

G.S. 150B-21.3A Report for 10A NCAC SUBCHAPTER 13P, EMERGENCY MEDICAL SERVICES AND TRAUMA RULES								
Agency - Medical Care Commission								
Comment Period - 05/29/2015 through 07/28/2015								
Date Submitted to APO - Filled in by RRC staff								
Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]
SECTION .0100 – DEFINITIONS	10A NCAC 13P .0101	ABBREVIATIONS	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		Yes	Necessary with substantive public interest
	10A NCAC 13P .0102	DEFINITIONS	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	Necessary with substantive public interest	No		No	Necessary with substantive public interest
SECTION .0200 – EMS SYSTEMS	10A NCAC 13P .0201	EMS SYSTEM REQUIREMENTS	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0203	SPECIAL SITUATIONS	Amended Eff. January 1, 2004	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0204	EMS PROVIDER LICENSE REQUIREMENTS	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	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0205	EMS PROVIDER LICENSE CONDITIONS	Amended Eff. February 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0206	TERM OF EMS PROVIDER LICENSE	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0207	GROUND AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0208	CONVALESCENT AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0209	AIR MEDICAL AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS	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	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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	10A NCAC 13P .0210	WATER AMBULANCE: WATERCRAFT AND EQUIPMENT REQUIREMENTS	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0211	AMBULANCE PERMIT CONDITIONS	Amended Eff. January 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0212	TERM OF AMBULANCE PERMIT	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0213	EMS NONTRANSPORTING VEHICLE REQUIREMENTS	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0214	EMS NONTRANSPORTING VEHICLE PERMIT CONDITIONS	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0215	TERM OF EMS NONTRANSPORTING VEHICLE PERMIT	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0216	WEAPONS AND EXPLOSIVES FORBIDDEN	Eff. April 1, 2003	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0217	MEDICAL AMBULANCE/EVACUATION BUS: VEHICLE AND EQUIPMENT REQUIREMENTS	Eff. July 1, 2011	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0218	PEDIATRIC SPECIALTY CARE GROUND AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS	Eff. July 1, 2011	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0219	STAFFING FOR MEDICAL AMBULANCE/EVACUATION BUS VEHICLES	Eff. July 1, 2011	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0220	STAFFING FOR PEDIATRIC SPECIALTY CARE GROUND AMBULANCES	Eff. July 1, 2011	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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	10A NCAC 13P .0221	PATIENT TRANSPORTATION BETWEEN HOSPITALS	Eff. July 1, 2012	Necessary with substantive public interest	No		No	Necessary with substantive public interest
SECTION .0300 – SPECIALTY CARE TRANSPORT PROGRAMS	10A NCAC 13P .0301	SPECIALTY CARE TRANSPORT PROGRAM CRITERIA	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	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0302	AIR MEDICAL SPECIALTY CARE TRANSPORT PROGRAM CRITERIA FOR LICENSED EMS PROVIDERS USING ROTARY-WING AIRCRAFT	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	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0305	AIR MEDICAL SPECIALTY CARE TRANSPORT PROGRAM CRITERIA FOR LICENSED EMS PROVIDERS USING FIXED-WING AIRCRAFT	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	Necessary without substantive public interest	No		No	Necessary without substantive public interest
SECTION .0400 - MEDICAL OVERSIGHT	10A NCAC 13P .0401	COMPONENTS OF MEDICAL OVERSIGHT FOR EMS SYSTEMS	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0402	COMPONENTS OF MEDICAL OVERSIGHT FOR SPECIALTY CARE TRANSPORT PROGRAMS	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0403	RESPONSIBILITIES OF THE MEDICAL DIRECTOR FOR EMS SYSTEMS	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0404	RESPONSIBILITIES OF THE MEDICAL DIRECTOR FOR SPECIALTY CARE TRANSPORT PROGRAMS	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0405	REQUIREMENTS FOR ADULT AND PEDIATRIC TREATMENT PROTOCOLS FOR EMS SYSTEMS	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0406	REQUIREMENTS FOR ADULT AND PEDIATRIC TREATMENT PROTOCOLS FOR SPECIALTY CARE TRANSPORT PROGRAMS	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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	10A NCAC 13P .0407	REQUIREMENTS FOR EMERGENCY MEDICAL DISPATCH PRIORITY REFERENCE SYSTEM	Amended Eff. January 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0408	EMS PEER REVIEW COMMITTEE FOR EMS SYSTEMS	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0409	EMS PEER REVIEW COMMITTEE FOR SPECIALTY CARE TRANSPORT PROGRAMS	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	Necessary without substantive public interest	No		No	Necessary without substantive public interest
SECTION .0500 – EMS PERSONNEL	10A NCAC 13P .0501	EDUCATIONAL PROGRAMS	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0502	INITIAL CREDENTIALING REQUIREMENTS FOR MR, EMT, EMT-I, EMT-P, AND EMD	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0503	TERM OF CREDENTIALS FOR EMS PERSONNEL	Eff. April 1, 2003	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0504	RENEWAL OF CREDENTIALS FOR MR, EMT, EMT-I, EMT-P, AND EMD	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0505	SCOPE OF PRACTICE FOR EMS PERSONNEL	Eff. April 1, 2003	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0506	PRACTICE SETTINGS FOR EMS PERSONNEL	Amended Eff. January 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0507	CREDENTIALING REQUIREMENTS FOR LEVEL I EMS INSTRUCTORS	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0508	CREDENTIALING REQUIREMENTS FOR LEVEL II EMS INSTRUCTORS	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0509	CREDENTIALING OF INDIVIDUALS TO ADMINISTER LIFESAVING TREATMENT TO PERSONS SUFFERING AN ADVERSE REACTION TO AGENTS THAT MIGHT CAUSE ANAPHYLAXIS	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .0510	RENEWAL OF CREDENTIALS FOR LEVEL I AND LEVEL II EMS INSTRUCTORS	Amended Eff. February 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0511	CRIMINAL HISTORIES	Amended Eff. January 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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SECTION .0600 – EMS EDUCATIONAL INSTITUTIONS	10A NCAC 13P .0601	CONTINUING EDUCATION EMS EDUCATIONAL INSTITUTION REQUIREMENTS	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0602	BASIC EMS EDUCATIONAL INSTITUTION REQUIREMENTS	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0603	ADVANCED EMS EDUCATIONAL INSTITUTION REQUIREMENTS	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
SECTION .0900 – TRAUMA CENTER STANDARDS AND APPROVAL	10A NCAC 13P .0901	LEVEL I TRAUMA CENTER CRITERIA	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0902	LEVEL II TRAUMA CENTER CRITERIA	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0903	LEVEL III TRAUMA CENTER CRITERIA	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .0904	INITIAL DESIGNATION PROCESS	Amended Eff. January 1, 2009	Necessary with substantive public interest	No		Yes	Necessary with substantive public interest
	10A NCAC 13P .0905	RENEWAL DESIGNATION PROCESS	Amended Eff. April 1, 2009	Necessary with substantive public interest	No		No	Necessary with substantive public interest
SECTION .1000 – TRAUMA CENTER DESIGNATION ENFORCEMENT	10A NCAC 13P .1003	MISREPRESENTATION OF DESIGNATION	Eff. April 1, 2003	Necessary without substantive public interest	No		No	Necessary without substantive public interest
SECTION .1100 – TRAUMA SYSTEM DESIGN	10A NCAC 13P .1101	STATE TRAUMA SYSTEM	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .1102	REGIONAL TRAUMA SYSTEM PLAN	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .1103	REGIONAL TRAUMA SYSTEM POLICY DEVELOPMENT	Amended Eff. January 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
SECTION 1400 – RECOVERY AND REHABILITATION OF CHEMICALLY DEPENDENT EMS PERSONNEL	10A NCAC 13P .1401	CHEMICAL ADDICTION OR ABUSE TREATMENT PROGRAM REQUIREMENTS	Eff. October 1, 2010	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .1402	PROVISIONS FOR PARTICIPATION IN THE CHEMICAL ADDICTION OR ABUSE TREATMENT PROGRAM	Eff. October 1, 2010	Necessary with substantive public interest	No		No	Necessary with substantive public interest

