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February 15, 2021

As members of the North Carolina Committee on Trauma (NC-COT) and past and present Trauma Medical Directors at Atrium Health Cleveland, we agree with the statement presented by Dr. Jacobs on behalf of the NC-COT and ***do not endorse the proposed Trauma Rules changes***.

Cleveland was the first Level III Trauma Center in North Carolina. Therefore, our collective experience with the NC trauma system spans the time between 1994 and the present during which the cooperative and non-funded efforts have continued to improve the care of the injured in North Carolina and provided a framework for other initiatives such as Code STEMI, Code Stroke etc.

A significant restructuring of the process of trauma system development with partnering between NC-COT and OEMS could progress trauma care for all NC citizens in a systematic and comprehensive way. Our designated trauma centers are outstanding and well-recognized across the country however, the system continues to lag as other states advance due to appropriated resources.

We respectfully request serious consideration of the points made in the attached document and an intense study of measures necessary to support North Carolina's Trauma System.

Sincerely,

Jiselle Bock, MD MPH
Trauma Director
Atrium Health Cleveland

Michael Barringer, MD
Past Trauma Director
Atrium Health Cleveland

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Atrium Health Cleveland

NC-COT Response to Proposed Changes to Trauma Rules

On behalf of the North Carolina Committee on Trauma (NC-COT), and the State Trauma Advisory Committee (STAC), we appreciate the opportunity to provide our thoughts and recommendations regarding the Trauma Rules changes proposed in the December 15, 2020 edition of the *North Carolina Register*. The NC-COT is a state-based chapter of the national organization, the American College of Surgeons Committee on Trauma (ACS-COT), and is comprised of approximately 60 surgeons, all board-certified Fellows of the American College of Surgeons, and all actively involved in the provision of trauma care in their communities. Our companion organization, the State Trauma Advisory Committee, is comprised of over 100 trauma professionals from across the state representing Trauma Center Administrators, Trauma Program Managers, Trauma Registrars, Injury Prevention Specialists, Trauma Quality Specialists, and Regional Advisory Committee (RAC) Coordinators. Together, these two organizations have dedicated countless hours and energy towards improving trauma care across the state of North Carolina. Thus, we believe that our organizations have the credibility, but more importantly the insight, to evaluate the strengths, weaknesses, opportunities, and threats to our currently existing trauma system.

In preparing this response, we have reviewed not just the proposed rules changes, but all the state's Trauma Rules as documented in **SUBCHAPTER 13P – EMERGENCY MEDICAL SERVICES AND TRAUMA RULES**. We have reviewed numerous documents and position statements from ACS-COT, as well as the findings and recommendations from the NC Trauma System Consultation conducted by the ACS-COT in 2004. We have had multiple conversations with the leadership of the Verification Review Committee (VRC) and the Trauma Systems Evaluation and Planning Committee (TSEP) of the ACS-COT. We have obtained input from many of our constituent trauma centers from across the state, as well as from subcommittee members of the STAC. Despite having received all this valuable input, our goal with regards to this written response, particularly since the stated purpose of these rules changes was to provide greater alignment with guidelines put forth by the ACS-COT, is to limit our comments to an assessment of how closely aligned these proposed rules changes are to ACS-COT positions and principles. The ACS-COT principles that serve as the foundation for the NC-COT's comments and recommendations recorded in this document are taken from 2 sources, and are reproduced verbatim below:

1) **From ACS-COT "*Statement on Trauma Center Designation Based upon System Need-2015*"**
    a) The importance of controlling the allocation of trauma centers, as well as the need for a process to designate trauma centers based upon regional population need, has been recognized as an essential component of trauma system design.
    b) Trauma center designation should be guided by the regional trauma plan based upon the needs of the population being served, rather than the needs of individual health care organizations or hospital groups.
    c) The designation of trauma centers is the responsibility of the governmental lead agency with oversight of the regional trauma system. The lead agency must have a strong mandate, clear statutory authority, and the political will to execute this responsibility.
    d) The lead agency should be guided by the local needs of the region(s) for which it provides oversight. As such, it is the responsibility of physicians, nurses, prehospital health care

providers, and their respective organizations to advocate for the interests of the patients and citizens they serve throughout the entire region.

e) Trauma system needs should be assessed using measures of trauma system access, quality of patient care, population mortality rates, and trauma system efficiency.

2) **From "*Resources for Optimal Care of the Injured Patient 2014*"**

a) 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.

b) The development of Level II trauma centers should not compromise the flow of patients to existing high volume Level I trauma centers.

A trauma system is much more than the sum of its constituent trauma centers. Injury prevention, emergency notification systems (i.e., 911), prehospital care (ground and aeromedical), and post-acute patient services are also critical components which, along with the trauma centers themselves, must be provided in a seamless and coordinated fashion to ensure timely and appropriate access for all NC citizens. According to the ACS-COT, it is the state designating agency, in our case, the North Carolina Office of Emergency Medical Services (OEMS), who has the ultimate responsibility for overseeing these multiple components of a trauma system, to ensure that the appropriate number, level, and location of these assets is optimal. The NC-COT believes that the net effect of the proposed rules changes is to diminish this fundamental role of OEMS, and likewise diminish, or entirely curtail, critical input from important regional stakeholders into trauma center designation and re-designation processes. **Thus, the NC-COT does not endorse these proposed changes.** Instead, we propose a thorough review of all currently existing trauma rules, with the goal of better defining our state trauma system's purpose and function, and OEMS' role in that trauma system. This refinement process is necessary to ensure timely access to state-of-the-art trauma care to all North Carolinians, while, at the same time, avoiding unnecessary duplication of trauma resources that will not provide direct benefit to our citizens.

