# DHHS / OSBM Review Permanent Rule Adoption With Substantial Economic Impact

# **Agencies Proposing Rule Change**

North Carolina Medical Care Commission

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## **Overview**

State Government Impact	Yes
Local Government Impact	Yes
Private Sector Impact	Yes
Substantial Economic Impact	Yes

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Appendix B: Community Paramedicine Pilot Program: Report to the Joint Legislative Oversight Committee on Health and Human Services and Fiscal Research Division

# **Authorizing Statutes**

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

G.S. 131E-155

G.S. 131E-156

G.S. 131E-158

G.S. 131E-162

G.S. 143-508

# **Titles of Rule Changes Proposed for Amendment**

The following rules reflect the changes needed to update unnecessary standards, clarify ambiguous language, incorporate changes in practice settings due to new initiatives, and to provide all regulated entities and the public the most efficient and effective structure for services regulated for emergency medical and trauma systems.

<u>10A NCAC 13P</u> (See proposed text of these rules as Appendix A.)

Section .0100 – Definitions

.0102 – Definitions (Amend)

Section .200 – EMS Systems

.0201 – EMS System Requirement (Amend)

.0222 – Transport of Stretcher Bound Patients (Amend)

Section .0300 – Specialty Care Transport Programs

.0301 – Specialty Care Transport Program Criteria (Amend)

Section .0500 – EMS Personnel

.0505 – Scope of Practice for EMS Personnel (Amend)

.0506 – Practice Settings for EMS Personnel (Amend)

<u>Section 0900</u> – Trauma Center Standards and Approval

.0904 – Initial Designation Process (Amend)

Section .1500 – Denial, Suspension, Amendment, or Revocation

.1502 – Licensed EMS Providers (Amend)

.1505 – EMS Educational Institutions (Amend)

Five rules are being amended with technical changes only with no economic impact: Rules .0222, .0301, .0904, .1502, and .1505.

The following sections of this report will analyze the expected costs and benefits of the rule amendments with economic impact:

- Change the setting and medical oversight of EMS-credentialed personnel to facilitate the formation of Community Paramedic/Mobile Integrated Healthcare programs (Rules .0102, .0505, .0506)
- Include federal facilities in the definition of a hospital (Rule .0102)
- Require local EMS Systems to provide mass gathering plans to OEMS for review upon request (Rule .0201)

# Analysis: Community Paramedic (CP)/Mobile Integrated Health (MIH) Program

## Community Paramedic/Mobile Integrated Healthcare Program Background

Statewide as well as nationally, growing challenges are adversely impacting healthcare facilities and EMS organizations. In most areas emergency departments and EMS agencies are becoming the safety net for non-emergency healthcare. "Repeat" users of EMS further compound these already overburdened services.

Emergency department overcrowding has been well documented in recent years. Many of the public are using the emergency departments as a source of primary care.<sup>ii</sup> Mental health and substance abuse patients consistently spend numerous hours in the emergency department in order to get medical clearance for admission to an appropriate treatment facility.<sup>iii</sup> Chronic disease patients that are readmitted to a hospital within an established timeframe and are no longer eligible for reimbursement, placing more pressure on healthcare facilities not only to manage these patients during their stay but also after discharge.<sup>iv</sup>

Under normal circumstances the EMS response results in the patient being transported to the emergency department, whether the "chief complaint" is an emergency or not. Individuals suffering from mental health/substance abuse account for a large proportion of repeat users and can overwhelm an EMS agency and the hospitals. The negative impacts are both in operational efficiency (lost/unproductive unit hours and bed capacity), increasing costs, and poor patient outcomes.

A solution requires "out of the box" ideas that go well beyond the typical 911 EMS ambulance response. If insanity is doing the same thing over and over again expecting different results, what does this say about the current system? The EMS response has to become more efficient and more focus placed on the patient outcome after the EMS assessment and the healthcare facility discharge. An EMS ambulance response is no longer the most appropriate means to meet the needs of these patients.

Existing reimbursement mechanisms do not reward EMS systems or hospital systems for providing the appropriate care in the most appropriate setting or providing post-discharge services to prevent readmissions. EMS reimbursement is tied to "transport" of the patient to a hospital, making even "outside the box" ideas or solutions a fiscal nightmare. CP/MIH programs often seek a way to avoid unnecessarily transporting patients to the Emergency Department. As a result, EMS must absorb the expense of the program as well as the foregone revenue from reduced transports. In many cases, EMS is incentivized to do the wrong thing for the patient if they want to be paid for their service.

# **Proposed Interventions**

A national trend has redefined a more appropriate response to these issues, community paramedic programs (also referred to as mobile integrated healthcare). The programs use credentialed EMS personnel to assess and monitor patients that local healthcare providers (EMS agencies or healthcare organizations) have previously identified as a concern. The proposed

rules will facilitate the voluntary formation and implementation of community paramedic programs statewide.

A "on size fits all" approach is not conducive to a successful community paramedic program. Therefore, the proposed rules provide only a broad definition of CP/MIH programs and the rules do not specify programmatic requirements for such programs. Each county, community, or healthcare organization will have different needs. Some may focus the mental health patients (which may include transport to an alternate facility rather than an emergency department). Other EMS agencies may focus on patients that repeatedly request EMS within a specified time period. Healthcare organizations may focus on chronic disease patients after discharge to reduce the readmission rates. Every community is different, the most important component of program development is focusing on the specific needs of the population served and designing a program around them.

The current rules provide sound guidance for the 911 EMS system in each county. The OEMS has a strong history of providing appropriate regulatory oversight and supporting the EMS Systems in North Carolina. The EMS systems are composed of dispatch centers, first responders, ambulance transport agencies, educational programs, and medical oversight. All of these components work well to provide appropriate emergency medical care to the patients who need transport to the emergency department.