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	10A NCAC 13P .1403	CONDITIONS FOR RESTRICTED PRACTICE WITH LIMITED PRIVILEGES	Eff. October 1, 2010	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .1404	REINSTATEMENT OF AN UNENCUMBERED EMS CREDENTIAL	Eff. October 1, 2010	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .1405	FAILURE TO COMPLETE THE CHEMICAL ADDICTION OR ABUSE TREATMENT PROGRAM	Eff. October 1, 2010	Necessary without substantive public interest	No		No	Necessary without substantive public interest
SECTION .1500 - DENIAL, SUSPENSION, AMENDMENT, OR REVOCATION	10A NCAC 13P .1501	ENFORCEMENT DEFINITIONS	Eff. January 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .1502	LICENSED EMS PROVIDERS	Eff. January 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .1503	SPECIALTY CARE TRANSPORT PROGRAMS	Eff. January 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .1504	TRAUMA CENTERS	Eff. January 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .1505	EMS EDUCATIONAL INSTITUTIONS	Eff. January 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .1506	EMS VEHICLE PERMITS	Eff. January 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .1507	EMS PERSONNEL CREDENTIALS	Eff. January 1, 2013	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	10A NCAC 13P .1508	SUMMARY SUSPENSION	Eff. January 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 13P .1509	PROCEDURES FOR DENIAL, SUSPENSION, AMENDMENT, OR REVOCATION	Eff. January 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest

Rule Title	Rule Citation	Date	First Name	Last Name	Company	Email Address	Zip	Comment
ABBREVIATIONS	10A NCAC 13P .0101	5/21/2015	Erin	Glendening	DHSR	erin.glendening@dhhs.nc.gov		This is a test comment to verify that the system is working.
INITIAL DESIGNATION PROCESS	10A NCAC 13P .0904	5/22/2015	Phil	Angelo	Novant Health Presbyterian Medical Center	pjangelo@novanthealth.org		I respectfully request that the above rule be reviewed and amended to remove the requirement that hospitals seeking a Level II Trauma designation meet a minimum admission requirement. 10A NCAC 13P .0904(b) describes the initial designation process for hospitals applying for Level I and Level II trauma designation and defines certain limiting criteria. Subsection (b)(3) states “Evidence the Trauma Center will admit at least 1,200 trauma patients yearly or show that its trauma service will be taking care of at least 240 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 yearly. This 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.” The admission requirement for Level I trauma Centers is based on the American College of Surgeons (ACS) recommendations for trauma centers as outlined in their Resources for Optimal Care of the Injured Patient 2014. This guideline states “A Level I trauma center must admit at least 1,200 trauma patients yearly or have 240 admissions with an Injury Severity Score of more than 15. This is the minimum volume that is believed to be adequate to support the education and research requirements for a Level I trauma center.” Only Level I Trauma Centers have this requirement under the ACS. As is noted in the above statement, the 1,200 trauma patient admission criteria is related to a Level I institution’s trauma research and education. The ACS defines the differences between a Level I and Level II trauma center as the following: “Level I trauma centers are distinguished from Level II centers in that they must do the following: • Meet the admission volume requirements. • Maintain a surgically directed critical care service. • Participate in the training of residents and be a leader in

							<p>education and outreach activities. • Conduct trauma research.” As is clearly stated in the above statements, only a Level I trauma center has minimum admission requirements. Level II trauma centers do not have a minimum admission requirement proscribed by the ACS as they do not have any research or education requirements. Enforcing a minimum admission requirement on hospitals seeking Level II trauma center designation that is based off of the education and research requirements that only Level I trauma centers have is innapropriate. This requirement poses an unfair restriction on hospitals seeking Level II trauma center designation. Furthermore, the ACS states that “A Level II trauma center provides comprehensive trauma care in two distinct environments that have been recognized in the ongoing verification program sponsored by the ACS-COT (American College of Surgeons Committee on Trauma). The first environment is a population-dense area in which a Level II trauma center may supplement the clinical activity and expertise of a Level I institution. In this scenario, the Level I and II trauma centers should work together to optimize resources expended to care for all injured patients in their area. This implies a cooperative environment between institutions that allows patients to flow between hospitals, depending on resources and clinical expertise and matched to patient need.” The requirement for hospitals seeking initial designation as a Level II trauma center, as currently stated in 10A NCAC 13P .0904, to admit at least 1,200 patients yearly or 240 with an ISS greater than or equal to 15 is contradictory to the above stated purpose of a Level II trauma center. The purpose of the Level II center is to “supplement the clinical activity and expertise of a Level I” center. The admission requirements, as currently written, are unwarranted and impede the ability to create a tiered trauma system that ensures a cooperative environment amongst trauma centers. Furthermore, this requirement deters the establishment of such a system by fostering a competitive environment and negatively impacts hospitals abilities to increase the level of trauma care provided to the citizens of this state. I request</p>
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							<p>this rule be changed to apply only to Level I trauma centers as is the national standard as stated by the American College of Surgeons. My recommended change to section .0904(b)(3) is as follows: (3) Level I Trauma Centers shall provide: (i) Evidence the Level I Trauma Center will admit at least 1200 trauma patients yearly or show that its trauma service will be taking care of at least 240 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 yearly. This criteria shall be met without compromising the quality of care or cost effectiveness of any other designated Level I 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. (ii) This is the minimum volume believed to be adequate to support the education and research requirements of a Level I Trauma Center. This change would more closely align this rule with the current proposed changes to 10A NCAC 13P by adapting ACS recommendations and guidelines for trauma centers and would improve the ability to establish a comprehensive network of trauma centers in the state. Ultimately, these changes will help ensure we continue to provide optimal trauma care for the citizens of North Carolina. Thank you for your consideration.</p>
INITIAL DESIGNATION PROCESS	10A NCAC 13P .0904	6/1/2015	Phil	Angelo	Novant Health Presbyterian Medical Center	pjangelo@novanthealth.org	<p>I respectfully request that the above rule be reviewed and amended to remove the requirement that hospitals seeking a Level II Trauma designation meet a minimum admission requirement. 10A NCAC 13P .0904(b) describes the initial designation process for hospitals applying for Level I and Level II trauma designation and defines certain limiting criteria. Subsection (b)(3) states 'Evidence the Trauma Center will admit at least 1,200 trauma patients yearly or show that its trauma service will be taking care of at least 240 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 yearly. This 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</p>

