

**DHHS / OSBM Review
Permanent Rule Adoption with Substantial Economic Impact**

Agencies Proposing Rule Change

North Carolina Medical Care Commission

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Overview

Quantified Impacts	Annual Impact
Total Benefits	~\$928,200
<i>State Government</i>	<i>\$0</i>
<i>Local Government</i>	<i>\$0</i>
<i>Private Entities ¹</i>	
<i>Ambulance Manufacturers</i>	<i>~\$928,200</i>
<i>Occupant Injuries – reduced severity</i>	<i>unquantified</i>
<i>Reduced Provider Liability</i>	<i>unquantified</i>
<i>Homeowner Benefits</i>	<i>unquantified</i>
Total Costs	~\$928,200
<i>State Government</i>	<i>~\$18,200</i>
<i>Local Government</i>	<i>~\$364,000</i>
<i>Private Entities ¹</i>	<i>~\$546,000</i>
Net Impact	~\$0
Aggregate Impact	~\$1,856,400

¹ Private entities include small businesses as well as individuals affected by these rules.

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Appendix A: The EMS and Trauma Rules under revision 10A NCAC 13P.

Authorizing Statutes

The following statutes are cited in the statutory authority of the rules under revision by the MCC.
 G.S. 131E-156
 G.S. 131E-157
 G.S. 131E-160
 G.S. 143-508

Titles of Rule Changes Proposed for Adoption

These rules are identified as follows:

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

Section .0200 – EMS Systems

.0224 – Ground Ambulance Vehicle Manufacturing Standards (Adopt)

Section .0400 – Medical Oversight

.0410 – Components of Medical Oversight for Air Medical Programs (Adopt)

Summary of Revisions and its Anticipated Impact

Rule .0224 – Ground Ambulance Vehicle Manufacturing Standards is being adopted to establish a minimum manufacturing standard for all ground ambulances used for the transport of emergent and non-emergent patients in North Carolina. Providers across North Carolina have requested OEMS adopt a standard after manufacturers began requiring a waiver if the ambulance purchased did not meet specifications for one of the two standards listed below. Previously, the National Highway Traffic Safety Administration (NHTSA) KKK-A-1822F - Ambulance Manufacturing Standard was considered the industry model for the manufacture of all ambulances. This standard is now obsolete and is not being supported for revision by NHTSA. This rule removes the NHTSA standard as an option for ambulances manufactured for use in North Carolina effective July 1, 2018.

In order to insure ambulances operating in North Carolina are safe and reliable, the Office of Emergency Medical Services (OEMS) has 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.1.0¹ or the National Fire Protection Association (NFPA) 1917-2016 Standard for Automotive Ambulances.² These are currently the only two standards that address “bumper-to-bumper” manufacturing standards. Currently, these are the only two American National Standards Institute (ANSI) accredited “standards developers” issuing ambulance manufacturing standards in the United States.

The most significant impact associated with adoption of the CAAS/NFPA standards is their incorporation of three Society of Automotive Engineers (SAE) Standards³ as a manufacturing requirement. These are:

- J3026 “Ambulance Patient Compartment Seating Integrity and Occupant Restraint”;
- J3027 “Ambulance Litter Integrity, Retention, and Patient Restraint”; and
- J3027 “Ambulance Equipment Mount Device or Systems (includes additional criteria from SAE J2917 and J2956).”

¹ A copy of the CAAS GVS v.1.0 “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 \$52.00.

³ A copy of the SAE Standards may be obtained online at www.sae.org for a cost of \$76.00 each.

Costs

Approximately 90% of ambulances sold in North Carolina are manufactured by companies belonging to the REV Group: Specialty Vehicle Manufacturers. Based on information provided by this organization, all REV Group members manufacture CAAS and NFPA compliant vehicles. However, most EMS agencies are still ordering ambulances using the NHTSA KKK standard with minor variants. For North Carolina to exclude the NHTSA KKK standard and require either the CAAS or NFPA standard, the average increase in cost could be up to ~\$10,000.00 per ambulance if opting for equipment meeting the minimum SAE requirements. Since there are an average of 51 ambulances sold in North Carolina each year (five year average of the sum totals in Tables 1 and 2), the total average increase statewide is estimated at approximately \$510,000.00 annually.

