed of five members of the commission in addition to the chairman and vice-chairman of the commission. Three members shall be appointed by a vote of the commission at the December meeting of each odd year and two members shall be appointed by the chairman of the commission at the December meeting of each even year. No member of the executive committee, except the chairman and vice-chairman, shall serve more than two two-year terms in succession. The chairman and vice-chairman of the commission shall also be chairman and vice-chairman of the executive committee.

(b) The functions of the executive committee shall be to:

(1) transact business in behalf of the commission, consistent with established policy, which in the opinion of the chairman is of such urgency that action is required before the next regularly scheduled commission meeting and the impact of the action would not justify the convening of a special meeting of the commission;

(2) transact business in behalf of the commission when a quorum is not obtained at any commission meeting for which prior notice of at least ten days has been given;

(3) review periodically the activities of the commission and the assignments and recommendations of the various committees for the purpose of developing policy recommendations for commission consideration.

(c) All actions of the executive committee shall be reviewed at the next commission meeting and if disagreement is expressed by a simple majority of the members present and voting at any commission meeting in which a quorum is present, the functions of the executive committee shall be suspended until resolved by later action of the commission.

(d) The initial approval of all projects under the Health Care Facilities Finance Act must be given by a quorum of the full commission.

(e) A quorum of the executive committee shall consist of at least four members of the executive committee.

History Note: *Authority G.S. 131A-4; 143B-165; 143B-166;*
Eff. January 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015.

SECTION .0200 - RULEMAKING

10A NCAC 13A .0201 PETITIONS

(a) Any person wishing to submit a petition requesting the adoption, amendment, or repeal of a rule or rules by the North Carolina Medical Care Commission shall submit the petition addressed to: Office of the Director, Division of Health Service Regulation, 2701 Mail Service Center, Raleigh, North Carolina, 27699-2701.

(b) The petition shall contain the following information:

(1) the text of the proposed rule or rules for adoption or amendment, the rule number of the proposed rule or rules for repeal, and the statutory authority for the agency to promulgate the rule or rules;

(2) a statement of the effect on existing rules;

(3) a statement of the effect of the proposed rule or rules on existing practices in the area involved, if known; and

(4) the name(s) and address(es) of 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 or rules, amendment or the repeal of an existing rule or rules;

(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 individuals or entities most likely to be affected by the proposed rule or rules.

(d) The North Carolina Medical Care Commission, based on a review of the facts stated in the petition, shall consider the following in the determination to grant the petition:

(1) whether the North Carolina Medical Care Commission has authority to adopt the rule or rules;
(2) the effect of the proposed rule(s) on existing rules, programs, and practices;
(3) probable costs and cost factors of the proposed rule or rules;
(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 Chairman of the North Carolina Medical Care Commission.

History Note: *Authority G.S. 143B-165; 150B-20;*
Eff. February 1, 1976;
Readopted Eff. December 19, 1977;
Amended Eff. November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015;
Amended Eff. October 1, 2023.

10A NCAC 13A .0202 RULEMAKING PROCEDURES

(a) The rulemaking procedures for the Secretary of the Department of Health and Human Services codified in 10A NCAC 01 are hereby adopted by reference pursuant to G.S. 150B-14(c) to apply to the actions of the Commission, with the following modifications:

(1) Correspondence related to the Commission's rulemaking actions shall be submitted to:

APA/Rule-making Coordinator
Office of the Director
Division of Health Service Regulation
2701 Mail Service Center
Raleigh, North Carolina 27699-2701

(2) The Secretary's designee shall mean the Director of the Division of Health Service Regulation (hereinafter referred to as the Division).
(3) The "Division" shall be substituted for the "Office of General Counsel" in 10A NCAC 01.
(4) "Hearing officer" shall mean the Chairman of the Medical Care Commission or his designee.

(b) Copies of 10A NCAC 01 may be inspected in the Division at the address shown in (a)(1) of this Rule. Copies may be obtained from the Office of Administrative Hearings, 424 North Blount Street, Raleigh, North Carolina, 27601.

History Note: *Authority G.S. 143B-165; 150B-11; 150B-14;*
Eff. November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015.

10A NCAC 13A .0203 DECLARATORY RULINGS

(a) The Commission shall have the power to make declaratory rulings. All requests for declaratory rulings shall be written and submitted to: Chairman, Medical Care Commission, 2701 Mail Service Center, Raleigh, North Carolina, 27699-2701.

(b) All requests for a declaratory ruling must include the following information:

(1) name and address of the petitioner;
(2) statute or rule to which petition relates;
(3) concise statement of the manner in which petitioner is aggrieved by the rule or statute or its potential application to him;
(4) the consequences of a failure to issue a declaratory ruling.

(c) Whenever the Commission believes for good cause that the issuance of a declaratory ruling will not serve the public interest, it may refuse to issue one. When good cause is deemed to exist, the Commission will notify the petitioner of the decision in writing stating reasons for the denial of a declaratory ruling.
(d) The Commission may refuse to consider the validity of a rule and therefore refuse to issue a declaratory ruling:

(1) unless the petitioner shows that the circumstances are so changed since adoption of the rule that such a ruling would be warranted;
(2) unless the rulemaking record evidences a failure by the agency to consider specified relevant factors;
(3) if there has been similar controlling factual determination in a contested case, or if the factual context being raised for a declaratory ruling was specifically considered upon adoption of the rule being questioned as evidence by the rulemaking record;
(4) if circumstances stated in the request or otherwise known to the agency show that a contested case hearing would presently be appropriate.

(e) Where a declaratory ruling is deemed to be in the public interest, the Commission will issue the ruling within 60 days of receipt of the petition.
(f) A declaratory ruling procedure may consist of written submissions, oral hearings, or such other procedure as may be appropriate in a particular case.
(g) The Commission 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.
(h) A record of all declaratory ruling procedures will be maintained for as long as the ruling has validity. This record will contain:

(1) the original request,
(2) reasons for refusing to issue a ruling,
(3) all written memoranda and information submitted,
(4) any written minutes or audio tape or other record of the oral hearing, and
(5) a statement of the ruling.

This record will be maintained in a file at the Director's office at Division of Health Service Regulation, 2701 Mail Service Center, Raleigh, North Carolina, 27699-2701 and will be available for public inspection during regular office hours.

History Note: *Authority G.S. 143B-165; 150B-4;*
Eff. November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015.

G.S. 150B-21.3A Report for 10A NCAC 13A, EXECUTIVE COMMITTEE

Agency - Medical Care Commission

Comment Period -

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]
SUBCHAPTER 13A – EXECUTIVE COMMITTEE	**SECTION .0100 – EXECUTIVE COMMITTEE**	10A NCAC 13A .0101	EXECUTIVE COMMITTEE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015	Necessary	No
	SECTION .0200 - RULEMAKING	10A NCAC 13A .0201	PETITIONS	Amended Eff. October 1, 2023	Necessary	No
		10A NCAC 13A .0202	RULEMAKING PROCEDURES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015	Necessary	No
		10A NCAC 13A .0203	DECLARATORY RULINGS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015	Necessary	No

10A NCAC 13S .0101 is proposed for adoption under temporary procedures as follows:

SUBCHAPTER 13S - LICENSURE OF SUITABLE FACILITIES FOR THE PERFORMANCE OF SURGICAL ABORTIONS

SECTION .0100 – LICENSURE PROCEDURE

10A NCAC 13S .0101 DEFINITIONS

The following definitions will apply throughout this Subchapter:

(1) "Abortion" means the termination of a pregnancy as defined in G.S 90-21.81(1c).

(2) "Clinic" means a freestanding facility neither physically attached nor operated by a licensed hospital for the performance of abortions completed during the first 12 weeks of pregnancy.

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

(4) "Gestational age" means the length of pregnancy as indicated by the date of the first day of the last normal monthly menstrual period, if known, or as determined by ultrasound.

(5) "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 abortion clinic is vested pursuant to Rule .0318 of this Subchapter.

(6) "Health Screening" means an evaluation of an employee or contractual employee, including tuberculosis testing, to identify any underlying conditions that may affect the person's ability to work in the clinic.

(7) "New clinic" means one that is not certified as an abortion clinic by the Division as of July 1, 2023, and has not been certified or licensed within the previous six months of the application for licensure.

(8) "Registered Nurse" means a person who holds a valid license issued by the North Carolina Board of Nursing to practice professional nursing in accordance with the Nursing Practice Act, G.S. 90, Article 9A.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0104 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0104 PLANS

Prior to issuance of a license pursuant to Rule .0107 of this Section, an applicant for a new clinic shall submit two copies of the building plans to the Division. When the clinic requires a review by the Division and the Department of Insurance, according to the North Carolina State Building Code, 2018 edition, including subsequent amendments and editions. Copies of the Code are available from the International Code Council at https://codes.iccsafe.org/content/NCAPC2018/chapter-1-administrative-code at no cost. When the local jurisdiction has authority from the North Carolina Building Code Council to review the plans, the clinic shall submit only one copy of the plans to the Division. In that case, the clinic shall submit an additional set of plans directly to the local jurisdiction.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0111 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0111 INSPECTIONS

(a) Any clinic licensed by the Division to perform abortions shall be inspected by representatives of the Division annually and as it may deem necessary as a condition of holding such license. An inspection may be conducted whenever the Division receives a complaint alleging the clinic is not in compliance with the rules of the Subchapter.

(b) Representatives of the Division shall make their identities known to the clinic staff prior to inspection of the clinic.

(c) Representatives of the Division may review any records in any medium necessary to determine compliance with the rules of this Subchapter. The Department shall maintain the confidentiality of the complainant and the patient, unless otherwise required by law.

(d) The clinic shall allow the Division to have immediate access to its premises and the records necessary to conduct an inspection and determine compliance with the rules of this Subchapter.

(e) A clinic shall file a written plan of correction for cited deficiencies within 10 business days of receipt of the report of the survey. The Division shall review and respond to a written plan of correction within 10 business days of receipt of the corrective action plan.

History Note: Authority G.S. 131E-153; 131E-153.2; 131E-153.5; 131E-153.6; 143B-165.

10A NCAC 13S .0112 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0112 ALTERATIONS

Any license holder or prospective applicant desiring to make alterations or additions to a clinic or to construct a new clinic, before commencing such alteration, addition or new construction shall submit plans and specifications to the Division for preliminary inspection and approval or recommendations with respect to compliance with this Subchapter.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0114 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0114 APPROVAL

(a) Approval of building plans shall be obtained from the Division of Health Service Regulation, in accordance with the rules in Section .0200 of this Subchapter.

(b) Approval of building plans 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 building plans.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0201 is proposed for adoption under temporary procedures as follows:

SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT

10A NCAC 13S .0201 BUILDING CODE REQUIREMENTS

(a) The physical plant for a clinic shall meet or exceed minimum requirements of the North Carolina State Building Code for Group B occupancy (business office facilities) which is incorporated herein by reference including subsequent amendments and editions. Copies of the Code can be obtained from the International Code Council online at http://shop.iccsafe.org/north-carolina-doi.discounts?ref=NC for a cost of five hundred twenty-seven dollars ($527.00) or accessed electronically free of charge at https://codes.iccsafe.org/content/NCAPC2018/chapter-1-administrative-code.

(b) The requirements contained in this Section shall apply to new clinics and to any alterations, repairs, rehabilitation work, or additions which are made to a previously licensed facility.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0202 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0202 SANITATION

Clinics that are licensed by the Division to perform abortions shall comply with the Rules governing the sanitation of hospitals, nursing homes, adult care homes, and other institutions, contained in 15A NCAC 18A .1300 which is hereby incorporated by reference including subsequent amendments and editions. Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Division of Public Health, Environmental Health Section, 1632 Mail Service Center, Raleigh, NC 27699-1632, or accessed electronically free of charge from the Office of Administrative Hearings at https://reports.oah.state.nc.us/ncac.asp.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0207 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0207 AREA REQUIREMENTS

The following areas shall comply with Rule .0212 of this Section, and are considered minimum requirements for clinics that are licensed by the Division to perform abortions:

(1) receiving area;
(2) examining room;
(3) preoperative preparation and holding room;
(4) individual patient locker facilities or equivalent;
(5) procedure room;
(6) recovery room;
(7) clean workroom;
(8) soiled workroom;
(9) a clean area for self-contained secure medication storage complying with security requirements of state and federal laws is provided;
(10) separate and distinct areas for storage and handling of clean and soiled linen;
(11) patient toilet;
(12) personnel lockers and toilet facilities;
(13) laboratory;
(14) nourishment station with storage and preparation area for serving meals or in-between meal snacks;
(15) janitor's closets;
(16) adequate space and equipment for assembling, sterilizing and storing medical and surgical supplies;
(17) storage space for medical records; and
(18) office space for nurses' charting, doctors' charting, communications, counseling, and business functions.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0209 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0209 ELEVATOR

(a) In multi-story buildings, the clinic shall provide at least one elevator for patient use.

(b) At least one dimension of the elevator cab shall be six and one-half feet to accommodate stretcher patients.

(c) The elevator door shall have an opening of no less than three feet in width, which is minimum for stretcher use.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0210 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0210 CORRIDORS

The width of patient use corridors shall be no less than 60 inches.

History Note: Authority 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0211 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0211 DOORS

Minimum width of doors to all rooms needing access for stretchers shall be three feet. No door shall swing into corridors in a manner that might obstruct traffic flow or reduce the required corridor width except doors to spaces not subject to occupancy.

History Note: Authority 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0212 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0212 ELEMENTS AND EQUIPMENT

The physical plant shall provide equipment to carry out the functions of the clinic with the following minimum requirements:

(1) Mechanical requirements.

(a) Temperatures and humidities:

(i) The mechanical systems shall be designed to provide the temperature and humidities shown in this Sub-Item:

Area	Temperature	Relative Humidity
Procedure	70-76 degrees F.	50-60%
Recovery	75-80 degrees F.	30-60%

(b) All air supply and exhaust systems for the procedure suite and recovery area shall be mechanically operated. All fans serving exhaust systems shall be located at the discharge end of the system. The ventilation rates shown herein shall be considered as minimum acceptable rates.

(i) The ventilation system shall be designed and balanced to provide the pressure relationships detailed in Sub-Item (b)(vii) of this Rule.

(ii) All air supplied to procedure rooms shall be delivered at or near the ceiling of the room and all exhaust or return from the area shall be removed near the floor level at not less than three inches above the floor.

(iii) Corridors shall not be used to supply air to or exhaust air from any procedure or recovery room except to maintain required pressure relationships.

(iv) All ventilation or air conditioning systems serving procedure rooms shall have a minimum of one filter bed with a minimum filter efficiency of 80 percent.

(v) Ventilation systems serving the procedure or recovery rooms shall not be tied in with the soiled holding or work rooms, janitors' closets, or locker rooms if the air is to be recirculated in any manner.

(vi) Air handling duct systems shall not have duct linings.

