February 5, 2021

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By email: DHSR.RulesCoordinator@dhhs.nc.gov

To Whom It May Concern:

Thank you for the opportunity to comment to the proposed rule changes related to North Carolina's trauma system. As leaders in the development of care models and training to support one of the nation's best trauma systems, we are fully committed to making sure every person in North Carolina has access to the highest quality of care in the most crucial hour potentially of their lives. We have reviewed the proposed rule changes to the NC Department of Health and Human Services, Emergency Medical Services and Trauma Rules 10A NCAC 13P received by our office on January 25, 2021. The proposed rule changes were reviewed for comparison to the national standards in trauma care, *Resources for Optimal Care of the Injured Patient* developed by the American College of Surgeons Committee on Trauma (ACS-COT) in 2014 and used for trauma center verification purposes.

Trauma is the leading cause of death in the ages of 1-44. Patients who experience a severe traumatic event and subsequent injury are optimally cared for at a state designated and American College of Surgeons verified Trauma Center. The public is largely unaware that most hospitals/health systems are not trauma centers. The assumption is frequently made that every hospital with a designated emergency department is equipped to optimally manage a trauma patient. State designated and verified trauma centers undergo a rigorous process to ensure adherence to rules and standards for verification of trauma centers based on national guidelines, including those established by the American College of Surgeons, to ensure these centers consistently provide optimal care to injured patients within their region. The need for a statewide, cohesive, uniform, and integrated trauma system, as well as the need to ensure the viability of existing trauma centers when designating new trauma centers is essential. Consistent with national standards, future trauma center designations must be based on regional population needs as a factor of demand and capacity. Trauma system needs should be assessed using measures of trauma system access, quality of patient care, population mortality rates, and trauma system efficiency. The lack of adequate trauma systems infrastructure, or potential actions which may disrupt existing infrastructure, risks undue preventable mortality and morbidities.

We are opposed to the proposed rule changes for the North Carolina state trauma system which contradict the widely-accepted national recommendations for trauma systems infrastructure. The proposed changes would effectively allow any hospital to become a trauma center, without the due diligence of quality assurances including state verification based upon national trauma center standards to include: 1) facility injured patient volumes; 2) quality and cost impact on current Level

I, II, III trauma centers in the primary catchment area; and 3) eliminating the collective collaboration of the Board of County Commissioners and RACs in the initial designation process of interested trauma centers. Included below, a summary of our position in response to the proposed rule changes:

Atrium Health Opposes
Proposed Change Rule 10A NCAC 13P .0904 INITIAL DESIGNATION PROCESS-Section b3
evidence for Level 1 applicants, evidence the Trauma Center will admit at least 1200 trauma patients annually or show that its trauma service will be taking care of at least 240 trauma patients yearly with an ISS greater than or equal to 15 yearly. 15. ~~These criteria shall be met without compromising 16 the quality of care or cost effectiveness of any other designated Level I or II Trauma Center sharing 17 all or part of its catchment area or by jeopardizing the existing Trauma Center's ability to meet this same 240-patient minimum~~.

Level I and Level II trauma centers must meet the same clinical trauma center standards and performance expectations. Volume exceptions for Level II centers risks variability in care and quality standards. Dooley et al. states, "additional urban centers only provide additional care to 1% of population but decrease volume at existing centers by 40%" (2020). Removing the considerations regarding quality of care and cost effectiveness impacts on existing Level I and II trauma centers directly opposes the national trauma standards defined by the American College of Surgeons Committee on Trauma (ACS-COT). The national standard states, "The designating authority, in partnership with the broader regional trauma system, should ensure that the optimum number and type of trauma centers exist in a given geographic region. The development of Level II trauma centers should not compromise the flow of patients to existing high volume Level I trauma centers (ACS-COT, Resources for Optimal Care of the Injured Patient, 2014). In Chapter 1 of the Resources for Optimal Care of the Injured Patient, it states, "It must be emphasized that in any trauma system, the designating authority should be responsible for determining the anticipated volume of major trauma patients and assessing available resources to determine the optimal number and level of trauma centers in a given area" (ACS, 2014). This proposal, coupled with proposed changes below, effectively block the designated body from appropriately vetting new center quality and impact to the system at large. Additionally, the Journal of Trauma and Acute Care Surgery, the American College of Surgeons Committee on Trauma and several state trauma systems have published reports stating that the designation of a new trauma center in close proximity to an established center does, in fact, cause detriment to the existing center regarding lost volume and increased competition for highly trained resources. The additional center results in increased costs for all involved organizations and ultimately the community.