Since the modifications to the stretcher mounting system will no longer be compatible with the “antler” style stretcher mounting hardware, new ambulances built using the CAAS and NFPA standards will also have to utilize an upgraded mounting system and stretcher. The OEMS has researched the prices associated with the new mounting assemble and has determined the cost for an acceptable mounting system compliant with the SAE J3027 standard is \$6,380 for a manual stretcher⁴ and an additional \$1,780 for the stretcher fastener system⁵ for a total of approximately \$8200 / vehicle.

Based on these estimates, a cost of 18,200 per vehicle is anticipated with a total annual statewide cost of approximately \$928,200.

The following numbers were obtained from the North Carolina OEMS Credentialing Information System database. However, the database is not configured to differentiate between new ambulances and remounted vehicles. The following numbers reflect the agency’s best estimation of new vehicle sales during the five year period 2012 through 2016. Assistance on determining market share and the estimated cost per vehicle to comply with the CAAS and NFPA standards was obtained through consultation with officials at the REV Group.

Table 1 Ambulance Sales in North Carolina by Manufacturers Belonging to the REV Group, Specialty Vehicle Manufacturers⁴

Manufacturer	2012	2013	2014	2015	2016	Total
AEV	27	30	23	27	33	140
Wheeled Coach	9	5	6	7	7	34
Road Rescue	12	4	2	0	0	18
Horton	1	2	1	3	0	7
McCoy-Miller	0	1	4	2	0	7
TOTALS	49	42	36	39	40	206

¹The manufacturers associated with the REV Group represent ~82% of the ambulances sold in NC.

⁴ Based on Ferno™ Model 35XWT ProFlexx™ Stretcher from MFI Medical Equipment and Supplies minus shipping and handling costs.

⁵ Based on Ferno™ Stat Trac™ Fastner System from MFI Medical Equipment and Supplies minus shipping and handling costs.

Table 2 Ambulance Sales in North Carolina by Non-REV Group Manufacturers

Manufacturer	2012	2013	2014	2015	2016	Total
Taylor Made	7	0	3	2	0	12
Excellance	5	0	0	0	0	5
Crestline	0	0	0	2	1	3
Braun	0	2	0	1	0	3
Others Combined	2	8	2	10	2	24
TOTALS	14	10	5	15	3	47

To determine how ambulances are distributed throughout North Carolina, the agency tallied the total number of licensed EMS providers by type (State, Local, and Private) and used the percentage of each type to extrapolate the number of new ambulances each may purchase using the new standards. Table 3 details the breakdown of each type.

Table 3 Number and Type of Licensed EMS Providers in North Carolina

Agency Type	Number	Percentage	Ambulances Per Year
State owned and operated	4	0.5%	<1
Local Government owned and operated	177	39.5%	~20
Privately owned and operated (Hospitals, For-Profit Non-Hospital Agencies, and Volunteer agencies)	265	60.0%	~30
TOTALS	446	100%	~51 ±

The proposed rule exempts the manufacturing standards requirement for the following reasons:

- vehicles owned and operated by an agency of the United States government are exempt pursuant to GS 131E-160;
- ambulances manufactured prior to July 1, 2018 are exempt because the expense of retrofitting these ambulances is prohibitive and are not included in the CAAS or NFPA standards;
- convalescent ambulances are not included in the CAAS or NFPA standards;
- remounted and refurbished ambulances are not included in the CAAS or NFPA standards; and
- medical ambulance/evacuation bus vehicles are not included in the CAAS or NFPA standards.

Cost Summary

	Costs	Frequency of Costs
State Government	~\$18,200	Annual Recurring
Local Government	~\$364,000	Annual Recurring
Private Entities	~\$546,000	Annual Recurring
Total	~\$928,200	

Benefits

The manufacturing standard rule is intended to reduce injury to patients and care givers involved in ambulance crashes. While the Division expects the new standards to improve ambulance occupant safety, the specific size of the injury severity reduction is unknown. Therefore, the Division cannot directly estimate the potential savings from reduced injury severity.