(vii) The following general air pressure relationships to adjacent areas and ventilation rates shall apply:

Area	Pressure Relationship	Minimum Air Changes/Hour
Procedure	P	6
Recovery	P	6
Soiled work, Janitor's closet,		

Toilets,		
Soiled holding	N	10
Clean work or		
Clean holding	P	4

(P = positive pressure N = negative pressure)

(2) Plumbing And Other Piping Systems.

(a) Medical Gas and Vacuum Systems

(i) Piped-in medical gas and vacuum systems, if installed, shall meet the requirements of NFPA-99-2012, category 1 system, which is hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA-99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, or accessed electronically free of charge at http://www.nfpa.org.

(ii) The facility must meet the inhalation anesthesia requirements of NFPA 70-2020 and NFPA 99-2021, which are hereby incorporated by reference including subsequent amendments and editions. Copies of NFPA 70-2011 and NFPA 99-2012 may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, or accessed electronically free of charge at http://www.nfpa.org.

(b) Lavatories and sinks for use by medical personnel shall have the water supply spout mounted so that its discharge point is a minimum distance of five inches above the rim of the fixture with mixing type fixture valves that can be operated without the use of the hands.

(c) Hot water distribution systems shall provide hot water at hand washing and bathing facilities at a minimum temperature of 100 degrees F. and a maximum temperature of 116 degrees F.

(d) Floor drains shall not be installed in procedure rooms.

(e) Building drainage and waste systems shall be designed to avoid installations in the ceiling directly above procedure rooms.

(3) Electrical Requirements.

(a) Procedure and recovery rooms, and paths of egress from these rooms to the outside shall have at a minimum, listed battery backup lighting units of one and one-half hour capability that will automatically provide at least five foot candles of illumination at the floor in the event needed for a utility or local lighting circuit failure.

(b) Electrically operated medical equipment necessary for the safety of the patient shall have, at a minimum, battery backup.

(c) Receptacles located within six feet of sinks or lavatories shall be ground-fault protected.

(d) At least one wired-in, ionization-type smoke detector shall be within 15 feet of each procedure or recovery room entrance.

(4) Buildings systems and medical equipment shall have preventative maintenance conducted as recommended by the equipment manufacturers' or installers' literature to assure operation in compliance with manufacturer's instructions.

History Note: *Authority G.S. 131E-153; 131E-153.5; 143B-165.*

10A NCAC 13S .0315 is proposed for adoption under temporary procedures as follows:

SECTION .0300 – SERVICES

10A NCAC 13S .0315 HOUSEKEEPING

In addition to the standards set forth in Rule .0202 of this Subchapter, clinics that are licensed by the Division to perform abortions shall meet the following standards:

(1) the floors, walls, woodwork, and windows must be cleaned at least daily;

(2) the premises must be kept free from rodents and insect infestation;

(3) bath and toilet facilities must be maintained in a clean and sanitary condition consistent with 15A NCAC 18A .1312; and

(4) linen that comes directly in contact with the patient shall be provided for each individual patient. No such linen shall be interchangeable from one patient to another before being cleaned, sterilized, or laundered.

Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Division of Public Health, Environmental Health Section, 1632 Mail Service Center, Raleigh, NC, 27699-1632, or accessed electronically free of charge from the Office of Administrative Hearings at https://www.oah.nc.gov/.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0318 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0318 GOVERNING AUTHORITY

(a) The governing authority, as defined in Rule .0101(6) of this Subchapter, shall appoint a chief executive officer or a designee of the clinic to represent the governing authority and shall define his or her authority and duties in writing. This person shall be responsible for the management of the clinic, implementation of the policies of the governing authority and authorized and empowered to carry out the provisions of these Rules.

(b) The chief executive officer or designee shall designate, in writing, a person to act on his or her behalf during his or her absence. In the absence of the chief executive officer or designee, the person on the grounds of the clinic who is designated by the chief executive officer or designee to be in charge of the clinic shall have access to all areas in the clinic 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 clinic shall notify the Division in writing of the change.

(d) The clinic's governing authority shall adopt operating policies and procedures that shall:

(1) specify the individual to whom responsibility for operation and maintenance of the clinic is delegated and methods established by the governing authority for holding such individuals responsible;

(2) provide for at least annual meetings of the governing authority, for which minutes shall be maintained; and

(3) maintain a policies and procedures manual designed to ensure safe and adequate care for the patients which shall be reviewed, and revised when necessary, at least annually, and shall include provisions for administration and use of the clinic, compliance, personnel quality assurance, procurement of outside services and consultations, patient care policies, and services offered.

(e) When the clinic contracts with outside vendors to provide services such as laundry or therapy services, the governing authority shall be responsible to assure the supplier meets the same local and State standards the clinic would have to meet if it were providing those services itself using its own staff.

(f) 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.

(g) The governing authority shall be responsible for ensuring the availability of supporting personnel to meet patient needs and to provide safe and adequate treatment.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0319 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0319 POLICIES AND PROCEDURES AND ADMINISTRATIVE RECORDS

(a) The following essential documents and references shall be on file in the administrative office of the clinic:

(1) documents evidencing control and ownerships, such as deeds, leases, or incorporation or partnership papers;

(2) policies and procedures of the governing authority, as required by Rule .0318 of this Section;

(3) minutes of the governing authority meetings;

(4) minutes of the clinic's professional and administrative staff meetings;

(5) a current copy of the rules of this Subchapter;

(6) reports of inspections, reviews, and corrective actions taken related to licensure; and

(7) contracts and agreements related to care and services provided by the clinic is a party.

(b) All operating licenses, permits, and certificates shall be displayed on the licensed premises.

(c) The governing authority shall prepare a manual of clinic policies and procedures for use by employees, medical staff, and contractual physicians to assist them in understanding their responsibilities within the organizational framework of the clinic. These shall include:

(1) patient selection and exclusion criteria;

(2) clinical discharge criteria;

(3) policy and procedure for validating the full and true name of the patient;

(4) policy and procedure for abortion procedures performed at the clinic;

(5) policy and procedure for the provision of patient privacy in the recovery area of the clinic;

(6) protocol for determining gestational age as defined in Rule .0101(5) of this Subchapter;

(7) protocol for referral of patients for whom services have been declined; and

(8) protocol for discharge instructions that informs patients who to contact for post-procedural problems and questions.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0320 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0320 ADMISSION AND DISCHARGE

(a) There shall be on the premises throughout all hours of operation an employee authorized to receive patients and make administrative decisions regarding patients.

(b) All patients shall be admitted only under the care of a physician who is currently licensed to practice medicine in North Carolina.

(c) Any patient not discharged within 12 hours following the abortion procedure shall be transferred to a hospital licensed pursuant to Chapter 131E, Article 5 of the General Statutes.

(d) Following admission and prior to obtaining the consent for the procedure, representatives of the clinic's management shall provide to each patient the following information:

(1) a fee schedule and any extra charges routinely applied;

(2) the name of the attending physician or physicians and hospital admitting privileges, if any. In the absence of admitting privileges a statement to that effect shall be included;

(3) instructions for post-procedure problems and questions as outlined in Rule .0329(d) of this Section;

(4) grievance procedures a patient may follow if dissatisfied with the care and services rendered; and

(5) the telephone number for Complaint Intake of the Division.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0321 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0321 MEDICAL RECORDS

(a) The clinic shall maintain a complete and permanent record for all patients including:

(1) the date and time of admission and discharge;

(2) the patient's full and true name;

(3) the patient's address;

(4) the patient's date of birth;

(5) the patient's emergency contact information;

(6) the patient's diagnoses;

(7) the patient's duration of pregnancy;

(8) the patient's condition on admission and discharge;

(9) a voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure witnessed by a family member, other patient representative, or facility staff member;

(10) the patient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies that may impact the procedure or anesthetic to be administered; and

(11) documentation that indicates all items listed in Rule .0320(d) of this Section were provided to the patient.

(b) The clinic shall record and authenticate by signature, date, and time all other pertinent information such as pre- and post-procedure instructions, laboratory reports, drugs administered, report of abortion procedure, and follow-up instruction, including family planning advice.

(c) If Rh is negative, the clinic shall explain the significance to the patient and shall record the explanation. The patient in writing may reject Rh immunoglobulin. A written record of the patient's decision shall be a permanent part of her medical record.

(d) An ultrasound examination shall be performed by a technician qualified in ultrasonography and the results, including gestational age, placed in the patient's medical record for any patient who is scheduled for an abortion procedure.

(e) The clinic shall maintain a daily procedure log of all patients receiving abortion services. This log shall contain at least the following:

(1) the patient name;

(2) the estimated length of gestation;

(3) the type of procedure;

(4) the name of the physician:

(5) the name of the Registered Nurse on duty; and

(6) the date and time of procedure.

(f) Medical records shall be the property of the clinic and shall be preserved or retained in the State of North Carolina for a period of not less than 10 years from the date of the most recent discharge, unless the client is a minor, in which case the record must be retained until three years after the client's 18th birthday, regardless of change of clinic ownership or administration. Such medical records shall be made available to the Division upon request and shall not be removed from the premises where they are retained except by subpoena or court order.

(g) The clinic shall have a written plan for destruction of medical records to identify information to be retained and the manner of destruction to ensure confidentiality of all material.

(h) Should a clinic cease operation, the clinic shall arrange for preservation of records for at least 10 years. The clinic shall send written notification to the Division of these arrangements.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0322 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0322 PERSONNEL RECORDS

(a) Personnel Records:

(1) A record of each employee shall be maintained that includes the following:

(A) the employee's identification;

(B) the application for employment that includes education, training, experience and references;

(C) a resume of education and work experience;

(D) a copy of a valid license (if required), education, training, and prior employment experience; and

(E) a list of references.

(2) Personnel records shall be confidential.

(3) Representatives of the Division conducting an inspection of the clinic shall have the right to inspect personnel records.

(b) Job Descriptions:

(1) The clinic shall have a written description that describes the duties of every position.

(2) Each job description shall include position title, authority, specific responsibilities, and minimum qualifications. Qualifications shall include education, training, experience, special abilities, and valid license or certification required.

(3) The clinic shall review annually and, if needed, update all job descriptions. The clinic shall provide the updated job description to each employee or contractual employee assigned to the position.

(c) All persons having direct responsibility for patient care shall be at least 18 years of age.

(d) The clinic shall provide an orientation program to familiarize each new employee or contractual employee with the clinic, its policies, and the employee's job responsibilities.

(e) The governing authority shall be responsible for implementing health standards for employees, as well as contractual employees, which are consistent with recognized professional practices for the prevention and transmission of communicable diseases.

(f) Employee and contractual employee records for health screening as defined in Rule .0101(7) of this Subchapter, education, training, and verification of professional certification shall be available for review by the Division.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0323 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0323 NURSING SERVICE

(a) The clinic shall have an organized nursing staff under the supervision of a nursing supervisor who is currently licensed as a Registered Nurse and who has responsibility for all nursing services.

(b) The nursing supervisor shall report to the chief executive officer or designee and shall be responsible for:

(1) provision of nursing services to patients; and

(2) developing a nursing policy and procedure manual and written job descriptions for nursing personnel.

(c) The clinic shall have the number of licensed and ancillary nursing personnel on duty to assure that staffing levels meet the total nursing needs of patients based on the number of patients in the clinic and their individual nursing care needs.

(d) There shall be at least one Registered Nurse with experience in post-operative or post-partum care who is currently licensed to practice professional nursing in North Carolina on duty in the clinic at all times patients are in the clinic.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0324 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0324 QUALITY ASSURANCE

(a) The governing authority shall establish a quality assurance program for the purpose of providing standards of care for the clinic. The program shall include the establishment of a committee that shall evaluate compliance with clinic procedures and policies.

(b) The committee shall determine corrective action, if necessary to achieve and maintain compliance with clinic procedures and policies.

(c) The committee shall consist of at least one physician who is not an owner, the chief executive officer or designee, and other health professionals. The committee shall meet at least once per quarter.

(d) The functions of the committee shall include development of policies for selection of patients, approval for adoption of policies, review of credentials for staff privileges, peer review, tissue inspection, establishment of infection control procedures, and approval of additional procedures to be performed in the clinic.

(e) Records shall be kept of the activities of the committee for a period not less than 10 years. These records shall include:

(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.

(f) The clinic shall conduct orientation, training, or education programs to correct deficiencies that are uncovered as a result of the quality assurance program.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0325 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0325 LABORATORY SERVICES

(a) Each clinic shall have the capability to provide or obtain laboratory tests required in connection with the procedure to be performed.

(b) The governing authority shall establish written policies regarding which surgical specimens require examination by a pathologist.

(c) Each patient shall have the following performed and a record of the results placed in the patient's medical record prior to the abortion:

(1) pregnancy testing, except when a positive diagnosis of pregnancy has been established by ultrasound;

(2) anemia testing (hemoglobin or hematocrit); and

(3) Rh factor testing.

(d) Patients requiring the administration of blood shall be transferred to a local hospital having blood bank facilities.

(e) The clinic shall maintain a manual in a location accessible by employees, that includes the procedures, instructions, and manufacturer's instructions for each test procedure performed, including:

(1) sources of reagents, standard and calibration procedures, and quality control procedures; and

(2) information concerning the basis for the listed "normal" ranges.

(f) The clinic shall perform and document, at least quarterly, calibration of equipment and validation of test results.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0326 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0326 EMERGENCY BACK-UP SERVICES

(a) Each clinic shall have a written plan for the transfer of emergency cases from the clinic to the closest hospital when hospitalization becomes necessary. Emergency case is defined as a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the individual's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of bodily organs.

(b) The clinic shall have written protocols, personnel, and equipment to handle medical emergencies as defined above which may arise in connection with services provided by the clinic.

(c) The clinic shall have a written agreement between the clinic and a hospital to facilitate the transfer of patients who are in need of emergency care. A clinic that has documentation of its efforts to establish such a transfer agreement with a hospital that provides emergency services and has been unable to secure such an agreement shall be considered to be in compliance with this Rule.

(d) The clinic shall provide intervention for emergency situations. These provisions shall include:

(1) basic cardio-pulmonary life support;

(2) emergency protocols for:

(A) administration of intravenous fluids;

(B) establishing and maintaining airway support;

(C) oxygen administration;

(D) utilizing a bag-valve-mask resuscitator with oxygen reservoir;

(E) utilizing a suction machine; and

(F) utilizing an automated external defibrillator;

(3) emergency lighting available in the procedure room as set forth in Rule .0212 of this Subchapter; and

(4) ultrasound equipment.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0327 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0327 SURGICAL SERVICES

(a) The procedure room shall be maintained exclusively for surgical procedures and shall be so designed and maintained to provide an environment free of contamination. The clinic shall establish procedures for infection control and universal precautions.

(b) Tissue Examination:

(1) The physician performing the abortion is responsible for examination of all products of conception (P.O.C.) prior to patient discharge. Such examination shall note specifically the presence or absence of chorionic villi and fetal parts, or the amniotic sac. The results of the examination shall be recorded in the patient's medical record.

(2) If adequate tissue is not obtained based on the gestational age, the physician performing the procedure shall evaluate for ectopic pregnancy, or an incomplete procedure.