However, evaluating the need for a CP/MIH program may involve EMS credentialed personnel operating outside of the 911 System setting. The proposed rule changes more explicitly address credentialed EMS personnel functioning under a medical director in a setting other than the 911 System to provide greater flexibility and to expand this EMS practice setting capacity beyond the local government 911 System.

## Summary of Community Paramedic Related Revisions

**Rule .0102** – Definitions are being amended to clarify Alternative Practice Setting, Medical Director and Medical Oversight for practice settings. Definitions for Community Paramedicine and Mobile Integrated Healthcare have been added. Grammatical and technical changes are being updated as well.

The definition of "Alternative Practice Setting" is being amended to remove practice restrictions of "a clinical environment." This simplifies the Alternative Practice Setting as any setting that may not be affiliated with an EMS System. "Community Paramedicine" is being added to clarify the program as a practice setting under the EMS System. Definitions for "Medical Director" and "Medical Oversight" have been updated to reflect general practice settings. "Mobile Integrated Healthcare" was added as it is a nationally used term synonymous with community paramedicine.

Rule .0505 – Scope of Practice for EMS Personnel – is being amended as a technical change to more accurately reflect the expansion of practice settings. This change does not restrict the ability of credentialed EMS personnel function only when affiliated with an EMS System.

**Rule .0506 – Practice Settings for EMS Personnel** – is being amended to add CP/MIH programs as a practice setting. Refer to the previous discussion in the Overview and in Rule .0102 for details of this setting.

# Existing Research on the Effectiveness and Efficiency of CP/MIH Programs

National EMS journals and other publications have documented numerous articles of various programs, how they were established, the criteria for the program, and local successes based on patient outcomes. Vi The OEMS has worked with agencies to conduct pilot programs. During the past several years, North Carolina agencies have shared information presented and discussed at conference meetings hosted by the North Carolina Association of EMS Administrators.

To determine whether the benefits of any individual CP/MIH program exceeds the costs, three main questions must be answered:

- 1. How many emergency department visits are avoided as a result of the program?
- 2. Does the avoided cost of transport and treatment in the emergency room exceed the cost of operating the community paramedicine program plus any alternative treatment?
- 3. What is the difference in patient outcomes attributable to the program?

While observational data on patient outcomes and emergency department usage trends is promising, vii the effectiveness and efficiency of CP/MIH programs cannot be determined from the existing case studies. Thus far, program implementation designs do not allow researchers to separate the effect of the program on emergency department use and patient outcomes from other factors. Therefore, the number of avoided emergency department visits and improvements in patient outcomes attributable to the program is unknown. Comprehensive data on program cost and treatment costs are not available.

Furthermore, each CP/MIH program is unique. Individual programs differ in their target populations, interventions, and outcomes. Therefore, it is not possible to assess CP/MIH programs as a whole. North Carolina's three unique pilot programs are summarized below.

# Characteristics of North Carolina's Community Paramedic Pilot Programs

The North Carolina General Assembly allocated \$350,000 in 2015 to fund a Community Paramedicine Pilot Program. Session Law 2015-241 Section 12A.12 allowed the Department of Health and Human Services to establish up to three program sites. The three sites selected (on defined) are diverse and reflect the eastern, central, and western geographic areas of the state. McDowell County is a mostly rural, county based EMS system. Wake County is a large metropolitan, county based EMS system. New Hanover County is a medium metropolitan, hospital based EMS system. A report of the Pilot Programs to the Joint Legislative Oversight Committee on Health and Human Services and Fiscal Research Division yielded the following information.

#### McDowell County EMS

McDowell County's program has 2.5 Full Time Equivalent community paramedic positions which focused on 230 patients which were identified as high volume EMS and Emergency Department uses during a seven month period. Over the course of the pilot, these targeted individuals were

served by the program 125 times. It is unclear how many of these encounters actually prevented emergency department visits; it is not possible to determine whether the individuals would have visited the emergency department in the absence of the program.

Although the total avoided emergency department visit costs cannot be determined, a conservative estimate of the average cost of a single ambulance transport and emergency department visit is \$823. This estimate is based on the <u>average reimbursement rate</u> for the ambulance transport and the lowest acuity patient in the Emergency Department for all payor types.

McDowell County's figures were only based on average reimbursement rates for EMS transports for each payment type. This was combined with the average lowest acuity reimbursed rate for the Emergency Department. The reality is that the cost of providing the service usually exceeds the "average" reimbursement rates for EMS and the Emergency Department.

## New Hanover Regional EMS

New Hanover Regional EMS is a hospital based agency utilizing 5 FTE paramedics for their community paramedic program, serving multiple counties. New Hanover began their program after reviewing data which revealed that 10 patients accounted for over 700 "non-emergency" responses in a one year period. The program focuses on three main patient groups; high risk readmissions, high utilizers of the healthcare system, and readmission of ACO patients participating in a Medicare Shared Savings Plan.

The program performed 3,055 patient visits and assisted 824 new patients in FY 2016 to lower readmissions. Readmission rates for high risk patients in the program were 5% less than the hospital average. All patients enrolled in the program were 7% less than the hospital rate. The program also enrolled 20 of the highest EMS and Emergency Department utilizers. Over the course of one year, New Hanover observed a 27% reduction in their top users' transports. The community paramedic program documented a decreased in expenses of \$558,000 for these utilizers, including EMS transports, ED visits, and inpatient hospitalizations. The median decreased charge per patient was \$78,625. It is not possible to determine from the case study how much of this change is attributable to the program intervention or other factors.

# Wake County EMS

Wake County EMS (Raleigh) is a county based system utilizing 14 FTEs staffing 5 units across the county for their community paramedic program. Wake identifies these as Advanced Practice Paramedics (APP). These personnel also respond to high acuity 911 calls in the Wake system. The program partners with hospitals and healthcare systems in managing high utilizers, congestive heart failure, and other transitional care patients to reduce operational burdens and costs of care. As part of the 911 system, the program also evaluates patients for acute mental health or substance abuse crises. Medically approved screening criteria may be utilized to redirect patients to the primary psychiatric or substance abuse facility rather than the emergency department.