However, existing data can be used to make a judgement about whether the benefits of the rule are likely to exceed the costs. By quantifying the cost of crash injuries under the existing manufacturing standards, according to the injury severity, it is possible to answer the following questions:

- How much would the new manufacturing standards need to reduce injury severity to justify the costs of implementing the new rules?
- What size of a change is needed to ensure that the benefits will exceed the costs?

The current cost of ambulance occupant injuries can be calculated by using the number of reported ambulance crashes in North Carolina (ambulance occupants only)⁶, a National Highway Traffic Safety Administration (NHTSA) injury report conversion matrix⁷, and USDOT's estimates of the cost of each injury class.⁸

Ambulance crash injuries are categorized and reported based on a KABCO injury severity scale, ranging from no injury to fatal injury. It is understood that an injury observed and reported at the crash site may actually be more or less severe than the KABCO scale indicates when examined at a treatment facility. The NHTSA matrix provides the probability that each reported KABCO designation is a correct diagnosis of the injury severity. This information, together with USDOT's estimate of the cost of each injury type, can then be used to calculate the total cost associated with each designated injury in terms of 2016 dollars.⁹

The first table below reports the number of ambulance crashes in North Carolina from 2012-2016 as well as the number of occupant injuries by each KABCO severity designation. The subsequent table presents the estimated costs of those injuries.

Fatal and incapacitating ambulance occupant injuries are rare. The majority of crash injuries were reported as "possible injury" or "non-incapacitating." Excluding 2012, the last year with a fatal injury, the cost of ambulance occupant crash injuries was approximately \$4-6 million per year.

⁶ NCDOT Crash Data 1/1/12 – 12/31/16, at least one vehicle coded as "29 – EMS Vehicle, Rescue Squad."

⁷ NHTSA, July 2011, as published in the TIGER Benefit-Cost Analysis Resource Guide updated November 2016.

Accessed here: <https://cms.dot.gov/sites/dot.gov/files/docs/BCA%20Resource%20Guide%20-%20November%202016.pdf>

⁸ USDOT (November 2016). *TIGER Benefit-Cost Analysis Resource Guide*. accessed here:

<https://cms.dot.gov/sites/dot.gov/files/docs/BCA%20Resource%20Guide%20-%20November%202016.pdf>

⁹ For more detail on the methodology behind the injury severity probability matrix and the calculation of the costs by injury class, see:

USDOT (November 2016). *TIGER Benefit-Cost Analysis Resource Guide*. accessed here:

<https://cms.dot.gov/sites/dot.gov/files/docs/BCA%20Resource%20Guide%20-%20November%202016.pdf>

Number of Injuries from Reported Ambulance Crashes in NC – Ambulance Occupants Only

	2012	2013	2014	2015	2016
Reported Ambulance Crashes	284	321	367	315	419
Crashes without occupant injuries	248	300	337	286	374
Crashes with occupant injuries	36	21	30	29	45
Injuries by Type					
C (possible injury)	47	37	33	34	55
B (non-incapacitating)	13	5	10	9	12
A (incapacitating)	2	1	0	0	0
K (Fatal)	1	0	0	0	0
Total Injuries	63	43	43	43	67

Total Cost of Injuries from Reported Ambulance Crashes in NC – Ambulance Occupants Only, Reported in 2016 Dollars

Injury Designation	2012	2013	2014	2015	2016
O (no injury) ¹⁰	\$825,633	\$998,749	\$1,121,929	\$952,141	\$1,245,108
C (possible injury)	\$3,088,695	\$2,431,526	\$2,168,658	\$2,234,375	\$3,614,431
B (non-incapacitating)	\$1,673,063	\$643,486	\$1,286,972	\$1,158,275	\$1,544,366
A (incapacitating)	\$945,023	\$472,511	\$0	\$0	\$0
K (Fatal)	\$9,880,000	\$0	\$0	\$0	\$0
Total Cost	\$16,412,414	\$4,546,273	\$4,577,559	\$4,344,791	\$6,403,904