(3) The clinic shall establish procedures for obtaining, identifying, storing, and transporting specimens.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0328 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0328 MEDICATIONS AND ANESTHESIA

(a) No medication or treatment shall be given except on written order of a physician.

(b) Any medications shall be administered by a physician or Registered Nurse and shall be recorded in the patient's permanent record.

(c) The anesthesia shall be administered only under the direct supervision of a licensed physician. Direct supervision means the physician must be present in the clinic and immediately available to furnish assistance and direction throughout the administration of the anesthesia. It does not mean the physician must be present in the room when the anesthesia is administered.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0329 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0329 POST-OPERATIVE CARE

(a) A patient whose pregnancy is terminated shall be observed in the clinic to ensure that no post-operative complications are present. Thereafter, patients may be discharged according to a physician's order and the clinic's protocols.

(b) Any patient having a complication known or suspected to have occurred during or after the performance of the abortion shall be transferred to a hospital for evaluation or admission.

(c) The following criteria shall be documented prior to discharge:

(1) the patient shall be able to move independently with a stable blood pressure and pulse; and

(2) bleeding and pain are assessed to be stable and not a concern for discharge.

(d) Written instructions shall be issued to all patients in accordance with the orders of the physician in charge of the abortion procedure and shall include the following:

(1) symptoms and complications to be looked for; and

(2) a dedicated telephone number to be used by the patients should any complication occur or question arise. This number shall be answered by a person 24 hours a day, seven days a week.

(e) The clinic shall have a defined protocol for triaging post-operative calls and complications. This protocol shall establish a pathway for physician contact to ensure ongoing care of complications that the operating physician is incapable of managing.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0330 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0330 CLEANING OF MATERIALS AND EQUIPMENT

(a) All supplies and equipment used in patient care shall be cleaned or sterilized between use for different patients.

(b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use as determined by the clinic through their governing authority.

History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

10A NCAC 13S .0331 is proposed for adoption under temporary procedures as follows:

10A NCAC 13S .0331 FOOD SERVICE

Nourishments, such as crackers and soft drinks, shall be available and offered to all patients.

History Note: Authority G.S. 131E-153;131E-153.2; 131E-153.5; 143B-165.

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

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RE: Request for Comments for North Carolina Proposed Regulations Concerning Abortion Clinics

The North Carolina Section of the American College of Obstetricians and Gynecologists (ACOG) is pleased to submit these comments in response to the North Carolina Department of Health and Human Services proposed rules for the licensure of abortion clinics.[1]

The American College of Obstetricians and Gynecologists is the nation's leading group of physicians providing evidence-based obstetric and gynecologic care. With more than 62,000 members, ACOG maintains the highest standards of clinical practice and continuing education of its members; strongly advocates for equitable, exceptional, and respectful care for all women and people in need of obstetric and gynecologic care; promotes patient education; and increases awareness among its members and the public of critical issues facing patients and their families and communities.

I. Abortion Is a Safe and Essential Component of Women's Health Care

As the leading medical organization dedicated to the health of individuals in need of gynecologic and obstetric care, the American College of Obstetricians and Gynecologists (ACOG) supports the availability of high-quality reproductive health services for all people and is committed to protecting and increasing access to abortion. Abortion is a common medical intervention that improves the lives, health, and well-being of those who need it.

[1] See NC Health and Human Services *Medical Care Commission - 10A NCAC 13S .0101, .0104, .0106-.0107, .0109, .0111-.0112, .0114, .0201-.0202, .0207, .0209-.0212, .0315, .0318-.0331.* NCDHHS. Accessed on 12/4/2023: https://www.oah.nc.gov/documents/rules/10a-ncac-13s-proposed-temporary-rules/download?attachment.

Abortion is an extremely safe medical procedure.[2] The risk of maternal death associated with childbirth is approximately 14 times higher than the risk associated with abortion.[3] Decades of clinical evidence clearly show that the various methods of abortion care, medication or procedural care, are safe and effective.[4] In the United States, 88% of abortions occur within the first trimester, when abortion is safest.[5]

Serious complications from abortions are rare at all gestational ages.[6] Only about 2% of women who undergo abortion experience a complication associated with the abortion, and most complications are minor and easily treatable with follow-up procedures or antibiotics.[7] The risk of complication or mortality from abortion is less than the same risk from common procedures like wisdom tooth removal, cancer-screening colonoscopy, and plastic surgery.[8]

With roughly one-quarter of women in the United States accessing abortion care in their lifetime,[9] this essential medical care must be provided according to the best available medical evidence, not restricted based on political ideology.

II. The Proposed Rules Constitute Legislative Interference in Patient Medical Care

Sound health policy is best based on scientific fact and evidence-based medicine. The best health care is provided free of political interference in the patient-physician relationship. Personal decision-making by women and their doctors should not be replaced by political ideology. ACOG opposes facility and staffing requirements like those found in the proposed rules because they improperly regulate medical care and do not improve patient safety or quality of care.[10]

This type of restriction on abortion is a Targeted Restriction of Abortion Providers (TRAP). Facility and staffing requirements are often enacted under the guise of promoting patient safety but single out abortion from other outpatient procedures and imposed medically unnecessary requirements designed

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[2] Increasing access to abortion. ACOG Committee Opinion No. 815. American College of Obstetricians and Gynecologists. Obstet Gyne-col 2020; 136:e107-15, at e108.
[3] Raymond EG, Grimes DA. The comparative safety of legal induced abortion and childbirth in the United States. Obstet Gynecol. 2012 Feb;119(2 Pt 1):215-9. doi: 10.1097/AOG.0b013e31823fe923. PMID: 22270271.
[4] National Academies of Sciences, Engineering, and Medicine. 2018. The Safety and Quality of Abortion Care in the United States. Washington, DC: The National Academies Press. https://doi.org/10.17226/24950. Pg 10.
[5] Increasing access to abortion. ACOG Committee Opinion No. 815. American College of Obstetricians and Gynecologists. Obstet Gyne-col 2020; 136:e107-15, at e108.
[6] *Id*.
[7] Upadhyay UD, Desai S, Zlidar V, Weitz TA, Grossman D, Anderson P, Taylor D. Incidence of emergency department visits and complications after abortion. Obstet Gynecol. 2015 Jan;125(1):175-183. doi: 10.1097/AOG.0000000000000603. PMID: 25560122.
[8] *ACOG.* (n.d.) Accessed on 12/4/2023: https://www.acog.org/advocacy/abortion-is-essential/come-prepared/abortion-access-fact-sheet.
[9] R. K. Jones and J. Jerman "Population Group Abortion Rates and Lifetime Incidence of Abortion: United States, 2008–2014", American Journal of Public Health 112, no. 9 (September 1, 2022): pp. 1284-1296.
[10] Increasing access to abortion. ACOG Committee Opinion No. 815. American College of Obstetricians and Gynecologists. Obstet Gyne-col 2020; 136:e107-15, at e109.

to reduce access to abortion.[11] Restrictions like those in the proposed rules make abortion more difficult and expensive to obtain by imposing additional costs on the patients who can least afford them.[12] Barriers limiting abortion access most profoundly affect communities that already face health care and social inequities. Limiting access to abortion forces people to carry pregnancies to term and face these risks. For example, Black women face a maternal mortality rate that is three times higher than that of white women.[13]

Government serves a valuable role in the protection of public health and safety and the provision of essential health services; however, laws and regulations that veer from these functions and unduly interfere with patient-physician relationships are not appropriate. Absent a substantial public health justification, government should not interfere with individual patient-physician encounters.[14] ACOG welcomes evidence-based safety regulations and creates a number of best practice recommendations to improve patient safety for office-based procedures.

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The North Carolina Section of ACOG appreciates the opportunity to comment on the proposed rules to regulate the licensure of abortion clinics in the state. ACOG welcomes working with government officials and safety experts on ways to ensure our patients receive safe, high-quality care. If you require additional information about the issues raised in this letter, please contact Elizabeth Livingston at elizabeth.livingston@duke.edu.

Respectfully Submitted,

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Jamila Wade, MD
Section Secretary Treasurer
North Carolina Section – American College of Obstetricians and Gynecologists

[11] *Id.*
[12] *Id*.
[13] Hoyert DL. Maternal mortality rates in the United States, 2020. NCHS Health E-Stats. 2022. DOI: https://dx.doi.org/10.15620/cdc:113967.
[14] *ACOG*. (n.d.). Accessed on 12/4/2023: https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2019/legislative-interference-with-patient-care-medical-decisions-and-the-patient-physician-relationship.

December 6, 2023

VIA ELECTRONIC SUBMISSION

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Re: Request for Comments for Subchapter 13S Licensure of Suitable Facilities for the Performance of Surgical Abortions.

To North Carolina Medical Care Commission:

On behalf of Ipas, a non-profit, international non-governmental organization in Chapel Hill, I am pleased to submit the following evidence in response to the North Carolina Medical Care Commission's proposal to adopt rules cited as *10A NCAC 13S .0101, .0104, .0106, .0107, .0109, .0111, .0112, .0114, .0210, .0202, .0207, .0209-.0212, .0315 and .0318-.033* posted on November 6, 2023.

Ipas began its work on safe abortion in 1973 with the provision of life-saving manual vacuum aspiration (MVA) technology to health systems in several countries. Over the ensuing 50 years, Ipas has garnered enormous experience through its continued singular commitment to expanding access to and improving the quality and safety of abortion globally. Much of our work has been in countries with restrictive abortion laws and with low resources. Even in these settings with few clinical regulations and resources, abortion and miscarriage management with vacuum aspiration has proven to be safe, simple, and effective (Huber et al., 2016; Grimes et al., 2006; Henkel & Shaw, 2021).

Abortion is essential health care to which everyone has a right. However, in this state, the imposition of needless restrictions on abortion care, which are in direct conflict with the abundant, robust evidence on the safety of abortion provided with vacuum aspiration, make the delivery of abortion care unnecessarily difficult for clinics and providers and limits access for patients.

For your consideration, we offer the following summary of the evidence supporting the safety of abortion with manual vacuum aspiration.

Recommendations from leading international organizations

Vacuum aspiration is recommended for abortion care and miscarriage management by the World Health Organization (WHO) and the world's leading gynecological and obstetric organizations, including the American College of Obstetricians and Gynecologists (ACOG), the Royal College of Obstetricians and Gynaecologists (RCOG) and the International Federation of Gynecology and Obstetrics (FIGO).

"*Abortion, using medication or a simple outpatient surgical procedure, is a safe health-care intervention, when carried out with a method appropriate to the gestational age of pregnancy and – in the case of a*

facility-based procedure – by a person with the necessary skills. In these circumstances, complications or serious adverse effects are rare." (WHO, 2022).

"*Abortion is safer than many common medical procedures. The risk of complication or mortality from abortion is less than the same risk from common procedures like wisdom tooth removal, cancer-screening colonoscopy, and plastic surgery.*" (ACOG, 2023).

Safety

A 2015 systematic review analyzed 57 studies reporting data for 337,460 aspiration abortions performed before 14 weeks gestation in North America, Western Europe, Scandinavia and Australia/New Zealand (White, Carroll, & Grossman, 2015). Major complications requiring intervention (such as hemorrhage requiring transfusion or perforation necessitating repair) occurred in ≤ 0.1% of procedures; hospitalization was necessary in ≤ 0.5% of cases.

Studies looking at different cadres of providers (physician assistants, nurses, nurse midwives, etc.) in other settings have had similar results (Hakim-Elahi, Tovell, & Burnhill, 1990; Jejeebhoy et al., 2011; Warriner et al., 2006; Weitz et al., 2013). In two studies that compared newly trained midlevel providers to experienced physician providers (Jejeebhoy et al., 2011; Weitz et al., 2013), there were no observed differences in aspiration abortion success or complication rates.

A retrospective cohort study conducted in the United States compared rates of procedural complications during outpatient aspiration abortion through 13 weeks and six days gestation in women with at least one medical comorbidity (diabetes, hypertension, obesity, HIV, epilepsy, asthma, thyroid disease and bleeding/clotting disorders) to women without comorbidities. The overall rate of complications—which included uterine perforation, blood loss greater than 100mL, cervical laceration and retained products of conception that required re-aspiration— was 2.9%; there was no difference between the two groups (Guiahi et al., 2015). Two later retrospective cohort studies, that together included 5,288 aspiration abortion procedures performed before 13 weeks gestation, found no differences in complication rates between obese, overweight, and normal weight women (Benson et al., 2016; Mark et al., 2017).

Abortion safety compared to other outpatient procedures

The overall risk of having a complication at the time of an abortion is like that incurred during outpatient dental procedures (Jung et al, 2023). "The major incident rate for abortion (0.1%) is lower than the published rates for pregnancy (1.4%), as well as other common procedures such as colonoscopy (0.2%), wisdom tooth removal (1.0%), and tonsillectomy (1.4%). Abortion care is, thus, safer than many other unregulated outpatient procedures" (Upadhyay et al., 2018).

Mortality

In the United States, the mortality rate from all legal induced abortion between 2013-2020 was 0.45 deaths per 100,000 reported abortions; mortality rates disaggregated by abortion type or length of pregnancy are not available. "Since 1978, all rates for the preceding 5-year periods have been fewer than 1 death per 100,000 abortions, demonstrating the low risk for death associated with legal induced abortion" (Kortsmit et al., 2023). In comparison, during the period from 2007-2016 the mortality rate from live birth in the United States was 17 deaths per 100,000 live births (Creanga et al., 2017; Petersen

et al., 2019). A secondary data analysis that compared mortality rates associated with live birth to those from legal induced abortion in the United States found that the risk of death from childbirth was 14-fold higher than the risk of death from abortion (Raymond & Grimes, 2012). In the 2015 systematic review about the safety of vacuum aspiration in multiple countries referenced above, no deaths were reported (White et al., 2015).

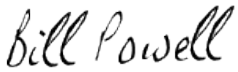
Effects of facility type on abortion safety

A retrospective cohort study of women who underwent induced abortions in ambulatory surgical centers (ASCs) versus office-based settings found that rates of abortion-related morbidities and adverse events did not differ significantly regardless of where the procedures were performed (Roberts et al, 2018). A systematic review found that the existing evidence, while limited, does not indicate a difference in patient safety for outpatient procedures performed in ASCs versus physician offices. Additionally, laws that have singled out abortion facilities with specific facility requirements appear to be associated with decreased availability of services (Berglas et al., 2018).

We ask the Committee to reconsider the proposed regulations and to adopt regulations that are in keeping with this evidence underscoring the profound safety of abortion with vacuum aspiration performed as a simple, office-based procedure.

Should you have questions about any of the cited evidence or have other questions, I welcome you to contact me at the address or email below.