							<p>jeopardizing the existing Trauma Center's ability to meet this same 240-patient minimum.' The admission requirement for Level I trauma Centers is based on the American College of Surgeons (ACS) recommendations for trauma centers as outlined in their Resources for Optimal Care of the Injured Patient 2014. This guideline states 'A Level I trauma center must admit at least 1,200 trauma patients yearly or have 240 admissions with an Injury Severity Score of more than 15. This is the minimum volume that is believed to be adequate to support the education and research requirements for a Level I trauma center.' Only Level I Trauma Centers have this requirement under the ACS. As is noted in the above statement, the 1,200 trauma patient admission criteria is related to a Level I institution's trauma research and education. The ACS defines the differences between a Level I and Level II trauma center as the following: 'Level I trauma centers are distinguished from Level II centers in that they must do the following: - Meet the admission volume requirements. - Maintain a surgically directed critical care service. - Participate in the training of residents and be a leader in education and outreach activities. - Conduct trauma research.' As is clearly stated in the above statements, only a Level I trauma center has minimum admission requirements. Level II trauma centers do not have a minimum admission requirement per the ACS as they do not have any research or education requirements. Enforcing a minimum admission requirement on hospitals seeking Level II trauma center designation that is based off of the education and research requirements that only Level I trauma centers have is inappropriate. This requirement poses an unfair restriction on hospitals seeking Level II trauma center designation. Furthermore, the ACS states that 'A Level II trauma center provides comprehensive trauma care in two distinct environments that have been recognized in the ongoing verification program sponsored by the ACS-COT (American College of Surgeons Committee on Trauma). The first environment is a population-dense area in which a Level II trauma center may supplement the</p>
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							<p>clinical activity and expertise of a Level I institution. In this scenario, the Level I and II trauma centers should work together to optimize resources expended to care for all injured patients in their area. This implies a cooperative environment between institutions that allows patients to flow between hospitals, depending on resources and clinical expertise and matched to patient need.' The requirement for hospitals seeking initial designation as a Level II trauma center, as currently stated in 10A NCAC 13P .0904, to admit at least 1,200 patients yearly or 240 with an ISS greater than or equal to 15 is contradictory to the above stated purpose of a Level II trauma center. The purpose of the Level II center is to 'supplement the clinical activity and expertise of a Level I' center. The admission requirements, as currently written, are unwarranted and impede the ability to create a tiered trauma system that ensures a cooperative environment amongst trauma centers. Furthermore, this requirement deters the establishment of such a system by fostering a competitive environment and negatively impacts hospitals abilities to increase the level of trauma care provided to the citizens of this state. I request this rule be changed to apply only to Level I trauma centers as is the national standard as stated by the American College of Surgeons. My recommended change to section .0904(b)(3) is as follows: (3) Level I Trauma Centers shall provide: (i) Evidence the Level I Trauma Center will admit at least 1200 trauma patients yearly or show that its trauma service will be taking care of at least 240 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 yearly. This criteria shall be met without compromising the quality of care or cost effectiveness of any other designated Level I 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. (ii) This is the minimum volume believed to be adequate to support the education and research requirements of a Level I Trauma Center. This change would more closely align this rule with the current proposed changes to 10A NCAC 13P 0901, 0902 & 0903 by adopting ACS recommendations and</p>
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INITIAL DESIGNATION PROCESS	10A NCAC 13P .0904	6/2/2015	William	Walker, MD, FACS, FASCRS		Walker52@mindspring.com		I respectfully request that the above rule be reviewed and amended to remove the requirement that hospitals seeking a Level II Trauma designation meet a minimum admission requirement. This will bring the rule into consistency with the American College of Surgeons recommendations which are applied elsewhere in the rules. 10A NCAC 13P .0904(b) describes the initial designation process for hospitals applying for Level I and Level II trauma designation and defines certain limiting criteria. Subsection (b)(3) states 'Evidence the Trauma Center will admit at least 1,200 trauma patients yearly or show that its trauma service will be taking care of at least 240 trauma patients with an Injury Severity Score (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.' The admission requirement for Level I trauma Centers is based on the American College of Surgeons (ACS) recommendations for trauma centers as outlined in their Resources for Optimal Care of the Injured Patient 2014. This guideline states 'A Level I trauma center must admit at least 1,200 trauma patients yearly or have 240 admissions with an Injury Severity Score of more than 15. This is the minimum volume that is believed to be adequate to support the education and research requirements for a Level I trauma center.' Only Level I Trauma Centers have this requirement under the ACS. As is noted in the above statement, the 1,200 trauma patient admission criteria is related to a Level I institution's trauma research and education. The ACS defines the differences between a