Although adopting this rule will not reduce the number of ambulance *accidents*, it is expected to result in less severe injuries when accidents do occur. In North Carolina, the most common ambulance occupant injury types are rated as “B” (non-incapacitating) and “C” (possible injury). An injury severity reduction from B (non-incapacitating) to a C (possible injury) could reduce cost by \$62,980 per injury. A reduction from a C (possible injury) to an O (no injury) could reduce cost by \$62,388 per injury.

Utilizing these figures, it is possible to calculate the size of the impact that would be needed for the safety benefits to meet or exceed the expected costs of the rule (\$928,200 per year). That impact is measured in terms of the number of injuries that must be made less severe. While there are many different combinations of B and C injury severity reductions that would achieve this break-even point, the goal of this analysis is to judge whether the extent of the necessary change is reasonably achievable by the proposed rules.

The figures below show that the safety benefits of the rules would meet or exceed the expected costs by reducing the severity of a relatively small number of injuries. For example, reducing the severity of approximately fifteen injuries at these levels would cost the annual cost to implement the rule. The second figure below shows all the combinations of B and C injury severity reductions

¹⁰ O, “no injury” is assigned at the accident site, statistically costs are associated with “no-injury” reports because of misdiagnoses. After being evaluated by a physician, some injuries are diagnosed that may not have been immediately apparent at the accident site.

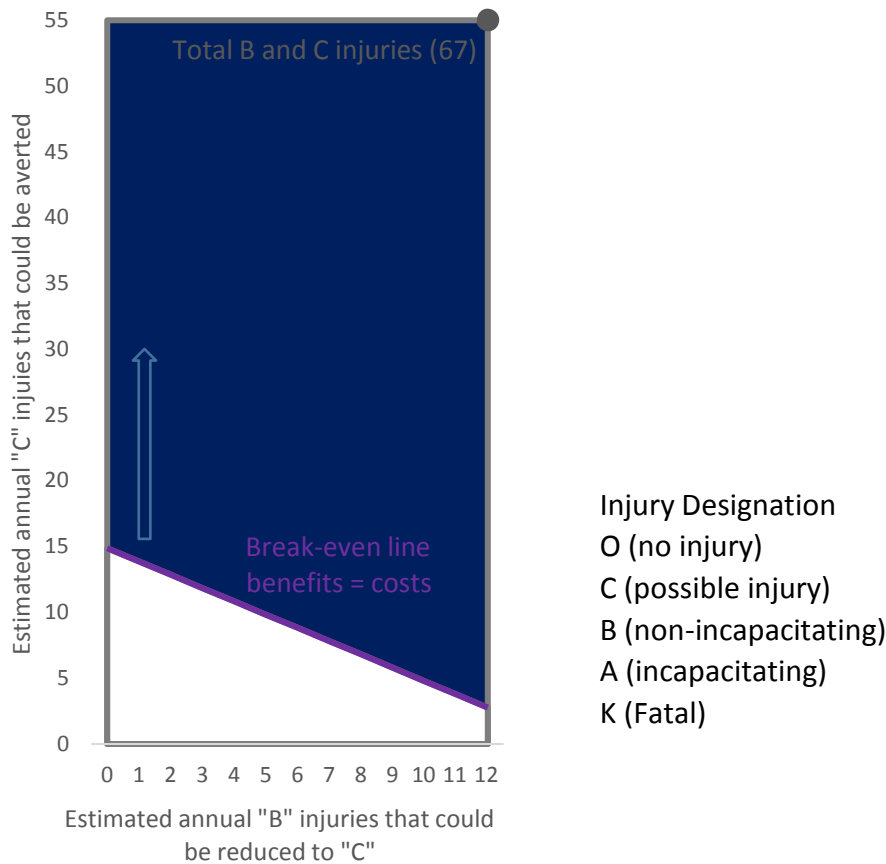
that will ensure that the benefits of the rule exceed the expected costs. This goal can be achieved by affecting a relatively small proportion of total B and C injuries. We believe this reduction is reasonably achievable with the implementation of these standards.