Respectfully,



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December 6, 2023

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Re: Request for Comments for North Carolina Medical Care Commission Proposed Temporary Rules for Abortion Clinics

Planned Parenthood South Atlantic (Planned Parenthood) submits these comments in response to the North Carolina Medical Care Commission proposal to adopt temporary rules for licensure of suitable facilities for the performance of surgical abortions, cited as 10A NCAC 13S .0101, .0104, .0106, .0107, .0109, .0111, .0112, .0114, .0201, .0202, .0207, .0209-.0212, .0315, and .0318-.0331. As a trusted health care provider, educator, and advocate, Planned Parenthood appreciates the opportunity to weigh in on policy recommendations that impact our health care clinics, and by extension our patients all across the state.

Planned Parenthood is a safety net provider for the populations in North Carolina most in need of health services. The majority of our clinics in North Carolina provide abortion care in addition to other types of health care, including birth control services, STI testing and treatment, preventive screenings, and other essential services. People across our state trust Planned Parenthood to provide them with quality, expert care in a confidential and non-judgmental setting, and we have done that in North Carolina for decades.

"Surgical"[1] — or procedural — abortion care is extremely safe.[2] It has a far lower complication rate (less than 1%) than many other procedures performed in outpatient clinic settings, such as colonoscopies, liposuction, and wisdom teeth extraction.[3] Abortions are routinely provided in

[1] Although certain outpatient abortion methods are sometimes referred to as "surgical abortion," that is a misnomer, as they do not entail the typical characteristics of surgery, such as an incision into bodily structures. According to the American College of Obstetricians and Gynecologists (ACOG), the leading professional organization for obstetrician-gynecologists, these methods are more appropriately characterized as a procedure, which is defined as a "short interventional technique that includes the following general categories . . . non-incisional diagnostic or therapeutic intervention through a natural body cavity or orifice" and is "generally associated with lower risk of complications."

[2] Nat'l Acads. of Scis., Eng'g, & Med., The Safety and Quality of Abortion Care in the United States, Nat'l Acads. Press 1, 74–75 (2018). The mortality risk for abortion is lower than that of many other common procedures that are not required to be performed in a hospital. For example, one recent and robust analysis found that in the United States, the mortality rate for colonoscopy is 2.9 per 100,000 procedures and the mortality rate for plastic surgery is 0.8 to 1.7 per 100,000 procedures. By contrast, the mortality rate for legal induced abortion is 0.7 per 100,000 procedures.

[3] Ushma D. Upadhyay et al., Incidence of Emergency Department Visits and Complications After Abortion, 125 Obstetrics & Gynecology 175, 181 (2015); Nat'l Acads. of Scis., Eng'g & Med., The Safety & Quality of Abortion Care in the United States 10 (2018) at 74–75. *See* Am. Soc'y for Gastrointestinal

office-based settings, with no effect on safety.[4] Despite this fact, the facilities requirements for abortion clinics in North Carolina are much more onerous than the facilities guidelines promulgated by the North Carolina Medical Board for the provision of safe and effective outpatient procedures — the standard for other similarly situated providers.[5] As a result of this medically unnecessary and costly regulation of abortion clinics, over time, the number of abortion clinics has decreased and stagnated — reducing access to these services.[6] Today, there are only fourteen freestanding abortion clinics in the entire state.

During this rulemaking process, the Medical Care Commission has the opportunity to reevaluate the regulation of abortion clinics in our state, and make additional changes to its proposed temporary rules that would protect patient health and safety without impeding access to health care. We do not ask for special treatment, but rather that abortion clinic regulations be right-sized to reflect the safety of the procedures occurring within them, and that abortion clinics be held to the same or similar standards that apply to other providers of comparable outpatient procedures.

Methods and Safety of Procedural Abortion Care

First, it may be helpful to understand the methods of procedural abortion care — what it is, and what it is not.

Up to approximately 14 to 15 weeks after a person's last menstrual period (LMP), procedural abortions typically involve the use of gentle suction to empty the contents of the uterus. This procedure, which is also referred to as an aspiration abortion, is the same procedure that is used to treat miscarriage. Aspiration abortion typically takes between five to ten minutes to

Endoscopy, Complications of Colonoscopy, 74 Gastrointestinal Endoscopy 745, 747 (2011); Grazer & de Jong, Fatal Outcomes from Liposuction: Census Survey of Cosmetic Surgeons, 105 Plastic & Reconstructive Surgery 436, 441 (2000); Francois Blondeau & Nach G. Daniel, Extraction of Impacted Mandibular Third Molars: Postoperative Complications and their Risk Factors, 73 J. Canadian Dental Ass'n 325 (2007).

[4] In a study of more than 50,000 abortions, there was no statistically significant difference in morbidities and adverse events between abortions performed in an ambulatory surgical setting versus those performed in an office-based setting. Sarah C.M. Roberts, Ushma Upadhyay & Guodong Liu, Association of Facility Type with Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions , 319(24) JAMA 2497-2504 (2018), https://jamanetwork.com/journals/jama/fullarticle/2685987.

[5] North Carolina Medical Board Position Statement 5.1.1, Office Based Procedures, (Sept. 2021), https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/office-based_procedures. The Facility Guidelines Institute – an independent not-for-profit organization that sets guidelines for the design and construction of health care facilities – notes that "a procedure that does not entail penetration of the protective surfaces [of the patient's body] is by definition not invasive and therefore not required . . . to be performed in an ASC." Brief for Amicus Curiae Facility Guidelines Institute in Support of Neither Party at 3, Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292 (2016), https://www.scotusblog.com/wp-content/uploads/2016/01/15-274-ac-Facility-Guidelines-Institute.pdf (hereinafter, "FGI Amicus Brief").

[6] The costs associated with abortions performed at ambulatory surgical centers are significantly higher than the costs associated with abortions performed in office-based settings, without any difference in safety. Douglas L. Leslie et al., Healthcare Costs for Abortions Performed in Ambulatory Surgery Centers vs. Office-Based Settings, 222 Obstetrics & Gynecology, 348 (2020).

complete. It can be done in a medical office under a local anesthetic — indeed, aspiration is routinely done in medical offices to treat miscarriage.[7]

Starting around 14 to 15 weeks LMP, and depending on specific patient needs, procedural abortions are generally performed using a method called dilation and evacuation ("D&E"), in which clinicians dilate the cervix and use a combination of suction and instruments to empty the uterus. This procedure can also be used to treat miscarriage.

Depending on the patient and method of cervical dilation, D&E can be performed as a one- or two-day procedure. As with aspiration abortions, D&E abortions are routinely and safely provided in outpatient, office-based settings. D&E generally involves no more than moderate sedation, though clinicians use different levels of sedation depending on the setting and patient preference. In North Carolina, this type of procedural abortion is now only utilized for abortions provided under the exceptions to the 12-week abortion ban — namely, in cases of rape, incest, "life-limiting" fetal anomaly, or if there is a medical emergency.

While sometimes referred to as "surgical" abortions, aspiration and D&E abortions are not what is commonly understood to be "surgery." For example, they involve no incision, do not require general anesthesia, and do not require a sterile field, because the vagina naturally contains bacteria.[8]

Procedural abortion care — whether aspiration or D&E — is safely provided on an outpatient basis, with extremely low complication rates. When complications do occur, they are usually minor and managed in an outpatient setting, either during the same visit as the abortion or in a follow-up visit. Major complications, which are defined as complications requiring hospital admission, surgery, or blood transfusion, occur in less than one-quarter of one percent (0.23%) of all abortions.[9] Abortion-related emergency room visits constitute just 0.01% of all emergency room visits among women aged 15–49 in the United States.[10] The risk of complications from an abortion in the first trimester of pregnancy — after which point abortion is banned in North Carolina except in very narrow circumstances — is even lower.[11]

[7] Courtney A. Schreiber et al., Treatment Decisions at the Time of Miscarriage Diagnosis, 128 Obstetrics & Gynecology 1347, 1347 (2016).
[8] See, e.g., Bonnie S. Jones, Sara Daniel & Lindsay K. Cloud, State Law Approaches to Facility Regulation of Abortion and Other Office Interventions , 108(4) Am. J. of Pub. Health 486, 486 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5844403/pdf/AJPH.2017.304278.pdf ("Like other procedures performed through an orifice naturally colonized with bacteria, procedural abortions need to be performed in 'clean,' but not 'sterile,' physical environments."); FGI Amicus Brief at 4-5.
[9] Ushma Upadhyay et al., Incidence of Emergency Department Visits and Complications After Abortion, 125 Obstetrics & Gynecology 175 (2015).
[10] Ushma Upadhyay et al., Abortion-Related Emergency Room Visits in the United States: An Analysis of a National Emergency Room Sample, 16 BMC Med. 1, 1 (2018).
[11] *Id*.

Comparison to Other Outpatient Procedures

Despite the extremely low complication rate associated with abortion care, the proposed temporary regulations require abortion clinics to comply with a thicket of rules that are administratively onerous and medically unnecessary. The regulations mirror others that have been in place for many years in this state.[12] They are outdated and based on misperceptions about the health care that is being provided.

In North Carolina, many other types of outpatient procedures with higher complication rates than abortion are performed in office-based settings (i.e., one that is not an ambulatory surgical center ("ASC") or other specialized facility). Among these procedures are invasive procedures and those where general anesthesia is used.[13] These office-based settings are not regulated by the State; rather, the Medical Board sets guidelines for such office-based procedures, which they differentiate into Level I, II, and III procedures based on, for example, the type of sedation used and risk of complications for a particular procedure.[14] This evidence-based guidance applies to various types of office-based gynecological procedures, including diagnostic procedures that remove tissue from the uterus for testing, which are substantially similar in technique and risk to procedural abortion. It also applies to office-based procedures used to manage incomplete miscarriages — care that is identical in technique and, in some cases, carries more risk of complication than procedural abortion.

In contrast to evidence-based guidance, the abortion clinic regulations mandate that any facility that provides procedural abortions must comply with myriad restrictions completely unrelated to patient health and safety. For example, a clinic that provides any procedural abortions and has more than one floor must have at least one elevator that can accommodate a stretcher, 10A N.C. Admin. Code 13S.0209, even though stretchers are not used in abortion care and the rate of serious complications that would require a hospital transfer, as noted above, are exceedingly rare. Likewise, patient-use corridors in any facility that provides abortions must be no less than 60 inches wide, again to facilitate stretcher use, 10A N.C. Admin. Code 13S.0210, and the minimum width of doors to all rooms needing access for stretchers must be three feet, 10A N.C. Admin. Code 13S.0211.

The proposed regulations also impose strict ventilation and air supply requirements. See 10A N.C. Admin. Code 13S.0212 Specifically, the ventilation and air supply requirements are

[12] Previously contained in Subchapter 14E of 10A NC Admin. Code; repealed effective July 1, 2023 following the repeal of G.S. 14-45.1 in Session Law 2023-14.
[13] These procedures include liposuction (5% complication rate), breast augmentation (10.6% complication rate for most common complication), and abdominoplasty (10–20% complication rate). Hannah Headon et al., Capsular Contracture after Breast Augmentation: An Update for Clinical Practice, 42 Archives Plastic Surgery 532 (2015); Pedro Vidal et al., Abdominoplasty: Risk Factors, Complication Rates, and Safety of Combined Procedures, 44 Archives Plastic Surgery 457 (2017). All of these procedures are currently performed in office-based, non-ASC facilities in North Carolina.
[14] Health centers providing abortion care are also appropriately regulated in the same manner as other medical offices through state and local building and fire safety codes, CLIA, OSHA, clinician licensure requirements, and other regulations of general applicability.

targeted at ensuring a sterile field for surgeries, which is unnecessary for the provision of abortion care.[15] While abortion providers of course sterilize equipment and maintain clean environments, procedural abortion, like other similar outpatient procedures, differs from surgery because it does not require a sterile field. This is because procedural abortion does not entail an incision into the body, but rather insertion of instruments into a body cavity through a natural orifice.[16]

Further, the proposed temporary regulations require non-hospital-affiliated facilities that provide abortions to have a multitude of separate, specially designated spaces — including a receiving area, examining room, preoperative preparation and holding room, procedure room, recovery room, clean workroom, soiled workroom, a space with patient lockers, and "nourishment station with storage and preparation area for serving meals or in-between meal snacks." 10A N.C. Admin. Code 13S .0207. There is no medical reason why these would need to all be separate spaces, but it makes finding adequate space for an abortion clinic more difficult and more costly. Notably, the Board of Medicine does not impose any such mandate on other providers of comparable office-based medical procedures.

Additionally, the proposed temporary regulations require health care facilities that provide abortions to have a licensed RN supervise and organize nursing staff, and there must be at least one licensed RN with experience in post-operative or post-partum care on duty at all times that procedural abortion patients are in the clinic. 10A N.C. Admin. Code 13S .0323. A health facility that provides abortion care is not exempt from this requirement even if one or more clinicians of comparable or even higher-level training (e.g., a physician or a PA) are present, as contemplated in the Medical Board's office-based procedures guidance. This means that regardless of who else is available, if there is no RN on duty, or if the RN has to leave suddenly, patients cannot receive an abortion. This blanket RN requirement serves no medical purpose, limits clinics' ability to provide care, and is out of line with the regulation of other similar office-based providers.

[15] The ACOG Consensus Guidelines on outpatient abortion care clearly state that no heightened environmental controls are required for the safe provision of in-clinic abortion: "Facilities should use adequate heating, ventilation, and cooling systems. Systems typical for offices are adequate in this context; no special heating, ventilation, or cooling systems are needed." ACOG, Consensus Guidelines for Facilities Performing Outpatient Procedures Evidence Over Ideology, 133 Obstetrics & Gynecology 255, 259 (2019), DOI: 10.1097/AOG.0000000000003058. These Consensus Guidelines were endorsed by a number of additional prominent national organizations and associations, including the American Public Health Association, American Academy of Family Physicians, American College of Nurse-Midwives, American College of Physicians, and the Society of Family Planning. *See* ACOG, Press Statements: New Guidelines for Facilities Performing Office-Based Procedures Including Abortion (Jan. 24, 2019), https://www.acog.org/news/news-releases/2019/01/new-guidelines-for-facilities-performing-office-based-procedures-including-abortion.

[16] *See, e.g.,* Bonnie S. Jones, Sara Daniel & Lindsay K. Cloud, State Law Approaches to Facility Regulation of Abortion and Other Office Interventions , 108(4) Am. J. of Pub. Health 486, 486 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5844403/pdf/AJPH.2017.304278.pdf ("Like other procedures performed through an orifice naturally colonized with bacteria, procedural abortions need to be performed in 'clean,' but not 'sterile,' physical environments."); FGI Amicus Brief at 4-5.

There is no medical reason or justification for requiring facilities that provide procedural abortions, which have lower complication rates than comparable office-based procedures[17] to accommodate stretchers, maintain specific temperatures or air flow and myriad unnecessary separate spaces, and adhere to rigid staffing structures while other medical offices do not face the same requirements. This arbitrary regulation of facilities where abortions are provided is without medical basis and at odds with statements from professional standard-setting bodies, including the American Medical Association and the American College of Obstetricians and Gynecologists.[18]

We urge you to take the opportunity to "adopt, amend, and repeal" regulations to ensure that the regulations applicable to licensed abortion clinics are actually suitable for facilities that provide procedural abortions. Using your judgment of the medical evidence, as medical providers and professionals, you can encourage a new and different standard that aligns more appropriately with the type and complexity of the care that is occurring in abortion clinics in our state.