Several NC verified trauma centers collaborate with the US military to provide robust education programs through the Mission Zero Act. It should be emphasized, that the utility of civilian trauma centers as military training platforms is threatened by the financially driven expansion of Level I and II trauma centers in certain geographic regions across the United States beyond levels required to meet the needs of the local population (Branas et al., 2005; Eastman et al., 2013; Johnson, 2015). This has the effect of diluting patient volume at existing centers, compromising the training mission

of these centers for military teams as envisioned by the committee as well as civilian trainees (Simon et al., 2009). In short, the proposed changes have a detrimental effect on trauma care to those serving in the Armed Forces.

Atrium Health Opposes

Proposed Change Rule 10A NCAC 13P .0904 INITIAL DESIGNATION PROCESS-Section c1-5 & d

(c) The hospital shall be participating in the State Trauma Registry as defined in Rule .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 of this ~~Subchapter who are~~: Subchapter.

~~(1) diverted to an affiliated hospital;~~

~~(2) admitted to the Trauma Center for greater than 24 hours from an ED or hospital;~~

~~(3) die in the ED;~~

~~(4) are DOA; or~~

~~(5) are transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital).~~

~~(d) OEMS shall review the regional Trauma Registry data from both the applicant and the existing trauma center(s), and ascertain the applicant's ability to satisfy the justification of need information required in Paragraph (b) of this Rule~~. The OEMS shall notify the applicant's primary RAC of the ~~application and provide the regional data submitted by the applicant in Paragraph (b) of this Rule for review and comment.~~ application. The applicant's primary RAC shall be given 30 days to submit written comments to the OEMS.

Trauma system needs should be assessed and guided by measures of trauma system access, quality of patient care, population mortality rates and trauma system efficiency. The ultimate goal must be assurance of appropriate standards for the optimal care of the trauma patient, ensure the right infrastructure and personnel, ensure high quality data for performance improvement, and verify quality outcomes. Additionally, in the military and civilian sectors, the failure to collect, integrate, and share trauma data from the entire continuum of care limits the ability to analyze long-term patient outcomes and use that information to improve performance at the front lines of care. (National Trauma Care System, 2016) National bodies including the CDC, NHTSA, NIH, NAM, and NQF advocate and recommend additional tracking of patient outcomes and quality control measures. The proposed changes are directly contradictory to this expert advice.

Atrium Health Opposes

Proposed Change Rule 10A NCAC 13P .0904 INITIAL DESIGNATION PROCESS-Section e

~~(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.~~

Injury remains a significant public health problem. A rigorous disease management approach to injury is necessary within an entire community regardless of trauma center levels or size. The community includes, but is not limited to verified trauma centers, non-trauma centers, EMS, law enforcement, post-acute care facilities-SNF, rehabilitation, home health, and LTACS, injury prevention, and elected officials. Developing criteria for trauma center designation is an example of process- and resource-based standards. Policy development is facilitated through collaboration and by educating elected officials and empowering stakeholders (ACS, 2014). Restricting the notification of changes in the trauma system is irresponsible. Stakeholders must be able to plan for changes to prevent lapses in service to the communities we serve.