Example Effect Size Needed to Break Even

Estimated One Step Reduction of Injuries by Type	2016 Totals	Reduction of C by 24% B by 17%	Reduction Savings Per Injury	Potential Annual Savings
C (possible injury) to O (no injury)	55	13	\$62,388	\$811,044
B (non-incapacitating) to C (possible injury)	12	2	\$62,980	\$125,960
Total Annual Savings				\$937,004

Break-Even Point from One-Step Reduction in Injury Severity

Reducing the severity of a small proportion of annual “B” and “C” injuries will create net benefits



Uncertainties

The Value of a Statistical Life (VSL) is the foundation for estimating the cost of fatal and non-fatal crash injuries. The VSL represents society's collective willingness to pay for reducing the risk of premature mortality within the population. The USDOT recommends a VSL of \$9.6 million in 2015 dollars. In 2016 dollars, after adjusting for inflation and income growth, the VSL is \$9.88 million.¹¹

Since it is impossible to directly measure every individual's willingness to pay for reducing the population's risk of mortality, the VSL is an estimate subject to some uncertainty. Knieser et al. (2012) suggest that a reasonable range of values for VSL is between \$5.4 million to \$13.4 million in 2015 dollars.

The table below shows the total cost of NC ambulance crash injuries recalculated under a range of different VSL values. The costs of ambulance crash injuries shown in **bold** are the estimates used in this model, calculated using a VSL of \$9.88M per USDOT guidance.

Using a lower VSL value would reduce the estimated cost per injury. Therefore, the proposed rules would need to create a larger impact (reduce the severity of more injuries) for the benefits to equal or exceed the costs of the rule.

Conversely, a higher VSL would suggest that the benefits of the rules would meet or exceed the expected costs more easily. The break-even point would be reached by affecting a smaller number of injuries than what is modeled above.

Cost of All Ambulance Crash Injuries – Sensitivity to VSL Value

	2012	2013	2014	2015	2016
\$ 5,000,000	\$ 8,305,878	\$ 2,300,745	\$ 2,316,578	\$ 2,198,781	\$ 3,240,842
\$ 6,000,000	\$ 9,967,053	\$ 2,760,894	\$ 2,779,894	\$ 2,638,537	\$ 3,889,011
\$ 7,000,000	\$ 11,628,229	\$ 3,221,043	\$ 3,243,210	\$ 3,078,293	\$ 4,537,179
\$ 8,000,000	\$ 13,289,404	\$ 3,681,192	\$ 3,706,525	\$ 3,518,049	\$ 5,185,348
\$ 9,000,000	\$ 14,950,580	\$ 4,141,341	\$ 4,169,841	\$ 3,957,806	\$ 5,833,516
\$ 9,880,000	\$ 16,412,414	\$ 4,546,273	\$ 4,577,559	\$ 4,344,791	\$ 6,403,904
\$ 11,000,000	\$ 18,272,931	\$ 5,061,640	\$ 5,096,472	\$ 4,837,318	\$ 7,129,853
\$ 12,000,000	\$ 19,934,106	\$ 5,521,789	\$ 5,559,788	\$ 5,277,074	\$ 7,778,021
\$ 13,000,000	\$ 21,595,282	\$ 5,981,938	\$ 6,023,103	\$ 5,716,830	\$ 8,426,190

Other Unquantified Benefits

EMS agencies purchasing new ambulances that do not meet these standards are being required to sign a waiver by the manufacturer. Agency leaders feel these waivers potentially expose them to higher risk if an accident were to occur involving that vehicle. EMS leaders approached the Office

¹¹ USDOT (August 8, 2016). "Guidance on Treatment of the Economic Value of a Statistical Life (VSL) in USDOT Analyses – 2016 Adjustment." Accessed here: <https://www.transportation.gov/sites/dot.gov/files/docs/2016%20Revised%20Value%20of%20a%20Statistical%20Life%20Guidance.pdf>

of EMS requesting endorsement of an established national manufacturing standard. Based on feedback from agency leaders as well as the North Carolina Association of EMS Administrators, the OEMS also supports established national standards which enhance the safety of EMS technicians and the public.