If you require additional information about the issues raised in this letter, please contact me at katherine.farris@ppsat.org.

Respectfully submitted,

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[17] *See, e.g.*, Nat'l Acads. of Scis., Eng'g & Med., The Safety & Quality of Abortion Care in the United States 10 (2018) at 74–75 ("Abortion-related mortality is also lower than that for colonoscopies (2.9 per 100,000), plastic surgery (0.8 to 1.7 per 100,000), dental procedures (0.0 to 1.7 per 100,000), and adult tonsillectomies (2.9 to 6.3 per 100,000).").

[18] Brief of Amici Curiae American College of Obstetricians and Gynecologists, American Medical Association, et al. in Support of June Medical Services, L.L.C., et al. at 20, June Med. Servs. LLC v. Russo, 140 S.Ct. 2103 (2020) (Nos. 18-1323, 18-1460); ACOG, New Guidelines for Facilities Performing OfficeBased Procedures Including Abortion (Jan. 24, 2019), https://www.acog.org/news/news-releases/2019/01/new-guidelines-for-facilities-performing-office-based-procedures-including-abortion; ACOG, Consensus Guidelines for Facilities Performing Outpatient Procedures Evidence Over Ideology, 133 Obstetrics & Gynecology 255, 255–60 (2019), DOI: 10.1097/AOG.0000000000003058.

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Re: Request for Comments for North Carolina Medical Care Commission Proposed Temporary Rules for Abortion Clinics

Thank you for the opportunity to submit comments on the proposed temporary rules for the Licensure of Suitable Facilities for the Performance of Surgical Abortions. Surgical, or procedural, abortion has a demonstrated history of safety.[1] The types of abortions that occur in a clinic setting are not what is commonly understood to be surgery at all – they involve no incision, do not require general anesthesia, and do not require a sterile field because the procedure occurs in a natural body orifice. Abortion has a far lower complication rate (less than 1%) than other procedures that occur in outpatient clinic settings.[2] Moreover, the mortality risk for abortion is lower than that of many other common procedures that are performed in outpatient clinics. For example, one recent and robust analysis found that in the United States, the mortality rate for colonoscopy is 2.9 per 100,000 procedures; the mortality rate for tonsillectomy ranges from 2.9 to 6.3 per 100,000 procedures; and the mortality rate for plastic surgery is 0.8 to 1.7 per 100,000 procedures.[3] By contrast, the mortality rate for legal induced abortion is 0.7 per 100,000 procedures.[4] These procedures of greater risk are routinely provided on an outpatient basis in a clinic setting.

Despite the safety of abortion care, especially when compared to other clinic-based procedures, the regulation of abortion clinics far outpaces the requirements or recommendations for other

[1] Ushma D. Upadhyay et al., Incidence of Emergency Department Visits and Complications After Abortion, 125 Obstetrics & Gynecology 175, 181 (2015).
[2] *Id.*
[3] Nat'l Acads. of Scis., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States*, Nat'l Acads. Press 1, 74–75 (2018).
[4] *Id.*

office-based procedures. For the next several pages, we are providing a chart that directly compares requirements included in the proposed temporary regulations (which mirror abortion clinic regulations that have been in place for many years) with the North Carolina Medical Board's Guidelines for Office Based Procedures.[5] The Medical Board sets guidelines for such office-based procedures, which they differentiate into Level I,[6] II,[7] and III[8] procedures based on, for example, the type of sedation used and risk of complications for a particular procedure. As you can see from the comparison, abortion clinics are required to meet standards far above those considered appropriate, best practice guidelines for other office-based procedures – even those where deep sedation is provided. An especially striking example is that clinics providing care for miscarriage are not required to meet guidelines specific to abortion clinics, even though the personnel and procedures are often identical.

As experienced healthcare providers familiar with outpatient procedures as well as the practice of abortion in North Carolina, we would suggest that abortion is a Level II office-based procedure as defined by the Medical Board Guidelines and should be regulated accordingly. "Level II office-based procedures are defined as "any surgical or special procedures" that (1) "require the administration of local or peripheral nerve block, minor conduction blockade, Bier block, minimal sedation, or conscious sedation"; and (2) "where there is only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely."[9] Currently, none of the free

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[5] N.C. Med. Bd., Position Statements: Office-Based Procedures (last amended Sept. 2021), https://www.ncmedboard.org/resources-information/professionalresources/laws-rules-position-statements/position-statements/office-based_procedures.

[6] Level I office-based procedures are defined as "any surgical or special procedures" that (1) "do not involve drug-induced alteration of consciousness"; (2) "where preoperative medications are not required or used other than minimal preoperative tranquilization of the patient (anxiolysis of the patient)"; (3) "where the anesthesia required or used is local, topical, digital block, or none"; and (4) "where the probability of complications requiring hospitalization is remote." *Id.*

[7] Level II office-based procedures are defined as "any surgical or special procedures" that (1) "require the administration of local or peripheral nerve block, minor conduction blockade, Bier block, minimal sedation, or conscious sedation"; and (2) "where there is only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely." *Id.*

[8] Level III office-based procedures are defined as "any surgical or special procedures" that (1) "require, or reasonably should require, the use of major conduction blockade, deep sedation/analgesia, or general anesthesia"; and (2) have "only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely." *Id.*

[9] *Id.*

standing clinics providing abortion in the state use deep sedation or general anesthesia for abortion procedures. Should a clinic wish to introduce deep sedation or general anesthesia, it could be required to meet requirements for Level III office-based procedures.

Thank you for considering these recommendations which would improve consistency in regulation of medical care in this state.

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Comparison of North Carolina regulations for Abortion Clinics and other Procedural Clinics[10]

	Proposed Abortion Clinic Regulations	**Medical Board Guidelines for Level I Procedures**	**Medical Board Guidelines for Level II Procedures**	**Medical Board Guidelines for Level III Procedures**
Physical Requirements	"(a) The physical plant for a clinic shall meet or exceed minimum requirements of the North Carolina State Building Code for Group B occupancy (business office facilities) which is incorporated herein by reference including subsequent amendments and editions. (b) The requirements contained in this Section shall apply to new clinics and to any alterations, repairs, rehabilitation work, or additions which are made to a previously certified facility." 10A NCAC 13S .0201. "Clinics that are licensed by the Division to perform abortions shall comply with the Rules governing the sanitation of hospitals, nursing homes, adult care homes, and other institutions, contained in 15A N.C. Admin. Code 18A.1300 which is hereby incorporated by reference including subsequent amendments and editions." 10A NCAC 13S .0202 Clinic must have receiving area; examining room; preoperative preparation and holding room; individual patient locker facilities or equivalent; procedure room; recovery room; clean workroom; soiled workroom; medicine room (which may be part of the clean workroom if certain requirements are met); separate and distinct areas for storage and handling clean and soiled linen; patient toilet; separate and distinct areas for storage and handling clean	None.	None.	None.

[10] Unless otherwise noted, all information in the columns regarding Medical Board guidelines for office- based procedures can be found in N.C. Med. Bd., *Position Statements: Office-Based Procedures* (last amended Sept. 2021), https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/office-based_procedures.

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	and soiled linen; patient toilet; personnel lockers and toilet facilities; laboratory; nourishment station with storage and preparation area for serving meals or in-between meal snacks; janitor's closets; adequate space and equipment for assembling, sterilizing, and storing medical and surgical supplies; storage space for medical records; and office space for nurses' charting, doctors' charting, communications, counseling, and business functions. *See* 10A NCAC 13S .0207. Any facility that provides abortions that has more than one floor must have at least one elevator that can accommodate a stretcher (six-and-one-half feet with an opening of no less than three feet in width). *See* 10A NCAC 13S .0209. Patient-use corridors in any facility that provides abortions must be no less than 60 inches wide. *See* 10A NCAC 13S .0210. The minimum width of doors to all rooms needing access for stretchers must be three feet. *See* 10A NCAC 13S .0211. A facility that provides abortion must comply with strict ventilation and air supply requirements. *See* 10A NCAC 13S .0212.			

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
License & Fee Requirements	"Any license holder or prospective applicant desiring to make alterations or additions to a clinic or to construct a new clinic, before commencing such alteration, addition or new construction shall submit plans and specifications to the Division for preliminary inspection and approval or recommendations with respect to compliance with this Subchapter" 10A NCAC 13S .0112 "(a) Approval of building plans shall be obtained from the Division of Health Service Regulation, in accordance with the rules in Section .0200 of this Subchapter. (b) Approval of building plans 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 building plans." 10A NCAC 13S .0114 "(a) Prior to the admission of patients, an applicant for a new clinic shall submit an application for licensure and receive approval from the Division. (b) Application forms may be obtained by contacting the Division (c) The application form shall set forth: (1) Name of applicant; (2) Name of facility; (3) Ownership disclosure; (4) Building owner; (5) Building owner; (6) Building management; (7) Sanitation services; (8) Medical director; (9) Other medical staff; (10) Director of nursing; (11) Other nursing staff; and (12) Consulting pathologist.	None.	Physician performing Level II procedures in an office "should be able to demonstrate, upon request by the Board, substantial compliance with these guidelines, or should obtain accreditation of the office setting by an approved accreditation agency or organization."	Physician performing Level III procedures in an office "should be able to demonstrate, upon request by the Board, substantial compliance with these guidelines, or should obtain accreditation of the office setting by an approved accreditation agency or organization."

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	(d) After construction requirements in Section .0200 of this Subchapter have been met and the application for licensure has been received and approved, the Division shall conduct an on-site, licensure survey. 10A NCAC 13S .0106 "(a) The Division shall issue a license if it finds the facility can: (1) Comply with all requirements described in this Subchapter; and (2) Have a board certified OB-GYN or board eligible physician by the American Board of Obstetrics and Gynecology shall be available in the event that complications arise from an abortion procedure. (b) Each license shall be issued only for the premises and persons or organizations named in the application and shall not be transferable. (c) The governing authority shall notify the Division in writing, within 10 working days, of any change in the name of the facility or change in the name of the administrator. (d) The facility shall report to the Division all incidents, within 10 working days, of vandalism to the facility such as fires, explosions, or other action that prevents services from providing abortion services." 10A NCAC 13S .0107 "(a) Each license, renewed at the beginning of each calendar year. (b) The renewal application form shall set forth: (1) Name of applicant; (2) Name of facility; (3) Ownership disclosure; (4) Building owner; (5) Building owner; (6) Building management; (7) Sanitation services; (8) Medical director;			

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	(9) Other medical staff; (10) Director of nursing; (11) Other nursing staff; (12) Consulting pathologist; (13) The number of procedures performed during the reporting period; and (14) The number of patients that were transferred to a hospital during a reporting period. (c) Upon the filing of a renewal application, the clinic must pay a non-refundable renewal fee as defined in G.S. 131E-153.2. (d) An application for renewal of licensure must be filed with the Division at least 30 days prior to the date of expiration. Renewal application forms shall be furnished by the Division. (e) Failure to file a renewal application shall result in expiration of the license to operate." 10A NCAC 13S .0109			
Inspection & Investigation Authority	"(a) Any clinic licensed by the Division to perform abortions shall be inspected by representatives of the Division annually and as it may deem necessary as a condition of holding such license. An inspection may be conducted whenever the Division receives a complaint alleging the clinic is not in compliance with the rules of the Subchapter. (b) Representatives of the Division shall make their identities known to the clinic staff prior to inspection of the clinic. (c) Representatives of the Division may review any records in any medium necessary to determine compliance with the rules of this Subchapter. The Department shall maintain the confidentiality of the complainant and the patient, unless otherwise required by law.			

	Proposed Abortion Clinic Regulations	**Medical Board Guidelines for Level I Procedures**	**Medical Board Guidelines for Level II Procedures**	**Medical Board Guidelines for Level III Procedures**
	(d) The clinic shall allow the Division to have immediate access to its premises and the records necessary to conduct an inspection and determine compliance with the rules of this Subchapter. (e) A clinic shall file a written plan of correction for cited deficiencies within 10 business days of receipt of the report of the survey. The Division shall review and respond to a written plan of correction within 10 business days of receipt of the corrective action plan" 10A NCAC 13S .0111			
Medical Staff Organization & Personnel Requirements	(c) All persons having direct responsibility for patient care shall be at least 18 years of age. (d) The clinic shall provide an orientation program to familiarize each new employee or contractual employee with the clinic, its policies, and the employee's job responsibilities. (e) The governing authority shall be responsible for implementing health standards for employees, as well as contractual employees, which are consistent with recognized professional practices for the prevention and transmission of communicable diseases. (f) Employee and contractual employee records for health screening as defined in Rule .0101(7) of this Subchapter, education, training, and verification of professional certification shall be available for review by the Division. 10A NCAC 13S .0322 (c)-(f). --- (b) The nursing supervisor shall report to the chief executive officer or designee and shall be responsible for: (1) provision of nursing services to patients; and (2) developing a nursing policy and procedure manual and	None.	Physician performing procedure or other health care professional present *should* be ACLS certified, and at least one other health care professional *should* be BCLS certified. "Recovery *should* be monitored by a registered nurse *or other health care professional* practicing within the scope of his or her license or certification who is BCLS certified and has the capability of administering medications as required for analgesia, nausea/vomiting, or other indications." (emphases added).	An anesthesiologist or a CRNA supervised by a physician *should* administer anesthesia. The physician cannot administer the anesthesia. Physician performing procedure or the anesthesia provider *should* be ACLS certified, and *at least one other health care professional should* be BCLS certified. "Recovery from a Level III procedure *should* be monitored by an ACLS certified (PALS or APLS certified when appropriate) health care professional using appropriate criteria for the level of anesthesia. *At least one health care professional* who is ACLS certified *should* be immediately available during postoperative monitoring and until the patient meets

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	written job descriptions for nursing personnel. (c) The clinic shall have the number of licensed and ancillary nursing personnel on duty to assure that staffing levels meet the total nursing needs of patients based on the number of patients in the clinic and their individual nursing care needs. 10A NCAC 13S .0323 (b)-(c)			discharge criteria." (emphases added).
Patient Transfer Agreement	"(a) Each clinic shall have a written plan for the transfer of emergency cases from the clinic to a nearby hospital when hospitalization becomes necessary. [...] (c) The clinic shall have a written agreement between the clinic and a hospital to facilitate the transfer of patients who are in need of emergency care. A clinic that has documentation of its efforts to establish such a transfer agreement with a hospital that provides emergency services and has been unable to secure such an agreement shall be considered to be in compliance with this Rule." 10A N.C. Admin Code 13S .0326(a),(c) "Any patient not discharged within 12 hours following the abortion procedure shall be transferred to a ~~general~~ hospital licensed pursuant to Chapter 131E, Article 5 of the General Statutes."-10A N.C. Admin Code 13S .0320(c) "`Any patient having a complication known or suspected to have occurred	None.	No written agreement required; physician should assure that a transfer protocol is in place, preferably with a hospital licensed in the same jurisdiction and within reasonable proximity.	No written agreement required; physician should assure that a transfer protocol is in place, preferably with a hospital licensed in the same jurisdiction and within reasonable proximity.