							<p>Level I and Level II trauma center as the following: 'Level I trauma centers are distinguished from Level II centers in that they must do the following: - Meet the admission volume requirements. - Maintain a surgically directed critical care service. - Participate in the training of residents and be a leader in education and outreach activities. - Conduct trauma research.' As is clearly stated in the above statements, only a Level I trauma center has minimum admission requirements. According to the ACS, Level II trauma centers do not have a minimum admission requirements since they have no research or education requirements. Since the ACS is the source of most trauma protocols and programs in the US and since the ACS is used throughout the rules as a reference, requiring a minimum admission requirement on hospitals seeking Level II trauma center designation is inconsistent with the ACS recommendations. This requirement poses an inconsistent and unsupported restriction on hospitals seeking Level II trauma center designation. Furthermore, the ACS states that 'A Level II trauma center provides comprehensive trauma care in two distinct environments that have been recognized in the ongoing verification program sponsored by the ACS-COT (American College of Surgeons Committee on Trauma). The first environment is a population-dense area in which a Level II trauma center may supplement the clinical activity and expertise of a Level I institution. In this scenario, the Level I and II trauma centers should work together to optimize resources expended to care for all injured patients in their area. This implies a cooperative environment between institutions that allows patients to flow between hospitals, depending on resources and clinical expertise and matched to patient need.' The requirement for hospitals seeking initial designation as a Level II trauma center, as currently stated in 10A NCAC 13P .0904, to admit at least 1,200 patients yearly or 240 with an ISS greater than or equal to 15 is contradictory to the above stated purpose of a Level II trauma center. The purpose of the Level II center is to 'supplement the clinical activity and expertise of a Level I'</p>
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Periodic Rules Review Public Comments and Agency Response
Submission to RRC

Rule Subchapter: 10A NCAC 13P

1) Rule Citation: 10A NCAC 13P .0101

Rule Title: DEFINITIONS

a) Commenter: Erin Glendening, DHSR

Comment:

This is a test comment to verify that the system is working.

Agency Response:

This comment has no merit. It is a test of the comment reporting system.