The NFPA standards allow fire-based providers to continue meeting all NFPA criteria for their respective department, which in turn helps maintain the lowest possible ISO ratings. These ratings have a direct impact on the insurance costs to the citizens in that fire district. The lower the department's ISO rating, directly corresponds to lower insurance costs for the home or property owner.

Alternatives

No Action:

Failure to adopt the Ambulance Manufacturing Standards may place licensed providers, personnel, and the public at avoidable risk from potential injuries and significant costs. This alternative was dismissed because NCOEMS expects the benefits of the proposed rule to exceed the costs. Taking no action would mean foregoing the benefits associated with reduced injury severity, reduced provider liability, and potentially lower homeowner insurance rates.

One Standard Only:

Recommending the two standards allows NCOEMS to better serve the needs of all providers. CAAS standards will benefit the non-fire based agencies, meeting national safety standards at a reasonable cost. The NFPA standards allow fire-based providers to continue meeting all NFPA criteria for their respective department, which in turn helps maintain the lowest possible ISO ratings. These ratings have a direct impact on the insurance costs to the citizens in that fire district.

Rule .0410 – Components of Medical Oversight for Air Medical Programs is being adopted to clarify medical oversight criteria for air medical programs in North Carolina. Effective January 1, 2017, various EMS and Trauma Rules were revised to reflect changes mandated by a federal court injunction involving the regulation of air medical services.

Federal Court Order of Permanent Injunction

On October 15, 2008, the Honorable Louise W. Flanagan, Chief United States District Judge, United States District Court for the Eastern District of North Carolina, Western Division issued an Order of Permanent Injunction; Case No. 5:07-cb-00222-FL, *Med-Trans Corporation, Plaintiff, v. Dempsy Benton, Secretary of the North Carolina Department of Health and Human Services, in his official capacity; Robert J. Fitzgerald, Director, Division of Health Service Regulation, North Carolina Department of Health and Human Services, in his official capacity; Lee B. Hoffman, Chief of the Certificate of Need Section, Division of Health Service Regulation, North Carolina Department of Health and Human Services, in her official capacity; Drexdal Pratt; Chief of the Office of Emergency Medical Services; Division of Health Service Regulation, North Carolina Department of Health and Human Services, in his official capacity, Defendants*, that directly affected language contained in the 10A NCAC 13P EMS and trauma rules.

This order of permanent injunction enjoined the Department and Office of Emergency Medical Services from enforcing regulatory authority on any rule conflicting the statutory and regulatory authority of the Federal Aviation Administration under the Airline Deregulation Act of 1973 for the regulation of air medical programs and aircraft equipment and permitting requirements.

One of the rules affected by this order of permanent injunction is .0204 – EMS Provider License Requirements. The Department in consult with the Office of the Attorney General have determined that the language in Rule .0204 requiring affiliation for rotary wing programs with a Level I or Level II Trauma Center, and affiliation with a hospital for fixed wing programs is enjoined by this federal order. This decision is based on the fact that a refusal by either the trauma center or hospital to affiliate a provider bars entry into the market place and is in conflict with the regulatory authority of the Federal Aviation Administration, and thus must be repealed.

Since the removal of these criteria will create a void in the mechanism whereby medical oversight is provided, the adoption of rule .0410 is proposed to address this issue. The federal order recognizes the State’s authority to manage the medical aspects of air medical programs. In 2016, the Department entered into a settlement agreement with MedTrans Corporation that authorized issuance of an EMS Provider License and Air Medical Program approval under specific terms. The content of this settlement agreement were used as the basis for the content contained in the proposed rule .0410.

Since there is no difference in the content of the settlement agreement requirements for licensing and air medical program approval and those contained in the .0410 rule, there are no anticipated costs associated with adopting this rule in excess of the requirements used prior to the repeal of the language in rule .0204.