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	during or after the performance of the abortion shall be transferred to a hospital for evaluation or admission."-10A N.C. Admin Code 13S .0329(b)			
Requirements for Medical Records	Shall maintain complete and permanent record containing: ● Date/time of admission and discharge; ● Patient's full and true name, address, date of birth, emergency contact information, diagnoses, duration of pregnancy, and condition on admission and discharge; ● Signed consent form; ● "[P]atient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the procedure or anesthetic to be administered, and documentation that indicates all items listed in Rule .0320(d) of this Section were provided to the patient." 10A N.C. Admin Code 13S .0321(a) Must maintain daily procedure log containing patients' name, length of gestation, type of procedure, name of physician, name of Registered Nurse on duty, and date/time of procedure. 10A N.C. Admin Code 13S .0321(e) Clinics must preserve or retain medical records in North Carolina for at least 10 years	None.	Medical record should include: procedure code or narrative description of procedure; "sufficient information to identify the patient, support the diagnosis, justify the treatment, and document the outcome and required follow-up care"; "Medical history, physical examination, lab studies obtained within 30 days of the	Medical record should include: procedure code or narrative description of procedure; "sufficient information to identify the patient, support the diagnosis, justify the treatment, and document the outcome and required follow-up care"; "Medical history, physical examination, lab studies obtained within 30 days of the

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	from the date of the most recent discharge. For minors, clinics must maintain such records until three years after the patient turns eighteen. 10A N.C. Admin Code 13S .0321(f)			
Requirements for Personnel Records	"(a) Personnel Records: (1) A record of each employee shall be maintained that includes the following: (A) employee's identification; (B) application for employment that includes education, training, experience and references; (C) resume of education and work experience; (D) copy of valid license (if required), education, training, and prior employment experience; and (E) list of references. (2) Personnel records shall be confidential. (3) representatives of the Division conducting an inspection of the clinic shall have the right to inspect personnel records. (b) Job Descriptions: (1) The clinic shall have a written description that describes the duties of every position. (2) Each job description shall include position title, authority, specific responsibilities, and minimum qualifications. Qualifications shall include education, training, experience, special abilities, and valid license or certification required. (3) The clinic shall review annually and, if needed, update all job descriptions. The clinic shall provide the updated job	None.	None.	None.

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	description to each employee or contractual employee assigned to the position. [...] (f) Employee and contractual employee records for health screening as defined in Rule .0101(7) of this Subchapter, education, training, and verification of professional certification shall be available for review by the Division." 10A N.C. Admin Code 13S .0322(a)(b)(f)			
Governing Authority Requirements	"When there is a planned change in ownership or in the chief executive officer, the governing authority of the clinic shall notify the Division in writing of the change." 10A N.C. Admin Code 13S .0318(c) "(a) The governing authority, as defined in Rule .0101(6) of this	None.	None.	None.

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
Governing Authority Requirements	"When there is a planned change in ownership or in the chief executive officer, the governing authority of the clinic shall notify the Division in writing of the change." 10A N.C. Admin Code 13S .0318(c) "(a) The governing authority, as defined in Rule .0101(6) of this Subchapter, shall appoint a chief executive officer or a designee of the clinic to represent the governing authority and shall define his or her authority and duties in writing. This person shall be responsible for the management of the clinic, implementation of the policies of the governing authority and authorized and empowered to carry out the provisions of these Rules. (b) The chief executive officer or designee shall designate, in writing, a person to act on his or her behalf during his or her absence. In the absence of the chief executive officer or designee, the person on the grounds of the clinic who is designated by the chief executive officer or designee to be in charge of the clinic shall have access to all areas in the clinic 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 clinic shall notify the Division in writing of the change. (d) The clinic's governing authority shall adopt operating policies and procedures that shall: (1) specify the individual to whom responsibility for	None.	None.	None.

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	operation and maintenance of the clinic is delegated and methods established by the governing authority for holding such individuals responsible; (2) provide for at least annual meetings of the governing authority, for which minutes shall be maintained; and (3) maintain a policies and procedures manual designed to ensure professional and safe care for the patients which shall be reviewed, and revised when necessary, at least annually, and shall include provisions for administration and use of the clinic, compliance, personnel quality assurance, procurement of outside services and consultations, patient care policies, and services offered. (e) When the clinic contracts with outside vendors to provide services such as laundry, or therapy services, the governing authority shall be responsible to assure the supplier meets the same local and state standards the clinic would have to meet if it were providing those services itself using its own staff. (f) 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. (g) The governing authority shall be responsible for ensuring the availability of supporting personnel to meet patient needs and to provide safe and adequate treatment." 10A N.C. Admin Code 13S .0318(a)(b)(c)(d)(f)(g)			

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	"(a) The following essential documents and references shall be on file in the administrative office of the clinic: (1) documents evidencing control and ownerships, such as deeds, leases, or incorporation or partnership papers; (2) policies and procedures of the governing authority, asrequired by Rule .0318 ~~.0302~~ of this Section; (3) minutes of the governing authority meetings; (4) minutes of the clinic's professional and administrative staff meetings; (5) a current copy of the rules of this Subchapter; (6) reports of inspections, reviews, and corrective actions taken related to licensure; and (7) contracts and agreements related to licensure to which the clinic is a party. (b) All operating licenses, permits, and certificates shall be displayed on the licensed premises. (c) The governing authority shall prepare a manual of clinic policies and procedures for use by employees, medical staff, and contractual physicians to assist them in understanding their responsibilities within the organizational framework of the clinic. These shall include: (1) patient selection and exclusion criteria; ~~and~~ (2) clinical discharge criteria; (3) policy and procedure for validating the full and true name of the patient; (4) policy and procedure for abortion procedures performed at the clinic; (5) policy and procedure for the provision of patient privacy in			

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	the recovery area of the clinic; (6) protocol for determining gestational age as defined in Rule .0101(5) of this Subchapter; (7) protocol for referral of patients for whom services have been declined; and (8) protocol for discharge instructions that informs patients who to contact for post-procedural problems and questions." 10A N.C. Admin Code 13S .0319(a)(b)(c)			
Required Information to Patient	"(d) Following admission and prior to obtaining the consent for the procedure, representatives of the clinic's management shall provide to each patient the following information: (1) a fee schedule and any extra charges routinely applied; (2) the name of the attending physician(s) and hospital admitting privileges, if any. In the absence of admitting privileges a statement to that effect shall be included; (3) instructions for post- procedure problems and questions as outlined in Rule .0329(d) of this Section; (4) grievance procedures a patient may follow if dissatisfied with the care and services rendered; and (5) the telephone number for Complaint Intake of the Division." 10A N.C. Admin Code 13S .0320(d) "(d) Written instructions shall be issued to all patients in accordance with the orders of the physician in charge of the abortion procedure and shall include the following: (1) symptoms and	None.	"The patient should receive verbal instruction understandable to the patient or guardian, confirmed by written post-operative instructions and emergency contact numbers. The instructions should include: ● the procedure performed; ● information about potential complications; ● telephone numbers to be used by the patient to discuss complications or should questions arise; ● instructions for medications prescribed and pain management; ● information regarding the follow-up visit date, time and location; and ● designated treatment hospital in the event of	"The patient should receive verbal instruction understandable to the patient or guardian, confirmed by written post-operative instructions and emergency contact numbers. The instructions should include: ● the procedure performed; ● information about potential complications; ● telephone numbers to be used by the patient to discuss complications or should questions arise; ● instructions for medications prescribed and pain management; ● information regarding the follow-up visit date, time and location; and ● designated treatment hospital in the event of

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	complications to be looked for; and (2) a dedicated telephone number to be used by the patients should any complication occur or question arise. This number shall be answered by a person 24 hours a day, seven days a week." 10A N.C. Admin Code 13S .0329(d)		emergency." "If the licensee is not going to be available after hours, the licensee must provide clear instructions to the patient for securing after-hours care. It is the responsibility of the licensee to ensure that the patient has sufficient information regarding how to secure after-hours care."[11]	emergency." "If the licensee is not going to be available after hours, the licensee must provide clear instructions to the patient for securing after-hours care. It is the responsibility of the licensee to ensure that the patient has sufficient information regarding how to secure after-hours care."[12]
Quality Assurance	"(a) The governing authority shall establish a quality assurance program for the purpose of providing standards of care for the clinic. The program shall include the establishment of a committee that shall evaluate compliance with clinic procedures and policies. (b) The committee shall determine corrective action, if necessary to achieve and maintain compliance with clinic procedures and policies. (c) The committee shall consist of at least one physician who is not an owner, the chief executive officer or designee, and other health professionals. The committee shall meet at least once per quarter. (d) The functions of the committee shall include development of policies for selection of patients, approval for adoption of policies, review of credentials for staff	None.	"A performance improvement program should be implemented to provide a mechanism to review yearly the current practice activities and quality of care provided to patients." "Performance improvement activities should include, but are not limited to, review of mortalities; the appropriateness and necessity of procedures performed; emergency transfers; reportable complications, and resultant outcomes (including all postoperative infections); analysis of patient satisfaction	"A performance improvement program should be implemented to provide a mechanism to review yearly the current practice activities and quality of care provided to patients." "Performance improvement activities should include, but are not limited to, review of mortalities; the appropriateness and necessity of procedures performed; emergency transfers; reportable complications, and resultant outcomes (including all postoperative infections); analysis of patient satisfaction

[11] N.C. Med. Bd., *Availability of Licensees to Their Patients* (last amended May 2012), https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/availability_of_licensees_to_their_patients.
[12] *Id*.

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	privileges, peer review, tissue inspection, establishment of infection control procedures, and approval of additional procedures to be performed in the clinic. (e) Records shall be kept of the activities of the committee for a period not less than 10 years. These records shall include: (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. (f) The clinic shall conduct orientation, training, or education programs to correct deficiencies that are uncovered as a result of the quality assurance program." 10A N.C. Admin Code 13S .0324		surveys and complaints; and identification of undesirable trends (such as diagnostic errors, unacceptable results, follow-up of abnormal test results, medication errors, and system problems). Findings of the performance improvement program should be incorporated into the practice's educational activity."	surveys and complaints; and identification of undesirable trends (such as diagnostic errors, unacceptable results, follow-up of abnormal test results, medication errors, and system problems). Findings of the performance improvement program should be incorporated into the practice's educational activity."
Laboratory Services Requirement	"(a) Each clinic shall have the capability to provide or obtain laboratory tests required in connection with the procedure to be performed. (b) The governing authority shall establish written policies regarding which surgical specimens require examination by a pathologist. requiring examination by a pathologist of all surgical specimens except for those types of specimens that the governing authority has determined do not require examination. (c) Each patient shall have the following performed and a record of the results placed in the patient's medical record prior	None.	"Appropriate laboratory studies should be obtained within 30 days of the planned surgical procedure."	"Appropriate laboratory studies should be obtained within 30 days of the planned surgical procedure."

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	to the abortion: (1) pregnancy testing, except when a positive diagnosis of pregnancy has been established by ultrasound; (2) anemia testing (hemoglobin or hematocrit); and (3) Rh factor testing. (d) Patients requiring the administration of blood shall be transferred to a local hospital having blood bank facilities. (e) The clinic shall maintain a manual in a location accessible by employees, that includes the procedures, instructions, and manufacturer's instructions for each test procedure performed, including: (1) sources of reagents, standard and calibration procedures, and quality control procedures; and (2) information concerning the basis for the listed 'normal' ranges. (f) The clinic shall perform and document, at least quarterly, calibration of equipment and validation of test results." 10A N.C. Admin Code 13S .0325			
Medical Requirements	"(b) The clinic shall have written protocols,; personnel, and-equipment to handle medical emergencies[...]which may arise in connection with services provided by the clinic. [...] (d) The clinic shall provide intervention for emergency situations. These provisions shall include: (1) basic cardio-pulmonary life support; (2) emergency protocols for: (A) administrati on of intravenous fluids; (B) establishing and maintaining airway support;	None.	"All office personnel should be familiar with and capable of carrying out written emergency instructions. The instructions should be followed in the event of an emergency, any untoward anesthetic, medical or surgical complications, or other conditions making hospitalization of a patient necessary. The instructions should include	"All office personnel should be familiar with and capable of carrying out written emergency instructions. The instructions should be followed in the event of an emergency, any untoward anesthetic, medical or surgical complications, or other conditions making hospitalization of a patient necessary. The instructions should include arrangements

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	(C) oxygen administration; (D) utilizing a bag-valve-mask resuscitator with oxygen reservoir; (E) utilizing a suction machine; and (F) utilizing an automated external defibrillator; (3) emergency lighting available in the procedure room as set forth in Rule- .2012 of this Subchapter; and (4) ultrasound equipment." 10A N.C. Admin Code 13S .0326(b)(d) "(a) The procedure room shall be maintained exclusively for surgical procedures and shall be so designed and maintained to provide an environment free of contamination. The clinic shall establish procedures for infection control and universal precautions. (b) Tissue Examination: (1) The physician performing the abortion is responsible for examination of all products of conception (P.O.C.) prior to patient discharge. Such examination shall note specifically the presence or absence of chorionic villi and fetal parts, or the amniotic sac. The results of the examination shall be recorded in the patient's medical record. (2) If adequate tissue is not obtained based on the gestational age, the physician performing the procedure shall evaluate for ectopic pregnancy, or an incomplete procedure. 10A N.C. Admin Code 13S .0328		arrangements for immediate contact of emergency medical services when indicated and when advanced cardiac life support is needed. When emergency medical services are not indicated, the instructions should include procedures for timely escort of the patient to the hospital or to an appropriate practitioner." "A physician who performs surgical or special procedures in an office requiring the administration of anesthesia services should be credentialed to perform that surgical or special procedure by a hospital, an ambulatory surgical facility, or substantially comply with criteria established by the Board." "If the physician administers the anesthetic as part of a surgical or special procedure (Level II only), he or she also should have documented competence to deliver the level of anesthesia administered."	for immediate contact of emergency medical services when indicated and when advanced cardiac life support is needed. When emergency medical services are not indicated, the instructions should include procedures for timely escort of the patient to the hospital or to an appropriate practitioner." "A physician who performs surgical or special procedures in an office requiring the administration of anesthesia services should be credentialed to perform that surgical or special procedure by a hospital, an ambulatory surgical facility, or substantially comply with criteria established by the Board."