During an eleven month period the program evaluated a total of 1,191 mental health and acute substance use patients. Nearly half (47%) were provided appropriate services in the home or in non-emergency department settings. It is not possible to determine whether, in the absence of the

program, those individuals would have visited the emergency department. Wake County did not have financial impact information listed in the report.

The program also partnered with Community Care of Wake and Johnston County to provide gap coverage for congestive heart failure and transitional patients recently discharged. The Wake County APP assisted 57 patients by conducting 169 home visits. Financial data was only provided for 8 of the patients.

Over the course of ten months, Community Care documented reductions in inpatient cost to Medicaid (62% reduction of \$31,179) and ED costs to Medicaid (75% reduction of \$19,090). 50% of the patients had no hospitalizations one year after enrolling in the program. It is not possible to determine how much of this change over time is attributable to the program intervention or other factors.

## Economic Impact of Implementing CP/MIH Programs in North Carolina

Since this is an optional program and defined locally, impact costs and benefits are unique for each program. OEMS expects at least 8 programs to be initiated or expanded in the near future. OEMS cannot predict how many of the numerous hospital systems and 101 EMS systems may eventually choose to implement a CP/MIH program.

Cost components of the programs could include development of processes (referrals, care plans, monitoring, transition of patients to other care agency or out of the program, obtaining assistance from other agencies), additional positions, additional education or training requirements, potential clinical hours, and any additional equipment (medical equipment, communications, or vehicles). Due to the diversity of individual programs, it is not possible to estimate costs for most program components. The minimum financial impact would be personnel and educations hours, estimated at an average of \$22 per hour (\$45,760 per year) for a paramedic. Reimbursement rates negotiated between DMH/DD/SA and OEMS for using alternative destinations for behavioral and substance abuse patients can be used for comparison purposes as a rough estimate of the perencounter operational costs of a CP/MIH program. DMH/DD/SA reimbursement rates ranged from \$164 to \$211 per patient, depending on whether the patient was transported to an alternative destination or treated by EMS in-home but not transported. Note that CP/MIH program costs can be highly variable, depending on the target population and the services provided.

The proposed rules expand the allowable EMS practice settings. If CP/MIH programs become reimbursable in the future and many hospital systems adopt CP/MIH programs, this could create competition between local EMS systems and hospital systems for EMS-credentialed employees.

As seen in these three programs, some personnel do only CP/MIH duties, others still provide 911 services and perform as community paramedics. In order to promote more cost efficiency, the OEMS has not set specific educational requirements for CP/MIH programs. Because the programs are so diverse, the program medical director is responsible for training and education in order to best meet the program needs. These rules provide flexibility for the needs of any program, but also insure that appropriate medical oversight is provided and EMS credentialed personnel must function within the scope of practice as defined by the North Carolina Medical Board.

The benefits are especially challenging to quantify for these programs given the unique nature of each individual program and the limitations of the research literature on the effectiveness of these programs. The three programs in the pilot program suggest not only savings/cost avoidance, but better patient outcomes. Benefits could include improved patient outcomes, reduced medical care costs for the private and public sector, more ambulances available for other calls, potentially decrease ambulance holding times in emergency departments, and reduce emergency department congestion. While many of these benefits are case-specific and unquantifiable, North Carolina's pilot program data provide a rough estimate of the magnitude of the potential benefits of avoided ED utilization on a per-unit basis:

- Cost estimates from the North Carolina Division of Medical Assistance used the <u>lowest</u> Medicaid reimbursement rate for ambulance transport and emergency department visit. The range was \$354 \$507 per avoided transport and emergency department visit combined.
- A 2013 study funded by the National Institute of Health, and published by the Public Library of Science, found that the median charge for the ten most common outpatient conditions in the emergency department was \$1,233.<sup>ix</sup>
- DMA provided NCOEMS with the actual amount paid for three common ED outpatient diagnoses, for the three pilot counties used in this grant (McDowell, New Hanover, and Wake). These three (congestive heart failure, pneumonia, and diabetes) are just a small sample of what is seen in the emergency department. The average amount paid for those three diagnoses, in the three pilot counties is \$189.16.

## Analysis: Hospital Definition (Trauma Related) Revisions and its Anticipated Impact

**Rule .0102** – Definitions are being amended to include federal facilities to the hospital definition. Womack Army Medical Center and Naval Medical Center Camp Lejeune are not licensed by the North Carolina Department of Health and Human Services. Administrators from these facilities have communicated an interest in pursuing state Trauma Center Designation from the OEMS.

The American College of Surgeons (ACS) and the U.S. Department of Defense Military Health Systems (MHS) have formed a partnership to improve educational opportunities, systems-based practices, and research capabilities to advance high quality, cost-effective care for surgical patients. The ACS is taking the lead role in a national effort to join the nation's military and civilian trauma systems into one composite national trauma system. This change will strengthen North Carolina's partnership with these federal facilities and ultimately provide a higher standard of trauma care for these patients in a closer proximity to the citizens they serve. Studies have shown injured patients treated at designated trauma centers have better outcomes than other hospitals.<sup>x</sup>

Since Trauma Center designation is optional, applications for either of these federal facilities would be processed as any other new application. The estimated time for a program manager processing a new trauma center applications is approximately 8 hours. Coordinating the site visit by clerical staff is estimated at approximately 24 hours. Site visits and designation renewals occur every 4 years.