2) Rule Citation: 10A NCAC 13P .0904

Rule Title: INITIAL DESIGNATION PROCESS

a) Commenter: Phil Angelo, Novant Health Presbyterian Medical Center

Comment:

I respectfully request that the above rule be reviewed and amended to remove the requirement that hospitals seeking a Level II Trauma designation meet a minimum admission requirement. 10A NCAC 13P .0904(b) describes the initial designation process for hospitals applying for Level I and Level II trauma designation and defines certain limiting criteria. Subsection (b)(3) states “Evidence the Trauma Center will admit at least 1,200 trauma patients yearly or show that its trauma service will be taking care of at least 240 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 yearly. This 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.” The admission requirement for Level I trauma Centers is based on the American College of Surgeons (ACS) recommendations for trauma centers as outlined in their Resources for Optimal Care of the Injured Patient 2014. This guideline states “A Level I trauma center must admit at least 1,200 trauma patients yearly or have 240 admissions with an Injury Severity Score of more than 15. This is the minimum volume that is believed to be adequate to support the education and research requirements for a Level I trauma center.” Only Level I Trauma Centers have this requirement under the ACS. As is noted in the above statement, the 1,200 trauma patient admission criteria is related to a Level I institution’s trauma research and education. The ACS defines the

differences between a Level I and Level II trauma center as the following: “Level I trauma centers are distinguished from Level II centers in that they must do the following:

- Meet the admission volume requirements.
- Maintain a surgically directed critical care service.
- Participate in the training of residents and be a leader in education and outreach activities.
- Conduct trauma research.”

As is clearly stated in the above statements, only a Level I trauma center has minimum admission requirements. Level II trauma centers do not have a minimum admission requirement proscribed by the ACS as they do not have any research or education requirements. Enforcing a minimum admission requirement on hospitals seeking Level II trauma center designation that is based off of the education and research requirements that only Level I trauma centers have is inappropriate. This requirement poses an unfair restriction on hospitals seeking Level II trauma center designation. Furthermore, the ACS states that “A Level II trauma center provides comprehensive trauma care in two distinct environments that have been recognized in the ongoing verification program sponsored by the ACS-COT (American College of Surgeons Committee on Trauma). The first environment is a population-dense area in which a Level II trauma center may supplement the clinical activity and expertise of a Level I institution. In this scenario, the Level I and II trauma centers should work together to optimize resources expended to care for all injured patients in their area. This implies a cooperative environment between institutions that allows patients to flow between hospitals, depending on resources and clinical expertise and matched to patient need.” The requirement for hospitals seeking initial designation as a Level II trauma center, as currently stated in 10A NCAC 13P .0904, to admit at least 1,200 patients yearly or 240 with an ISS greater than or equal to 15 is contradictory to the above stated purpose of a Level II trauma center. The purpose of the Level II center is to “supplement the clinical activity and expertise of a Level I” center. The admission requirements, as currently written, are unwarranted and impede the ability to create a tiered trauma system that ensures a cooperative environment amongst trauma centers. Furthermore, this requirement deters the establishment of such a system by fostering a competitive environment and negatively impacts hospitals abilities to increase the level of trauma care provided to the citizens of this state. I request this rule be changed to apply only to Level I trauma centers as is the national standard as stated by the American College of Surgeons. My recommended change to section .0904(b)(3) is as follows: (3) Level I Trauma Centers shall provide: (i) Evidence the Level I Trauma Center will admit at least 1200 trauma patients yearly or show that its trauma service will be taking care of at least 240 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 yearly. This criteria shall be met without compromising the quality of care or cost effectiveness of any other designated Level I 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. (ii) This is the minimum volume believed to be adequate to support the education and research requirements of a Level I Trauma Center. This change would more closely align this rule with the current proposed changes to 10A NCAC 13P by adapting ACS recommendations and guidelines for trauma centers and would improve the ability to establish a comprehensive network of trauma centers in the state. Ultimately, these changes will help ensure we continue to provide optimal trauma care for the citizens of North Carolina. Thank you for your consideration.

Agency Response:

The agency has determined that the contents of the 10A NCAC 13P .0904 are necessary to ensure that quality trauma care is provided at our state's designated Level I and II trauma centers. Since the type of patients and care expectations are equivalent at Level I and II centers, it is felt that Level II centers would be unable to maintain the same level of expertise and quality of care if a lesser number of injured patients were treated at the Level II facility.

The proposed changes to 10A NCAC 13P .0901, .0902 and .0903 rules that reference ACS criteria as the care requirements are intended to reflect direct patient care standards that are expected of our states trauma centers. The State will always maintain the independent process of designating trauma centers and therefore will maintain requirements for initial and renewal designations that is felt to best serve the environment that is unique to NC. A one size fits all national process may not ensure that the highest quality of care is provided for our citizens.

b) Commenter: Phil Angelo, Novant Health Presbyterian Medical Center

Comment:

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c) Commenter: William Walker, MD, FACS, FASCRS

Comment:

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