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
Post-Operative Discharge Requirements	"(a) A patient whose pregnancy is terminated on an ambulatory basis shall be observed in the clinic to ensure that no post-operative complications are present. Thereafter, patients may be discharged according to a physician's order and the clinic's protocols. [...] (c) The following criteria shall be documented prior to discharge: (1) the patient shall be ambulatory with a stable blood pressure and pulse; and (2) bleeding and pain are assessed to be stable and not a concern for discharge. [...] (e) The clinic shall have a defined protocol for triaging post-operative calls and complications. This protocol shall establish a pathway for physician contact to ensure ongoing care of complications that the operating physician is incapable of managing." 10A N.C. Admin Code 13S .0329(a)(c)(e)	None.	"Criteria for discharge for all patients who have received anesthesia should include the following: ● confirmation of stable vital signs; ● stable oxygen saturation levels; ● return to pre-procedure mental status; ● adequate pain control; ● minimal bleeding, nausea and vomiting; ● resolving neural blockade, resolution of the neuraxial blockade; and ● eligible to be discharged in the company of a competent adult."	"Criteria for discharge for all patients who have received anesthesia should include the following: ● confirmation of stable vital signs; ● stable oxygen saturation levels; ● return to pre-procedure mental status; ● adequate pain control; ● minimal bleeding, nausea and vomiting; ● resolving neural blockade, resolution of the neuraxial blockade; and ● eligible to be discharged in the company of a competent adult."
Sanitation and Housekeeping Requirements	"(a) All supplies and equipment used in patient care shall be cleaned or sterilized between use for different patients. (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use as determined by the clinic through their governing authority." 10A N.C. Admin Code 13S .0330 "Clinics that are licensed by the Division to perform abortions	None.	"The practice should comply with state and federal regulations regarding infection control. For all surgical and special procedures, the level of sterilization should meet applicable industry and occupational safety requirements. There should be a procedure and schedule for cleaning, disinfecting and sterilizing equipment and patient care items. Personnel	The practice should comply with state and federal regulations regarding infection control. For all surgical and special procedures, the level of sterilization should meet applicable industry and occupational safety requirements. There should be a procedure and schedule for cleaning, disinfecting and sterilizing equipment and patient care items. Personnel

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
	shall comply with the Rules governing the sanitation of hospitals, nursing homes, adult care homes, and other institutions, contained in 15A NCAC 18A .1300 which is hereby incorporated by reference including subsequent amendments and editions. 10A N.C. Admin Code 13S .0202 "In addition to the standards set forth in Rule .0202 of this Subchapter, clinics that are licensed by the Division to perform abortions shall meet the following standards: (1) the floors, walls, woodwork, and windows must be cleaned at least daily; (2) the premises must be kept free from rodents and insect infestation; (3) bath and toilet facilities must be maintained in a clean and sanitary condition consistent with 15A NCAC 18A .1312; and (4) linen that comes directly in contact with the patient shall be provided for each individual patient. No such linen shall be interchangeable from one patient to another before being cleaned, sterilized, or laundered." 10A N.C. Admin Code 13S .0315		should be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment should be readily available."	should be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment should be readily available."

	Proposed Abortion Clinic Regulations	Medical Board Guidelines for Level I Procedures	Medical Board Guidelines for Level II Procedures	Medical Board Guidelines for Level III Procedures
Food Service	"Nourishments, such as crackers and soft drinks, shall be available and offered to all patients." 10A N.C. Admin Code 13S .0331	None.	None.	None.

CENTER *for* REPRODUCTIVE RIGHTS

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December 6, 2023

Submitted via electronic mail
Taylor Corpening
Rulemaking Coordinator, North Carolina Division of Health Service Regulation
809 Ruggles Drive
2701 Mail Service Center
Raleigh, NC 27699

Re: Request for Comments for Subchapter 13S Licensure of Suitable Facilities for the Performance of Surgical Abortions.

Dear Ms. Corpening and members of the North Carolina Medical Care Commission,

The Center for Reproductive Rights ("Center") is pleased to submit these comments in response to the Medical Care Commission's ("Commission") proposal to adopt temporary rules cited as 10A NCAC 13S .0101, .0104 .0106, .0107, .0109, .0111, .0112, and .0114 (imposing licensure, inspection, and building plan requirements); 0210, .0202, .0207, and .0209-.0212 (imposing construction and equipment requirements); and .0315 and .0318-.033 (regulating how services are provided, including emergency transfer and staffing requirements) posted on November 6, 2023.[1]

We urge the Commission to reconsider the proposed regulations. As a threshold matter, we object to the new licensing scheme and accompanying regulations as arbitrarily singling out non-hospital facilities offering procedural abortion care, subjecting them to onerous and medically unjustified requirements that no other providers of office-based medical care must meet. This interference with the provision of abortion services will harm patients. Clinics that provide procedural abortion care should be subject to the same generally applicable rules that govern other outpatient, office-based care.[2]

[1] Dept. of Health and Hum. Serv., Proposed Rule Changes Governing Abortion Clinics (proposed Oct. 30, 2023), https://www.oah.nc.gov/documents/rules/10a-ncac-13s-proposed-temporary-rules/download?attachment. [hereinafter "Proposed Temporary Rule"],
[2] See N.C. Medical Bd., Position Statement, 5.1.1 Office-Based Procedures, (Amended Sep. 2021), https://www.ncmedboard.org/resources-information/professional-

In addition, the proposed regulations go much further than required by S.B. 20, imposing a host of medically unnecessary restrictions that clinics must navigate in order to provide essential healthcare. While S.B. 20 authorizes the Commission to create regulations to implement its licensing scheme, the statutory text by no means requires the thicket created by the proposed regulations.

The history of the targeted regulation of abortion providers ("TRAP") nationally and in North Carolina makes clear that these regulations are part of a national effort to make abortion inaccessible.[3] State legislatures have enacted TRAP restrictions under the guise of protecting patient health and safety, but they undermine those stated interests. We strongly urge the Commission to reconsider the proposed regulations and instead draft regulations that are factually aligned with the stated reason for this regulatory action: "protecting the health and safety of people obtaining reproductive health care."[4]

The Center is a legal advocacy organization that uses the power of the law to advance reproductive rights as human rights around the world. Since 1992, the Center has worked to protect the right to abortion and other reproductive health care services, including maternal health and assisted reproduction. As part of our mission, we aim to ensure that all people have meaningful access to abortion care. The Center has successfully challenged restrictive abortion laws, including TRAP restrictions, before state and federal courts, including U.S. Supreme Court cases *Whole Woman's Health v. Hellerstedt* and *June Medical Service*s *v. Russo*, discussed in more detail below. As an organization that works to expand access to abortion care, we value the opportunity to contribute to the regulatory process.

This comment provides an overview of how TRAP laws emerged and their demonstrated purpose of shuttering abortion clinics. Section I illustrates North Carolina's TRAP scheme as part of a coordinated national effort to hinder abortion access. Section II reviews Supreme Court cases demonstrating that TRAP restrictions are not rooted in patient safety. Section III demonstrates that the proposed regulations

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resources/laws-rules-position-statements/position-statements/office-based_procedures. [hereinafter "Medical Board Guidelines for Office-Based Procedures"].

[3] *Targeted Regulations of Abortion Providers*, CENTER FOR REPRODUCTIVE RIGHTS (2015), https://reproductiverights.org/targeted-regulation-of-abortion-providers-trap/.

[4] Proposed Temporary Rule, *supra* note 1.

undermine patient health and safety and requests that the Commission reconsider the proposed regulations.

I. North Carolina's TRAP scheme is part of a nationwide effort to regulate abortion out of existence.

TRAP restrictions chip away at the right to abortion and, while this incrementalist approach reached its zenith in the 2010s, these efforts continue in states where abortion remains legal, even if not always accessible.

After *Roe* protected the right to abortion at the national level, the anti-abortion movement pivoted to a strategy of passing restrictions under the guise of "protecting women's health." This approach was informed by market research conducted by the National Right to Life Committee(NRLC), which found the public believed the anti-abortion movement's fetus-centered strategy[5] failed to take the health of the pregnant person into account.[6] A shift in the focus to justifying restrictions under the purported interest of "protecting women's health" emerged.[7] This shift is exemplified by the anti-abortion model legislation that has permeated state legislatures across the country. Since 2005, Americans United for Life (AUL) has released annual guides commonly referred to as a "playbook" of model anti-abortion legislation.[8]
The timing of the introduction of TRAP restrictions in North Carolina is noteworthy given the context of these national efforts. North Carolina was one of five states in 2013 that implemented new TRAP restrictions

[5] Daniel Mansbach & Alisa Von Hagel, *The Changing Strategies of the Anti-Abortion Movement*, POLITICAL RESEARCH ASSOCIATES (Jan. 7, 2021), https://politicalresearch.org/2021/01/07/changing-strategies-anti-abortion-movement#_ftn1. *See also* *Woman vs. Fetus: Frame Transformation and Intramovement Dynamics in the Pro-Life Movement*, Sociological Spectrum 34(2), 163, 184 (2014), https://www.tandfonline.com/doi/full/10.1080/02732173.2014.878624. ("[T]his strategy is based on the claims that the fetus, from the moment of conception, is a human being deserving equal protection under the law.").
[6] *Id.*
[7] David Cohen et. al., *Rethinking Strategy After Dobbs*, Stanford Law Review (Aug. 2022), https://www.stanfordlawreview.org/online/rethinking-strategy-after-dobbs/. *See also* Reva B. Siegel, Brainerd Currie Lecture, *The Right's Reasons: Constitutional Conflict and the Spread of the Woman-Protective Antiabortion Argument*, 57 DUKE L.J. 1641 (2008) (describing the rise of the woman-protective antiabortion argument).
[8] Jacqueline Y. Ma, "Undue" Delegation: Private Delegation and Other Strategies to Challenge Admitting-Privileges Laws, 30 Colum. J. Gender & L. 549, 555–57 (2016), https://journals.library.columbia.edu/index.php/cjgl/article/view/2737/1242.

for abortion providers, including requirements that abortion clinics meet standards similar to ASCs.[9] Importantly, there was no medical justification for these restrictions in North Carolina but what did change was a shift in the makeup of the North Carolina General Assembly and the election of an anti-abortion Governor in 2012.[10] In fact, then-Speaker of the House, Thom Tillis, infamously added numerous abortion restrictions, including a licensing scheme like the one created by S.B. 20, to a motorcycle safety bill as a backdoor attempt to quietly erode reproductive rights on the final day of the 2013 legislative session.[11] Following the enactment of the state's TRAP laws, reproductive rights advocates began bringing attention to the proliferation of TRAP in the United States, highlighting North Carolina in explaining how such restrictions do not align with patient safety.[12]

Requiring clinics offering procedural abortion to comply with burdensome licensure, inspection, and building requirements is unnecessary and undermines patient health by requiring abortion providers to expend time and resources that clinic staff would otherwise use to serve patients. For instance, the proposed regulations include licensure and inspection requirements that exceptionalize abortion providers, as other office-based providers are not subject to such requirements.[13] Failure to meet and comply with arduous administrative processes to maintain licensure includes harsh penalties including

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[9] Elizabeth Nash & Rachel Benson Gold,, GUTTMACHER INSTITUTE, LAWS AFFECTING REPRODUCTIVE HEALTH AND RIGHTS: 2013 STATE POLICY REVIEW (Dec. 2013), https://www.guttmacher.org/laws-affecting-reproductive-health-and-rights-2013-state-policy-review.

[10] *See* Election 2012: North Carolina, N.Y. TIMES (2012), https://www.nytimes.com/elections/2012/results/states/north-carolina.html.

[11] Tim Murphy, *Mr. Motorcycle Abortion Bill Goes to Washington,* MOTHER JONES (July 29, 2013), https://www.motherjones.com/politics/2013/07/kay-hagan-thom-tillis-abortion-race/.

[12] ELIZABETH NASH & RACHEL BENSON GOLD, GUTTMACHER INSTITUTE, LAWS AFFECTING REPRODUCTIVE HEALTH AND RIGHTS: 2013 STATE POLICY REVIEW (Dec. 2013), https://www.guttmacher.org/laws-affecting-reproductive-health-and-rights-2013-state-policy-review. *See* RACHEL BENSON GOLD & ELIZABETH NASH, GUTTMACHER INSTITUTE, TRAP LAWS GAIN POLITICAL TRACTION WHILE ABORTION CLINICS— AND THE WOMEN THEY SERVE—PAY THE PRICE GUTTMACHER INSTITUTE, (2013), https://www.guttmacher.org/sites/default/files/pdfs/pubs/gpr/16/2/gpr160207.pdf.

[13] Medical Board Guidelines for Office-Based Procedures, *supra* note 2.

cessation of operation.[14] Further, the proposed rule regarding inspections places abortion clinics under constant burden of having to divert time and resources from patient care to comply with the inspection process as "[a]n inspection may be conducted whenever the Division receives a complaint alleging the clinic is not in compliance with the rules of the subchapter" with no safeguard to substantiate complaints.[15]

Construction and equipment requirements subjecting abortion clinics to physical plant requirements resembling those of ASCs,[16] are unnecessary and threatens patient access. Compliance with such burdensome requirements is insurmountable for many clinics due to cost alone.[17] Although North Carolina has sixteen clinics offering abortion care, 91% of counties do not have an abortion provider. Subjecting clinics to such requirements undermine the Department of Health and Human Service's objective to maintain continuity of care as such prohibitive requirements has resulted in fewer clinics being able to provide procedural abortion care. These requirements provide no added patient health or safety benefit, as there is no significant difference in rates of complications between abortions provided in an ASC compared to office-based settings.[18] For instance, the proposed regulations mandate that abortion facilities have door widths to fit a stretcher.[19] Such a requirement is not necessary to advance patient health and safety as abortion is a far safer procedure than those provided at ASCs and the state does not require other outpatient facilities to meet such stringent plant requirements.

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[14] Proposed Temporary Rule, *supra* note 1. Medical Board Guidelines for Office-Based Procedures, *supra* note 2.
[15] Proposed Temporary Rule, *supra* note 1.
[16] North Carolina Subchapter 13C – Licensing of Ambulatory Surgical Facilities, http://reports.oah.state.nc.us/ncac/title%2010a%20-%20health%20and%20human%20services/chapter%2013%20-%20nc%20medical%20care%20commission/subchapter%20c/subchapter%20c%20rules.pdf.
[17] Medical Board Guidelines for Office-Based Procedures, *supra* note 2.
[18] *Safety of Abortion in Ambulatory Surgical Centers v. Office-base settings*, NEW STANDARDS IN REPRODUCTIVE HEALTH (June 2018), https://www.ansirh.org/sites/default/files/publications/files/safety_of_abortion_in_ascs_fact_sheet.pdf.
[19] Proposed Temporary Rule, *supra* note 1 (10A NCAC 13S.0211"Minimum width of doors to all rooms needing access for stretchers shall be three feet. No door shall swing into 5 corridors in a manner that might obstruct traffic flow or reduce the required corridor width except doors to spaces not subject to occupancy.").

The proposed regulations also impose strict ventilation and air supply requirements. Specifically, the ventilation and air supply requirements are targeted at ensuring a sterile field for surgeries, which is unnecessary for the provision of abortion care. While the state's abortion providers of course sterilize equipment and maintain clean environments, the sterile field required for surgery is unnecessary for a procedural abortion as it does not entail an incision into the body, but rather insertion of instruments into a body cavity through a natural orifice.[20] Conversely, these requirements align with the model legislation promoted by AUL,[21] and the unnecessarily burdensome plant requirements at issue in *Whole Woman's Health* which resulted in 80% of clinics closing when the Texas law took effect.[22] In fact, the purpose is not to further patient safety at all. Instead, the intent of such restrictions, as outlined above, is to regulate abortion providers out of existence.