Salary Grade to Represent Comparable Position	Average Annual Compensation	Cost/Hr.
Management level positions (sg 76-78)	~102,000	~\$49
Clerical level positions (sg 59- 61)	~\$47,850	~\$23

References to OEMS staff hourly salaries are an average for each salary range grade based on the position levels including fringe currently budgeted for agency employees

Application Review – Manager	~\$392
Coordination of Site Visit – Clerical	~\$552

The facility must function at a trauma service corresponding to the respective level applied for and include submission of trauma data for twelve months prior to the designation as defined in Rules .0901 Trauma Center Criteria and .0904 Initial Designation Process. The facility seeking designation would have to comply with specific positions to include a trauma program manager and trauma register. The average trauma program manager and trauma register costs are based upon salary estimates from different North Carolina locations.<sup>xi</sup> The initial purchase for the North Carolina Trauma Registry software program, provided through Digital Innovation, Inc., as well as the estimated annual maintenance contract agreement is estimated below.

Trauma Program Manager Salary with Benefits	~\$160,800	~\$77 hr
Trauma Registrar Salary with Benefits	~\$68,500	~\$33 hr
•		
Digital Innovation, Inc. initial software purchase (	(5 users)	~\$15,000
Digital Innovation, Inc. annual maintenance agree	ment	~\$5,000

OEMS assumes the initial request for designation will be as a Level III Trauma Center. The site team for a Level III initial visit is defined in Rule .0904. These include one trauma surgeon (defined), one emergency physician (defined), and one trauma program manager (defined). The OEMS contracts with individual team members and the facility requesting designation is billed for the team's time, travel, and lodging. Costs typically vary due to locations of team members. Average site visit costs range between \$3500 and \$5000.

Approximately 12 hours of OEMS manager-level staff time is devoted to each site visit at a cost of \$588. Costs to OEMS staff serving as site visit team members are not passed on to the facility

## **Impact Summary**

Year 1 Economic Impacts	Costs	Benefits
Federal Government	~\$254,300	
State Government	~\$6,532	5,000
Local Government		
Private Entities	Revenue shifting between service facilities (unquantified)	Better trauma care for local residents (unquantified)
Total	~\$260,832	5,000

#### **Analysis: EMS System Requirements**

Rule .0201 – Section (13)(G) is being amended to provide EMS Systems the ability to have more clear oversight of coverage provided for the public at mass gathering. This change clarifies how and which EMS credentialed personnel will provide coverage to the public-at-large at such events. Local EMS System officials and the Medical Director determine the appropriate EMS coverage for the mass gathering events to insure the care provided is compliant with local medical oversight protocols and practices. These plans are not reviewed by OEMS and are kept locally.

#### **Impact**

## **County Government Employees**

Position	Average Annual Compensation (plus	Cost/Hr
	20% benefits)	
Assistant Director of EMS	~\$70,069	~\$33

These positions are classified in the *University of North Carolina School of Government "County Salaries in North Carolina 2017" http://www.sog.unc.edu/publications/reports/county-salaries-north-carolina-2017* 

OEMS estimates a maximum of two hours to update the mass gathering plan and would be completed by an assistant chief or director of the agency. The plan does not require review by OEMS, but it must be available if requested. There are 101 EMS Systems in North Carolina.

Federal Government	~\$6,666
State Government	\$0
Local Government	\$0
Private Entities	Unquantified benefits from appropriate EMS coverage
Total	~\$6,666

#### Conclusion

Community Paramedicine and Mobile Integrated Healthcare are synonymous terms for the nationwide growth of broader EMS services' efforts to reduce repeat users of ambulance response/transports, reduce unnecessary emergency department visits, coordinating multiple services to insure better patient outcomes, and reducing hospital readmission rates. The OEMS has defined these programs to allow local communities and healthcare organizations to establish "customized" programs to meet the local needs. The "Community Paramedic Pilot Programs" report has documented the successes of several those programs, well enough that the Legislature has approved the grant funding for another year.

The expansion of practice settings to include CP/MIH programs further opens the door to career options for EMS personnel other than the 911 EMS provider setting. The setting may also serve to push the EMS profession towards future licensure and recognition as an "allied health" provider.

Every effort has been made to minimize any financial burden that may be associated with compliance with these proposed rules. The primary building block for the programs centers on the medical oversight. The Medical Director defines the plan of care, insures the scope of practice, and guides the multidisciplinary team to insure quality patient-centered care. The CP/MIH programs strive to avoid costly repetitive transports, emergency department visits, and readmissions to facilities.

An unfortunate reality is that EMS reimbursement is based on transport. The success of these programs results in fewer transports and unnecessary emergency department visits. The dilemma facing EMS organizations is doing what is best for the patient, but the cost is lost reimbursement. Currently, CP/MIH programs are not eligible for reimbursement. However, expansion of the programs may create a larger base to push for reimbursement in the future. Until then, agencies will continue to absorb the costs, but also compile valuable data on patient outcomes. OEMS is optimistic that increasing data will continue to validate better patient outcomes and cost savings (specifically impacts on the emergency departments). This data will be vital in the efforts to achieve future reimbursement for the CP/MIH programs. The OEMS will continue to partner with EMS providers, other stakeholders, and the Division of Medical Assistance to seek new alternatives for funding for these programs.

Amending the "Hospital" definition to include the federal military facilities allows the opportunity for those facilities to enhance their relationship and influence with the surrounding communities. The American College of Surgeon is also a driving force for civilian and military collaboration for trauma. If they choose to seek state trauma center designation, the rapport and support from these

facilities will further strengthen available state resources related to trauma and disaster management.

The impact of the proposed rule change is likely to be substantial but is unquantified; however, there is reason to believe the impact would be substantial. Overall, OEMS believes that the effect of incorporating these changes will benefit the quality of care and safety provided to the citizens of North Carolina.

#### **Alternatives**

OEMS could mandate and define a one-size-fits-all paramedicine program. Mandated programs would require specific outcome goals, operational criteria, education, and monitoring. Establishing an education program criteria would add significant cost to OEMS to develop the content as well as to each local program. The top down directive would further burden the local EMS with compliance for a program that may not even meet their local community needs. Mandating a program would be costly, ineffective, and potentially adversely impact patient outcomes. Local systems/agencies conducting gap analysis of their community to build a program is vital for success.