Atrium Health Opposes

Proposed Change Rule 10A NCAC 13P .0904 INITIAL DESIGNATION PROCESS-Section j

~~(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.~~

In accordance with national standards, timely response to needs of the trauma system are crucial to ensuring access to care. If, after review of appropriate impact and needs assessments, it is determined that additional centers are warranted, centers should be vetted with national standards, such as ACS-COT verification, as soon as possible. We advocate for additional OEMS resources – as opposed to decreased quality standards— to achieve this aim as a statewide trauma system plan is in the best interest of the community. While *we support the effort of a state trauma system to align with the American College of Surgeons Committee on Trauma standards for verification*, these standards are the **minimum requirements**. A state must consider a needs-based assessment to ensure adequate trauma system access, high quality injured patient care, a reduction in population mortality rates, and trauma system efficiencies. The state of North Carolina trauma system should continue efforts to be better than the minimum standards.

DHHS Fiscal Note: October 6, 2020

The Department of Health and Human Services provided a supplemental document providing economic analysis to the proposed rules published on October 6, 2020. Under the analysis, the review asserts that the volume requirement established in Paragraph (b)(3) presents "a challenge for some Level III Trauma Centers that otherwise may meet other criteria to obtain Level II designation." The analysis further asserts the change "provides better opportunity for military hospitals to build more community influence as state designated Trauma Centers." The assessment ends with OEMS unable to determine impacts "except positive impacts from the military hospitals being able to achieve Level II Trauma Center designation but does not expect substantial economic impacts."

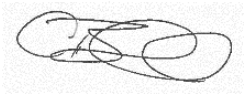
While Atrium Health understands the intent of the change, the assessment fails to understand the high fixed costs to operate a Level I trauma hospital. While removing minimum volume criteria creates market entry, it has the unintended consequence to drive up healthcare costs and reduce

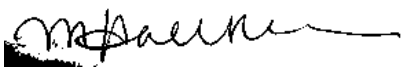
quality. Providing care as a Level I trauma hospital requires significant investment from the hospital to ensure the right medical providers, sub-specialists and support staff from pre-hospital to post-acute care are available around the clock every day of the year. Providing round the clock care everyday requires high volume of patients to offset the fixed expenses and drive costs down for consumers. Additionally, low volume high risk cases require surgical precision. Reduction in patient volume prevents the development of expertise and potentially jeopardizes high quality care provided at our Level I trauma facility, thus limiting the resources that an individual facility is willing to invest in for the care of injured patients.

While OEMS does not "justify" or evaluate "cost effectiveness" of a designated trauma hospital, it does provide oversight to the care and has a vested interest in the regional approach to trauma in the State of North Carolina. Failure to recognize the potential negative impacts of unrestricted trauma center designations is suboptimal. The North Carolina trauma system is highly regarded in the nation as a best practice model in the country.

If you have any questions regarding the comments or information used in the review, please contact A. Britton Christmas at ashley.christmas@atriumhealth.org or Melissa Hall at melissa.n.hall@atriumhealth.org

Sincerely,





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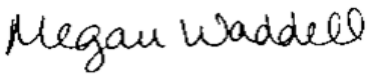

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Resources

Related to Quality:

Trauma System Agenda for the Future: Comprehensive Trauma Care System: Fundamental Components of Trauma Care - Acute Care Facilities (nhtsa.gov) (NHTSA future plan explicitly calls for the quality metric reporting that will be omitted by the proposed changes)

A National Trauma Care System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury (2016)

NQF: Trauma Outcomes (qualityforum.org)

Home - National Academy of Medicine (nam.edu)

NHTSA | National Highway Traffic Safety Administration

Related to Need:

Location, location, location: Utilizing Needs-Based Assessment of Trauma Systems-2 in trauma system planning Jennings H Dooley 1, Esra Ozdenerol, John P Sharpe, Louis J Magnotti, Martin A Croce, Peter E Fischer Affiliations PMID: 31856019 DOI: 10.1097/TA.0000000000002463

Unregulated proliferation of trauma centers undermines cost efficiency of population-based injury control. Joseph J Tepas 3rd 1, Andrew J Kerwin, Jin Hee Ra PMID: 24553522 DOI: 10.1097/TA.0000000000000125

A National Trauma Care System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury (2016)

General:
NVSS - Leading Causes of Death (cdc.gov)