Requiring abortion providers to comply with stringent emergency transfer and staffing regulations when abortion is safer than other procedures offered at outpatient facilities is arbitrary and does not further patient health and safety. For instance, the proposed regulations require abortion clinics have a written plan for the transfer of emergency cases to the closest hospital.[23] Such a requirement is similar to the regulatory burden at issue in both *Whole Woman's Health* and *June Medical Services*,[24] requiring providers to obtain admitting privileges. In contrast, other office-based providers are not required to maintain such a written plan. Instead, the Medical Board has outlined guidelines for level II and level III procedures in which individual providers should "assure that a transfer protocol is in place, preferably with a hospital licensed in the same jurisdiction and within reasonable proximity."[25]

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[20] Proposed Temporary Rule, *supra* note 1 (10A NCAC 13S .0212 Elements and Equipment "All air supply and exhaust systems for the procedure suite and recovery area shall be mechanically operated. All fans serving exhaust systems shall be located at the discharge end of the system. The ventilation rates shown herein shall be considered as minimum acceptable rates. (i-vii).").

[21] AMERICANS UNITED FOR LIFE, *see* supra note 17. (https://aul.org/wp-content/uploads/2022/12/Womens-Health-Protection-Act-11-2022.pdf.).

[22] See *infra* text accompanying note 38. Miriam Berg, *New Map: 80% of Abortion Providers in Texas Close Overnight*, PLANNED PARENTHOOD (Oct. 9, 2014), New Map: 80% of Abortion Providers in Texas Close Overnight (plannedparenthoodaction.org)

[23] Proposed Temporary Rule, *supra* note 1.

[24] See *infra* text accompanying note 37-44

[25] Medical Board Guidelines for Office-Based Procedures, *supr*a note 2.

The way abortion providers are arbitrarily targeted by the proposed regulations can be further demonstrated by the requirements in .0323(d).[26] This regulation requires procedural abortion clinics to always have a nurse on duty when patients are in the clinic. A health facility that provides abortion care is not exempt from this requirement even if one or more clinicians of comparable or even higher-level training (e.g., a physician or an advanced practice clinician) are present. This requirement means that regardless of who else is available, if there is no registered nurse on duty, or if the nurse has to leave suddenly, patients cannot have an abortion. Subjecting procedural abortion providers to such a requirement appears arbitrary as compared to the NCMB guidelines for outpatient procedures, which specify that recovery "should be monitored by a registered nurse or other health care professional within the scope of his or her license or certification…"[27]

Further, the TRAP licensing scheme enacted by S.B. 20 mirrors the model language in the most recent AUL playbook.[28] Specifically, AUL's "Women's Health Protection Act" includes model legislation and policy guidance, boilerplate bill text, legislative intent, definitions, and regulations mirroring ASC requirements and directs the Department of Health to promulgate rules.

II. Courts have recognized that TRAP schemes undermine patient health and safety.

TRAP laws regulate abortion facilities without medical justification and more stringently than other similar outpatient medical facilities, including those providing riskier procedures. Abortion is incredibly safe and is far safer than carrying a pregnancy to term.[29] Abortion is also safer than

[26] Proposed Temporary Rule, *supra* note 1.
[27] Medical Board Guidelines for Office-Based Procedures, *supr*a note 2.
[28] Women's Health Protection Act (Abortion Clinic Regulations), Model Legislation & Policy Guide, Americans united for Life (2022), https://aul.org/wp-content/uploads/2022/12/Womens-Health-Protection-Act-11-2022.pdf.

[29] Elizabeth G. Raymond & David A. Grimes, The Comparative Safety of Legal Induced Abortion and Childbirth in the United States, 119 Obstetrics & Gynecology 215, 216 (2012)

other common procedures such as colonoscopy, wisdom tooth removal, and tonsillectomy."[30]

Yet, the true intent of this tactic is not to improve health and safety of patients, but instead to regulate abortion clinics out of existence. Following the Court's decisions in *Roe v. Wade*, [31] *Planned Parenthood of Southeastern Pennsylvania v. Casey*, [32] and *Gonzales v. Carhart*, [33] which refined the parameters of the abortion right, anti-abortion groups responded with model legislation testing the limits of these judgments. This model legislation gave rise to two cases in which the U.S. Supreme Court struck down TRAP restrictions, *Whole Woman's Health v. Hellerstedt*[34] and *June Medical Services v. Russo*.[35] Although abrogated on other grounds by the 2022 Supreme Court decision *Dobbs v. Jackson Women's Health Organization*,[36] *Whole Woman's Health* and *June Medical* both shed light on the actual intent and effect of TRAP restrictions.

Whole Woman's Health challenged two Texas laws: (1) a requirement that doctors who provide abortion services obtain admitting privileges at a local hospital and (2) a requirement that abortion facilities meet the same requirements as ambulatory surgical centers. Texas enacted these laws to shut down abortion clinics, and they did just that, forcing more than half of Texas' clinics to close their doors. In striking down these laws, the Court observed that "abortions taking place in an abortion facility are safe—indeed, safer than numerous procedures that take place outside hospitals" and yet are not subject to similar facility requirements.[37]

Organizations of healthcare providers, such as the National Physicians Alliance, American Academy of Nursing, and Doctors for America "who

[30] National Academies Report, *supra* note 12, at 74–75 ("Abortion-related mortality is also lower than that for colonoscopies (2.9 per 100,000), plastic surgery (0.8 to 1.7 per 100,000), dental procedures (0.0 to 1.7 per 100,000), and adult tonsillectomies (2.9 to 6.3 per 100,000).")
[31] Roe v. Wade, 410 U.S. 113 (1973).
[32] Pa. V. Casey, 505 U.S. 833 (1992).
[33] Gonzales v. Carhart, 550 U.S. 124 (2007).
[34] Whole Woman's Health v. Hellerstedt, 579, U.S. 582 (2016).
[35] June Medical Services L.L.C. v. Russo, 591 U.S. __ (2020).
[36] Acknowledging the U.S. Supreme Court's June 2022 ruling which declared no federal constitutional right to abortion., Dobbs v. Jackson Women's Health Org., 597 U.S. __ (2022).
[37] Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292, 2315 (2016)

share a profound concern that the increasing political interference with – and pretextual regulation of —their professions will harm patients" submitted a brief in the case analyzing the law's intent.[38] These organizations acknowledged the legitimate role of states in regulating the provision of healthcare and examined how Texas used "health and safety" as mere pretext to make it difficult, and at times impossible, to provide abortion. The brief includes statements by leading national health organizations explaining that the Texas law would not promote patient health and safety. We encourage the Commission to review these.[39] *June Medical* challenged a Louisiana law that would have similarly prevented doctors from providing abortion services in the state unless they secured admitting privileges at a local hospital. Again, this law was designed to close clinics and undermine access to abortion—and was identical to the Texas admitting privileges law struck down in *Whole Woman's Health.*[40]

The Court struck down the challenged admitting privileges requirement, once again calling out the state for using deceptive medical regulations to shut down clinics. The ruling cited a brief led by the American College of Obstetricians and Gynecologists, and other American medical associations which underscored that "local admitting-privileges requirements for abortion providers offer no medical benefit and do not meaningfully advance continuity of care."[41]Another brief submitted by State Attorneys General outlined that the state failed to provide credible evidence to justify the need for the law to protect patient health. The brief highlights the lower court's finding that "'abortion in Louisiana has been extremely safe, with particularly low rates of serious complications" And just as in *Whole Woman's Health*, "[t]he state introduced no evidence

[38]Brief for National Physicians Alliance, et al. as Amici Curiae Supporting Petitioners, Whole Woman's Health v. Hellerstedt, 579 U.S 582 (2016),https://www.reproductiverights.org/sites/default/files/documents/National%20Physicians%20Alliance%20Skadden.pdf,
[39] *Id.* at 11-12.
[40] *June Medical Services*, 591 U.S. at 1 ("Louisiana's Act 620, which is almost word-for-word identical to the Texas "admitting privileges" law at issue in Whole Woman's Health v. Hellerstedt…").
[41] *Id.* at 38 (citing Brief for American College of Obstetrics and Gynecologists, et al. as Amici Curiae Supporting Respondents, June Medical Services L.L.C. v. Russo, 591 U.S. __ (2020), https://www.acog.org/-/media/project/acog/acogorg/files/advocacy/amicus-briefs/2019/120219-june-medical-services-llcvrusso.pdf).

showing that patients have better outcomes when their physicians have admitting privileges" or "of any instance in which an admitting privileges requirement would have helped even one woman obtain better treatment.""[42]

Further, the State Attorneys General highlight ways the Louisiana law actually would worsen patient health. "The district court found on the basis of the record before it that Louisiana's admitting-privileges requirement would affirmatively undermine the State's interest in women's health by drastically reducing the availability of safe and legal abortions in Louisiana."[43] Despite the outcome of *Dobbs*, these cases illuminate how TRAP restrictions, such as the proposed regulations, actually undermine the stated objectives of protecting patient health and safety.

III. The proposed regulations undermine patient health and safety.

Repealing North Carolina's TRAP scheme would further the Department of Health and Human Services' stated objectives to protect patient health and safety while maintaining continuity of care,[44] as the North Carolina Medical Board sets guidelines for such office-based procedures, which

[42] Brief for States of New York et al. as Amici Curiae Supporting Petitioners, June Medical Services L.L.C. v. Gee, No. 17-30391 (5th Cir. 2019). *June Medical Services* 591 U.S. at 4-6.
[43] Brief for States of New York et al., June Medical Services L.L.C. v. Gee, No. 17-30391 (5th Cir. 2019) at 15.
[44] Proposed Temporary Rule, *supra* note 1.

they differentiate into Level I,[45] II,[46] and III[47] procedures, based on, for example, the type of sedation used and risk of complications for a particular procedure. In North Carolina, non-abortion procedures performed in the office-based setting (i.e., one that is not an ASC or other specialized facility)[48] include invasive procedures and include procedures where general anesthesia is used. Such procedures are more invasive than abortion and have higher complication rates than abortion, including liposuction (5% complication rate); breast augmentation (10.6% complication rate for most common complication[49]); abdominoplasty (10–20% complication rate[50]); gluteal fat grafting (mortality rate of one in 3,000,96 compared to 0.58 in 100,000 for abortion[51]). All of these

[45] Level I office-based procedures are defined as "any surgical or special procedures" that (1) "do not involve drug-induced alteration of consciousness"; (2) "where preoperative medications are not required or used other than minimal preoperative tranquilization of the patient (anxiolysis of the patient)"; (3) "where the anesthesia required or used is local, topical, digital block, or none"; and (4) "Where there is only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely." N.C. Med. Bd., Position Statements: Office-Based Procedures (last amended Sept. 2021), https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/office-based_procedures.

[46] Level II office-based procedures are defined as "any surgical or special procedures" that (1) "require, or reasonably should require, the use of a major conduction blockade, deep sedation/analgesia, or general anesthesia;" and (2) "where there is only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely." *Id.*

[47] Level III office-based procedures are defined as "any surgical or special procedures" that (1) "require,
or reasonably should require, the use of major conduction blockade, deep sedation/analgesia, or general
anesthesia"; and (2) "where there is only a moderate risk of surgical and/or anesthetic complications and the need
for hospitalization as a result of these complications is unlikely." *Id.*

[48] Such settings include dialysis facilities, cancer treatment facilities, and plastic surgery practices.

[49] Hannah Headon et al., Capsular Contracture after Breast Augmentation: An Update for Clinical
Practice, 42 Archives Plastic Surgery 532 (2015).

[50] Pedro Vidal et al., Abdominoplasty: Risk Factors, Complication Rates, and Safety of Combined
Procedures, 44 Archives Plastic Surgery 457 (2017).

[51] Am. Soc'y of Plastic Surgeons, Plastic Surgery Societies Issue Urgent Warning About the Risks
Associated with Brazilian Butt Lifts (Aug. 6, 2018),
https://www.plasticsurgery.org/news/press-releases/plastic-surgery-societies-issue-urgent-warning-about-the-risks-associated-with-brazilian-butt-lifts.

procedures are currently performed in office-based, non-ASC facilities in North Carolina.

Further, doctors, nurses, and medical professionals who provide or assist in the provision of abortion care are already subject to North Carolina's generally applicable professional licensure, health, and tort laws and regulations. For instance, the Medical Board has the power to place physicians and physicians assistants on probation, impose other sanctions, or suspend or revoke their licenses for a variety of acts or conduct.[52]

In the year and a half following the overturning of *Roe*, public health experts, medical associations, and legal scholars have worked to educate government officials and the public about the dire effects of abortion bans and the related public health consequences, including an increase in maternal and infant mortality.[53] North Carolina's twelve-week ban has demonstrably hindered patient care as abortion has decreased by 31% since the law took effect in July.[54] In addition to the ban, the state's TRAP restrictions further exacerbate this public health crisis as compliance with such burdensome restrictions depletes resources, especially time, that providers would otherwise use to serve patients.[55] As a long-standing body comprised of healthcare providers responsible for licensing and regulating healthcare facilities in furtherance of the Department of Health and Human Services objectives to ensure patient health and safety,[56] the Commission is well poised to put forth regulations that are based on medical evidence as opposed to those put forth by state legislators seeking to undermine abortion access in the state.

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[52] N.C. Gen. Stat. § 90-14.

[53] THE U.S. MATERNAL HEALTH DIVIDE: THE LIMITED MATERNAL HEALTH SERVICES AND WORSE OUTCOMES OF STATES PROPOSING NEW ABORTION RESTRICTIONS, COMMONWEALTH FUND (Dec. 2022), U.S. Maternal Health Divide: Limited Services and Worse Outcomes | Commonwealth Fund.

[54] *New Data Show a 31% Decrease in Abortion in North Carolina After Recent Implementation of 12-Week Ban and In-Person Counseling Requirement*, GUTTMACHER INST. (Oct. 11, 2023), https://www.guttmacher.org/news-release/2023/new-data-show-31-decrease-abortions-north-carolina-after-recent-implementation-12.

[55] MERCIER ET AL., *TRAP laws and the invisible labor of US abortion providers*, CRIT PUBLIC HEALTH. 26(1),77-87 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4999072/.

[56] HEALTH CARE FACILITIES FINANCE ACT ANNUAL REPORT, N.C. MEDICAL CARE COMM'N, 4-5 (June 30, 2022), https://info.ncdhhs.gov/dhsr/ncmcc/pdf/2022/HealthCareFacilitiesFinanceActAnnualReport-June302022.pdf.

For the reasons outlined above, we request that the Commission reconsider promulgating regulations that would undermine the health and safety of North Carolinians and instead craft rules that are more aligned with those asserted interests.

Thank you for the opportunity to submit these comments.

Respectfully Submitted,

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