OEMS could also mandate that any paramedicine program or alternative practice setting must function under the system and system medical oversight. This may place undue burden on the county government that may not want to participate in or take the risk for personnel working in a setting other than the 911 system. Why require a system medical director and the county to be responsible for EMS credentialed personnel working in a hospital emergency department or a hospital based mobile integrated healthcare program working with discharged patients. Tying these practice setting to the EMS system prohibits free enterprise. The EMS Systems are designed to meet the community's emergency response needs. These changes allow credentialed EMS personnel to progress into more of an allied health professional status. These rules allow such flexibility.

#### **Endnotes**

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- NC DHHS, (March 2017). "Community Paramedicine Pilot Program: Report to the Joint Legislative Oversight Committee on Health and Human Services and Fiscal Research Division."
- Agency for Healthcare Research and Quality (USDHHS) (2014). Specially Trained Paramedics Respond to Nonemergency 911 Calls and Proactively Care for Frequent Callers, Reducing Inappropriate Use of Emergency Service. Accessed at innovations.ahrq.gov/profiles/specially-trained-paramedics-respond-nonemergency-911-calls-and –proactively-care-frequent
- ii Tang N, Stein J, Hsia RY, Maselli JH, Gonzales R. (2010). Trends and Characteristics of US Emergency Department Visits, 1997-2007. JAMA;304(6):664–670. Accessed at: <a href="https://jamanetwork.com/journals/jama/fullarticle/186383">https://jamanetwork.com/journals/jama/fullarticle/186383</a>
  - CDC (2016). Reasons for Emergency Room Use Among U.S. Adults Aged 18-64: National Health Interview Survey, 2013 and 2014, National Health Statistics Reports, Number 90. Accessed at: <a href="https://www.cdc.gov/nchs/data/nhsr/nhsr090.pdf">https://www.cdc.gov/nchs/data/nhsr/nhsr090.pdf</a>
- iii Murawski, John (2017). Wake County EMS has one solution to overcrowded emergency rooms. *Raleigh News and Observer*. Accessed at <a href="http://www.newsobserver.com/news/local/counties/wake-county/article14433806.html">http://www.newsobserver.com/news/local/counties/wake-county/article14433806.html</a>
  - Vaya Health (2017), WNC initiative to promote mental health, reduce emergency department use. Accessed at http://rhahealthservices.org/wp-content/uploads/2017/04/News-release\_WNC-initiative-to-promote-mental-health-reduce-ED-use.pdf
- <sup>iv</sup> CMS (2016). Readmissions Reduction Program (HRRP). https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html;
  - Kaiser Family Foundation (2017). "Aiming for Fewer Hospital U-turns: The Medicare Hospital Readmission Reduction Program,". Accessible at https://www.kff.org/medicare/issue-brief/aiming-for-fewer-hospital-u-turns-the-medicare-hospital-readmission-reduction-program/
- <sup>v</sup> Soril LJ et al (2016). Characteristics of frequent users of the emergency department in the general adult population: A systematic review of international healthcare systems. Health Policy: 120(5). Accessed at: https://www.ncbi.nlm.nih.gov/pubmed/26947060
  - Bernstein, S. L. (2009), The Clinical Impact of Health Behaviors on Emergency Department Visits. Academic Emergency Medicine, 16: 1054–1059. doi:10.1111/j.1553-2712.2009.00564.x
  - NC DHHS, (November 2016). "Final Report on the Community Paramedic Mobile Crisis Management Pilot Program: Report to the Joint Legislative Oversight Committee on Health and Human Services and Fiscal Research Division." Accessible at https://ncdhhs.s3.amazonaws.com/s3fs-public/SL%202015-241%20Section%2012F%208%20d%20Community%20Paramedicine.pdf.
- vi National Association of Emergency Medical Technicians (2015). "Mobile Integrated Healthcare and Community Paramedicine (MIH-CP)," Accessible at https://www.naemt.org/docs/default-source/MIH-CP/naemt-mih-cp-report.pdf
- vii Ibid:
  - Bryan Y. Choi et al, (2016). "Mobile Integrated Health Care and Community Paramedicine: An Emerging Emergency Medical Services Concept", In *Annals of Emergency Medicine*, Volume 67, Issue 3. https://doi.org/10.1016/j.annemergmed.2015.06.005.;
  - AHRQ (2016). New Care and Referral Pathways for Nonemergent 911 Callers and At-Risk Patients Reduce Emergency Department Visits and Readmissions, Generate Substantial Cost Savings.

<sup>&</sup>lt;sup>i</sup> A total of 17,763 patients met the definition of a high utilizer in NC for calendar year 2015 according to OEMS analysis of hospital records. These patients accounted for a total of 141,176 EMS calls for service and were transported to the ED a total of 103,221 times. See Appendix B.

- https://innovations.ahrq.gov/profiles/new-care-and-referral-pathways-nonemergent-911-callers-and-risk-patients-reduce-emergency
- viii Average annual salary reported by UNC plus 20% benefits, assuming a work schedule of 2080 hours per year. *University of North Carolina School of Government "County Salaries in North Carolina 2017" http://www.sog.unc.edu/publications/reports/county-salaries-north-carolina-2017*
- ix Caldwell N, Srebotnjak T, Wang T, Hsia R (2013) "How Much Will I Get Charged for This?" Patient Charges for Top Ten Diagnoses in the Emergency Department. PLOS ONE 8(2): e55491. doi: 10.1371/journal.pone.0055491
- <sup>x</sup> Bowman, S. M., Zimmerman, F. J., Sharar, S. R., Baker, M. W. and Martin, D. P. (2008), Rural Trauma: Is Trauma Designation Associated With Better Hospital Outcomes?. The Journal of Rural Health, 24: 263–268. doi:10.1111/j.1748-0361.2008.00167.x
  - Juillard, C.J., Mock, C., Goosen, J. et al (2009). Establishing the Evidence Base for Trauma Quality Improvement: A Collaborative WHO-IATSIC Review. World J Surg 33: 1075. https://doi.org/10.1007/s00268-009-9959-8
- xi Paysa.com was used determine base salaries for the positions in North Carolina. The benefits for a private sector hospital worker, based on national data from the Bureau of Labor Statistics' Employer Cost for Employee Compensation series for the Hospitals sector, was valued at 52% of base salaries in the second quarter of 2017 (https://www.bls.gov/iag/tgs/iag622.htm).