Impact

No impact associated with adopting this rule.

Conclusion

These proposed rules have been drafted to address all areas required for supporting the growth in the EMS industry and changes that have occurred with national EMS standards. The intent was also twofold. The manufacturing standard rule is intended to reduce injury to patients and care givers involved in ambulance crashes.

The rule for air medical providers is to abide by the terms of the federal court order and restrict the oversight of air medical programs solely to medical oversight. There is no increase in cost for Rule .0401 as it mirrors the content of the settlement agreement determined by the federal injunction.

Every effort has been made to minimize any financial burden that may be associated with compliance with these proposed rules. Although there will be an increase in state government, local government, and private expenditures, there are also many benefits associated with the proposed rules. 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 at minimal costs.

10A NCAC 13P .0224 is proposed for adoption 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) “Re mo un ted ” mea ns a gr o un d a mb ula nce p atie nt co mp ar t me nt mo dule that has been removed from its original chassis and mounted onto a different chassis.
- (2) “Ref ur b is hed ” mea ns up gr ad ing o r r ep air ing a n exi sti ng gr o un d a mb ula nce p atient ca re mo dule o r 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, based and operated in North Carolina shall meet one of the following manufacturing standards:

- (1) the Co mmi ss io n o n Acc r ed itat io n o f Amb ula nce Ser vice s (C AAS) “Gr o un d Vehicle Standards for Amb u lance s” (GVS) v. 1 . 0 ., inco r p o r ated her ein b y r efer enc e includ ing all subsequent amendments and editions. This document is available online at no cost at www.groundvehiclestandards.org/; or
- (2) the National Fire Protection Association (NFPA) 1917-2016 “S tandard for Automotive Ambulances,” inco r p o r ated her ein b y r efer enc e incl ud ing all subsequent amendments and editions. This document is available for purchase online at www.nfpa.org for a cost of \$52.00.

(c) The following are 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) convalescent ambulances as defined in Rule .0102 of this Subchapter;
- (4) remounted and refurbished ambulances; and
- (5) 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 will no longer meet the minimum manufacturing standard for new ambulances as set forth in Paragraph (b) of this 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; 131E-160; 143-508(d)(8);
Eff. January 1, 2018.*

10A NCAC 13P .0410 is proposed for adoption 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, a “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) Licensed EMS providers seeking to offer rotary-wing or fixed-wing air medical program services within North Carolina shall make application and receive approval from the OEMS prior to beginning operation.

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

(d) 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 program 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 program in their EMS System plan, as set forth in Rule .0201(a)(11) of this Subchapter;
- (5) permit inspections of all aircraft used within North Carolina as set forth in Rule .0209 of this Subchapter including the supplemental information contained on the program’s SAPS form;
- (6) populate and maintain a current roster in the North Carolina Credentialing Information System 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 current and active North Carolina license or credential in accordance with the rules and regulations of the appropriate licensing or credentialing body. 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;
- (8) continued membership and active participation in the 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) for all interstate and intrastate transports as set forth in Rule .0204(b)(6) of this Subchapter;
- (10) provide information regarding procedures performed during transport within North Carolina to the OEMS to allow review by the North Carolina OEMS Medical Director;

(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 organized and coordinated dispatch of resources between air medical programs to enhance scene safety, ensure only the number of air medical resources needed respond to the incident location are provided, and arrange for the receiving hospital to prepare for the incoming patient.

(e) In addition to the requirements set forth in Paragraph (d) 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 conditions 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: Medical Oversight and Data Collection" standards, and make any modifications identified by the OEMS to ensure compliance with the North Carolina standards as set forth in Paragraph (d)(2) of this Rule.;

(2) permit inspections of all aircraft used within North Carolina as set forth in Paragraph (b)(5) of this Rule, to be conducted at a location inside North Carolina at a time mutually 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.

(f) Significant failure to comply with the criteria set forth in this Rule shall result in revocation of the Air Medical Program approval.

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