Rule Title	Rule Citation	Date	First Name	Last Name	Company	Email Address	Zip	Comment	Agency Response
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.	This comment has no merit. It is a test of the comment reporting system.
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. (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	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

								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	NC. A one size fits all national process may not ensure that the highest quality of care is provided for our citizens.

								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.	
INITIAL DESIGNATION PROCESS	10A NCAC 13P .0904	6/1/2015	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	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

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								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	

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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.	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.

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								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. Please amend the rule to use volume requirements only for Level I trauma centers consistent with 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. These 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 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. Will Walker, MD, FACS, FASCRS Medical Director, Surgical Services Novant Health Greater Charlotte Market Office: 704-384-5169 Cell: 704-533-0466 wwalker@novanthealth.org	