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 to with a specific county EMS system as a condition for EMS Provider Licensing as required by Rule .0204(b)(1) .0204 of this Subchapter.
- "Affiliated Hospital" means a non-trauma center hospital that is owned by the Trauma Center or there is 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 clinical environment a practice setting that utilizes credentialed EMS personnel that may not be affiliated with or under the oversight of the 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 an EMS System or SCTP.
- (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 a hospital of its own volition reroutes a patient from the scene of an accident or medical emergency or referring hospital to a facility with a higher level of care.
- (9) "Community Paramedicine" means an EMS System utilizing credentialed personnel who have received additional training as determined by the EMS system Medical Director to provide knowledge and skills for the community needs beyond the 911 emergency response and transport operating guidelines defined in the EMS system plan.
- (9) (10) "Contingencies" mean conditions placed on a designation that, if unmet, may result in the loss or amendment of a designation.
- (10) (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.
- (11) (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.
- (12) (13) "Department" means the North Carolina Department of Health and Human Services.
- (13) (14) "Diversion" means the hospital is unable to accept a patient due to a lack of staffing or resources.

- (14) (15) "Educational Medical Advisor" means the physician responsible for overseeing the medical aspects of approved EMS educational programs.
- (15) (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.
- (16) (17) "EMS Educational Institution" means any agency credentialed by the OEMS to offer EMS educational programs.
- (17) (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.
- (18) (19) "EMS Peer Review Committee" means a committee as defined in G.S. 131E-155(6b).
- (19) (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.
- (20) (21) "EMS Provider" means those entities defined in G.S. 131E-155(13a) that hold a current license issued by the Department pursuant to G.S. 131E-155.1.
- (21) (22) "EMS System" means a coordinated arrangement of local resources under the authority of the county government (including all agencies, personnel, equipment, and facilities) organized to respond to medical emergencies and integrated with other health care providers and networks including public health, community health monitoring activities, and special needs populations.
- (22) (23) "Essential Criteria" means those items that are the requirements for the respective level of trauma center designation (I, II, or III), as set forth in Rule .0901 of this Subchapter.
- (23) (24) "Focused Review" means an evaluation by the OEMS of corrective actions to remove contingencies that are a result of deficiencies following a site visit.
- (24) (25) "Ground Ambulance" means an ambulance used to transport patients with traumatic or medical conditions or patients for whom the need for specialty eare care, or emergency emergency, or non-emergency medical care is anticipated either at the patient location or during transport.
- (25) (26) "Hospital" means a licensed facility as defined in G.S. 131E 176. 131E-176 or an acute care inpatient diagnostic and treatment facility located within the State of North Carolina that is owned and operated by an agency of the United States government.
- (26) (27) "Immediately Available" means the physical presence of the health professional or the hospital resource within the trauma center to evaluate and care for the trauma patient.

- (27) (28) "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) (29) "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) (30) "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) (31) "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) (32) "Level II Trauma Center" means a hospital that provides trauma care regardless of the severity of the injury injury, but may lack the comprehensive care as a Level I trauma center center, and does not have trauma research as a primary objective.
- (32) (33) "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) (34) "Licensed Health Care Facility" means any health care facility or hospital licensed by the Department of Health and Human Services, Division of Health Service Regulation.
- (34) (35) "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.
- (35) (36) "Medical Director" means the physician responsible for the medical aspects of the management of an EMS System, Alternative Practice Setting, SCTP, a practice setting utilizing credentialed EMS personnel or medical crew members, or a Trauma Center.
- (36) (37) "Medical Oversight" means the responsibility for the management and accountability of the medical care aspects of an EMS System, Alternative Practice Setting, or SCTP: 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.
- (38) "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) (39) "Off-line Medical Control" means medical supervision provided through the EMS System Medical Director or SCTP Medical Director who is responsible for the day-to-day medical care provided by EMS personnel. This includes EMS personnel education, protocol development, quality management, peer review activities, and EMS administrative responsibilities related to assurance of quality medical care.
- (38) (40) "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.
- (39) (41) "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.
- (40) (42) "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.
- (41) (43) "Participating Hospital" means a hospital that supplements care within a larger trauma system by the initial evaluation and assessment of injured patients for transfer to a designated trauma center if needed.
- (42) (44) "Physician" means a medical or osteopathic doctor licensed by the North Carolina Medical Board to practice medicine in the state of North Carolina.
- (43) (45) "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 trauma planning, establishing, and maintaining a coordinated trauma system.
- (44) (46) "Request for Proposal" means a State document that must be completed by each hospital seeking initial or renewal trauma center designation.
- (45) (47) "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.
- (46) (48) "State Medical Asset and Resource Tracking Tool" means the Internet web-based program used by the OEMS both daily in its daily operations and during times of disaster to identify, record record, and monitor EMS, hospital, health care care, and sheltering resources statewide, including facilities, personnel, vehicles, equipment, and pharmaceutical and supply caches.
- (47) (49) "Specialty Care Transport Program" means a program designed and operated for the transportation of a patient by ground or air requiring specialized interventions, monitoring 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.

- (48) (50) "Specialty Care Transport Program Continuing Education Coordinator" means a Level I EMS Instructor within a SCTP who is responsible for the coordination of EMS continuing education programs for EMS personnel within the program.
- (49) (51) "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.
- (50) (52) "Stroke" means an acute cerebrovascular hemorrhage or occlusion resulting in a neurologic deficit.
- (51) (53) "System Continuing Education Coordinator" means the Level I EMS Instructor designated by the local EMS System who is responsible for the coordination of EMS continuing education programs.
- (52) (54) "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 at no cost.
- (53) (55) "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.
- (54) (56) "Trauma Center Criteria" means essential criteria to define Level I, II, or III trauma centers.
- (55) (57) "Trauma Center Designation" means a process of approval in which a hospital voluntarily seeks to have its trauma care capabilities and performance evaluated by experienced on-site reviewers.
- (56) (58) "Trauma Diversion" means a trauma center of its own volition declines to accept an acutely injured patient due to a lack of staffing or resources.
- (57) (59) "Trauma Guidelines" mean standards for practice in a variety of situations within the trauma system.
- (58) (60) "Trauma Minimum Data Set" means the basic data required of all hospitals for submission to the Trauma Registry.
- (59) (61) "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 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 online at https://www.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html at no cost.
- (60) (62) "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.
- (61) (63) "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://www.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html at no cost.
- (62) (64) "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.
- (63) (65) "Triage" means the assessment and categorization of a patient to determine the level of EMS and healthcare facility based care required.
- (64) (66) "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. 2017;

Amended Eff. 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;
  - 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(a)(4) .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(28) .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 by-pass 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) a disaster plan;
  - (G) a mass-gathering <del>plan;</del> plan that includes how the provision of EMS standby coverage for the public-at-large will be provided;
  - (H) a mass-casualty plan;
  - (I) a weapons plan for any weapon as set forth in Rule .0216 of this Section;
  - (J) a plan on how EMS personnel shall report suspected child abuse pursuant to G.S. 7B-301;
  - (K) a plan on how EMS personnel shall report suspected abuse of the disabled pursuant to G.S. 108A-102; and
  - (L) 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;
- (14) affiliation as defined in Rule .0102(3) .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
- (3) EMD responsibilities in special situations, such as disasters, mass-casualty incidents, or situations requiring referral to specialty hotlines.
- (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, <del>2017.</del> 2017; Amended Eff. July 1, 2018. 10A NCAC 13P .0222 is proposed for amendment as follows:

#### 10A NCAC 13P .0222 TRANSPORT OF STRETCHER BOUND PATIENTS

- (a) Any person transported on a stretcher as defined in Rule  $\frac{.0102(49)}{.0102}$  of this Subchapter meets the definition of patient as defined in G.S. 131E-155(16).
- (b) Stretchers may only be utilized for patient transport in an ambulance permitted by the OEMS in accordance with G.S. 131E-156 and Rule .0211 of this Section.
- (c) The Medical Care Commission exempts wheeled chair devices used solely for the transportation of mobility impaired persons in non-permitted vehicles from the definition of stretcher.

History Note: Authority G.S. 131E-156; 131E-157; 143-508(d)(8);

Eff. January 1, <del>2017.</del> <u>2017;</u> Amended Eff. July 1, 2018. 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 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;" 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 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 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  $\frac{.0102(47)}{.0102}$  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. 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. 2017;

Amended Eff. July 1, 2018.

10A NCAC 13P .0505 is proposed for amendment as follows:

## 10A NCAC 13P .0505 SCOPE OF PRACTICE FOR EMS PERSONNEL

EMS Personnel educated in approved programs, credentialed by the OEMS, and affiliated with an approved EMS System functioning under physician medical oversight may perform acts and administer intravenous fluids and medications as allowed by the North Carolina Medical Board pursuant to G.S. 143-514.

*History Note:* Authority G.S. 143-508(d)(6); 143-514;

Temporary Adoption Eff. January 1, 2002;

Eff. April 1, 2003;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2,

<del>2016.</del> 2016;

Amended Eff. July 1, 2018.

10A NCAC 13P .0506 is proposed for amendment as follows:

#### 10A NCAC 13P .0506 PRACTICE SETTINGS FOR EMS PERSONNEL

- (a) Credentialed EMS Personnel may function in the following practice settings in accordance with the protocols approved by the OEMS and by the Medical Director of the EMS System or Specialty Care Transport Program with which they are affiliated:
  - (1) at the location of a physiological or psychological illness or injury, including transportation to a treatment facility if required; injury;
  - (2) at public or community health facilities in conjunction with public and community health initiatives;
  - (3) in hospitals and clinics;
  - (4) in residences, facilities, or other locations as part of wellness or injury prevention initiatives within the community and the public health system; and
  - (5) at mass gatherings or special events: events; and
  - (6) community paramedicine programs.
- (b) Individuals functioning in an alternative practice setting as defined in Rule  $\frac{.0102(4)}{.0102}$  of this Subchapter consistent with the areas identified in Subparagraphs (a)(2) (a)(1) through (a)(4) (a)(5) of this Rule that are not affiliated with an EMS System shall:
  - (1) be under the medical oversight of a physician licensed by the North Carolina Medical Board that is associated with the practice setting where the individual will function; and
  - (2) be restricted to performing within the scope of practice as defined by the North Carolina Medical Board pursuant to G.S. 143-514 for the individual's level of EMS credential.
- (c) Individuals holding a valid EMR or EMT credential that are not affiliated with an approved first responder program or EMS agency and that do not administer medications or utilize advanced airway devices are approved to function as a member of an industrial or corporate first aid safety team without medical oversight or EMS System affiliation.

History Note: Authority G.S. 143-508(d)(7);

Temporary Adoption Eff. January 1, 2002;

Eff. April 1, 2003;

Amended Eff. January 1, 2004;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016:

Amended Eff. July 1, 2018; January 1, 2017.

10A NCAC 13P .0904 is proposed for amendment as follows:

#### 10A NCAC 13P .0904 INITIAL DESIGNATION PROCESS

- (a) For initial 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:
  - 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 trauma patients yearly 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(61) .0102 of this Subchapter, and submit data to the OEMS weekly a minimum of 12 months prior to application that includes all the Trauma Center's trauma patients as defined in Rule .0102(59) .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 Subparagraphs (b)(1) through (3) 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 Subparagraphs (b)(1) through (3) 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 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. The hospital and the OEMS shall agree on the date of the site visit.

- (k) Except for OEMS representatives, any in-state reviewer 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;
  - (4) for Level I designation, one out-of-state trauma program manager with an equivalent license from another state;
  - (5) for Level II designation, one in-state program manager who is licensed to practice professional nursing in North Carolina in accordance with the Nursing Practice Act, Article 9A, Chapter 90 of the North Carolina General Statutes; and
  - (6) OEMS Staff.
- (1) All site team members for a Level III visit shall be from in-state, and, 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 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, 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 professional nursing in North Carolina in accordance with the Nursing Practice Act, Article 9A, Chapter 90 of the North Carolina General Statutes; and
  - (4) OEMS Staff.
- (m) On the day of the site visit, 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 is 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, <del>2017.</del> 2017;

Amended Eff. July 1, 2018.

10A NCAC 13P .1502 is proposed for amendment as follows:

#### 10A NCAC 13P .1502 LICENSED EMS PROVIDERS

- (a) The OEMS shall deny an initial or renewal EMS Provider license for any of the following reasons:
  - (1) significant failure to comply, as defined in Rule .0102(45) .0102 of this Subchapter, with the applicable licensing requirements in Rule .0204 of this Subchapter;
  - (2) making false statements or representations to the OEMS or willfully concealing information in connection with an application for licensing;
  - (3) tampering with or falsifying any record used in the process of obtaining an initial license or in the renewal of a license; or
  - (4) disclosing information as defined in Rule .0223 of this Subchapter that is determined by OEMS staff staff, based upon review of documentation, to disqualify the applicant from licensing.
- (b) The Department shall amend any EMS Provider license by amending it to reduce the license from a full license to a provisional license whenever the Department finds that:
  - (1) the licensee failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that Article;
  - (2) there is a probability that the licensee can take corrective measures to resolve the issue of non-compliance with Rule .0204 of this Subchapter, and be able thereafter to remain in compliance within a reasonable length of time determined by OEMS staff on a case-by-case basis; and
  - (3) there is a probability, determined by OEMS staff using their professional judgment, based upon analysis of the licensee's ability to take corrective measures to resolve the issue of non-compliance with the licensure rules, that the licensee will be able thereafter to remain in compliance with the licensure rules.
- (c) The Department shall give the licensee written notice of the amendment of the EMS Provider license. This notice shall be given personally or by certified mail and shall set forth:
  - (1) the duration of the provisional EMS Provider license;
  - (2) the factual allegations;
  - (3) the statutes or rules alleged to be violated; and
  - (4) notice of the EMS provider's right to a contested case hearing, as set forth in Rule .1509 of this Subchapter, on the amendment of the EMS Provider license.
- (d) The provisional EMS Provider license is effective upon its receipt by the licensee and shall be posted in a location at the primary business location of the EMS Provider, accessible to public view, in lieu of the full license. Pursuant to G.S. 131E-155.1(d), the provisional license remains in effect until the Department:
  - (1) restores the licensee to full licensure status; or
  - (2) revokes the licensee's license.
- (e) The Department shall revoke or suspend an EMS Provider license whenever the Department finds that the licensee:
  - (1) failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that Article and it is not probable that the licensee can remedy the licensure deficiencies within 12 months or less;

- (2) failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that Article and, although the licensee may be able to remedy the deficiencies, it is not probable that the licensee will be able to remain in compliance with licensure rules;
- (3) failed to comply with the provision of G.S. 131E, Article 7, and the rules adopted under that Article that endanger the health, safety, or welfare of the patients cared for or transported by the licensee;
- (4) obtained or attempted to obtain an ambulance permit, EMS nontransporting vehicle permit, or EMS Provider license through fraud or misrepresentation;
- (5) continues to repeat the same deficiencies placed on the licensee in previous compliance site visits;
- (6) has recurring failure to provide emergency medical care within the defined EMS service area in a manner as determined by the EMS System;
- (7) failed to disclose or report information in accordance with Rule .0223 of this Subchapter;
- (8) was deemed by OEMS to place the public at risk because the owner owner, or any officer officer, or agent was convicted in any court of a crime involving fiduciary misconduct or a conviction of a felony;
- (9) altered, destroyed, attempted to destroy, withheld, or delayed release of evidence, records, or documents needed for a complaint investigation being conducted by the OEMS; or
- (10) continues to operate within an EMS System after a Board of County Commissioners has terminated its affiliation with the licensee, resulting in a violation of the licensing requirement set forth in Rule .0204(a)(1) .0204 of this Subchapter.
- (f) The Department shall give the EMS Provider written notice of revocation. This notice shall be given personally or by certified mail and shall set forth:
  - (1) the factual allegations;
  - (2) the statutes or rules alleged to be violated; and
  - (3) notice of the EMS Provider's right to a contested case hearing, as set forth in Rule .1509 of this Section, on the revocation of the EMS Provider's license.
- (g) The issuance of a provisional EMS Provider license is not a procedural prerequisite to the revocation or suspension of a license pursuant to Paragraph (e) of this Rule.

*History Note:* Authority G.S. 131E-155.1(d); 143-508(d)(10);

Eff. January 1, 2013;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;

Amended Eff. July 1, 2018; January 1, 2017.

10A NCAC 13P .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:
  - (1) significant failure to comply with the provisions of Section .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 Section .0600 of this Subchapter within 12 months or less.
- (d) The Department shall 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 <u>.0102(45)</u> <u>.0102</u> 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 12 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(b)(6) of this Subchapter;
  - (4) the EMS Educational Institution failed to meet the requirements of a focused review within 12 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 revocation and denial. 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. July 1, 2018; January 1, 2017.