Although the primary focus of our response is on the proposed changes to the state Trauma Rules, our review of those rules also revealed some internal inconsistencies within the Rules document itself, and some external inconsistencies between the description of the designation process contained in the Trauma Rules, and the current practice of trauma center designation in North Carolina. These inconsistencies, we believe, provide further justification for our argument that undertaking a thorough review and update of all our Trauma Rules would be a valuable investment for North Carolina at this time. Regarding the proposed rules changes, we have six specific areas of concern:

1) **Rule: 10A NCAC 13P .0904 (b) (3) [INITIAL DESIGNATION PROCESS]**

Proposed Change: The letter of intent submitted to OEMS by a hospital interested in pursuing trauma center designation would no longer need to include evidence that that hospital becoming designated as a trauma center might compromise "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".

Response: This proposed change would appear to contradict ACS-COT's position that 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". Nor does this proposed change provide OEMS all of the information necessary for them to determine that the "development of Level II trauma centers will "not compromise the flow of patients to existing high volume Level I

trauma centers". The actual trauma center site surveys performed by the ACS-COT (or by the OEMS utilizing ACS criteria) do not, and are not intended to, address any potential impact of designating a new trauma center on the function of currently existing trauma centers in the same catchment area. They only assess whether the applicant hospital meets ACS-COT trauma center criteria, as outlined in the *Resources for Optimal Care of the Injured Patient* document. Since the ACS-COT believes that "the designation of trauma centers is the responsibility of the governmental lead agency with oversight of the regional trauma system", and that the "lead agency should be guided by the local needs of the region(s) for which it provides oversight", inclusion of this critical information within the letter of intent is fundamental to the ability of OEMS to carry out this vital oversight responsibility.

2) **Rule: 10A NCAC 13P .0904 (d) [INITIAL DESIGNATION PROCESS]**
Proposed Change: Removes the obligation on the part of OEMS to "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."
Response: Similar to our response under 1) above, review of the regional Trauma Registry data from both the applicant and the existing trauma center(s) is critical and necessary in order for OEMS to ensure that trauma center designation is guided by the "needs of the population being served, rather than the needs of individual health care organizations or hospital groups".

3) **Rule: 10A NCAC 13P .0904 (d) [INITIAL DESIGNATION PROCESS]**
Proposed Change: Removes the obligation on the part of OEMS to "provide [the applicant's primary RAC] the regional data submitted by the applicant in Paragraph (b) of this Rule for review and comment"
Response: Given the ACS-COT's stated position that "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 RAC should have input into the decision-making process regarding trauma center initial and renewal designation. In order that their input be accurate and informed, we believe the RAC should have access to the regional data submitted by the applicant in Paragraph (b). The proposed changes appropriately preserve the RAC's right to provide comment on the hospital's application during the 30-day comment period, but the RAC's should be provided with all the necessary information on which to base their commentary. Furthermore, this proposed change would directly contradict language in **.1102 (e) [REGIONAL TRAUMA SYSTEM PLAN]**, where it is stated "Upon OEMS' receipt of a letter of intent for initial Level I or II Trauma Center designation by a hospital in the lead RAC agency's catchment area as set forth in Rule .0904(b) of this Subchapter, *the applicant's lead RAC agency shall be provided the applicant's data from the OEMS* for distribution to all RAC members for review and comment, as set forth in Rule .0904(d) of this Subchapter."

4) **Rule: 10A NCAC 13P .0904 (e) [INITIAL DESIGNATION PROCESS]**
Proposed Change: Removes the obligation on the part of OEMS to "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" [prior to OEMS deciding whether to allow submission of an RFP].
Response: Once again, given the ACS-COT's stated position that "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 respective Board of County

Commissioners in the applicant's primary catchment area, given their critical role in the local community, should be notified of the applicant hospital's intent to seek initial trauma center designation, and provided an opportunity to submit comment on the necessity of such designation for their community.

5) **Rule: 10A NCAC 13P .0905 (c) (3) [RENEWAL DESIGNATION PROCESS]**
Proposed Change: Removes the obligation on the part of OEMS to "notify the Board of County Commissioners within the trauma center's trauma primary catchment area of the Trauma Center's request for renewal to allow 30 days for comments."
Response: Similar to our response under 4) above, the respective Board of County Commissioners in the applicant's primary catchment area, given their critical role in the local community, should be notified of the applicant hospital's intent to seek renewal of their trauma center designation, and provided an opportunity to submit comment on the necessity of such re-designation for their community. Furthermore, this proposed change would directly contradict the process outlined in **.0905 (b) (1)** for hospitals choosing to renew their Trauma Center designation by undergoing a site visit conducted by OEMS to obtain a four-year renewal. That renewal process stipulates "OEMS shall notify the respective Board of County Commissioners in the applicant's trauma primary catchment area of the request for renewal to allow 30 days for comment."

6) We have refrained here from commenting on 2 other proposed rules changes pertaining to 1) elimination of volume requirements for Level II Trauma Centers, and 2) elimination of specific NC Trauma Registry data elements as reporting requirements for the Initial Designation process. We have done so because these requirements have not been specifically addressed by the ACS-COT, and, as we stipulated at the outset of this document, our intent in responding to the proposed rules changes is to limit our comments to an assessment of how closely aligned these proposed rules changes are to ACS-COT positions and principles. That is not to say that we necessarily endorse these 2 proposed rules changes. Furthermore, we recognize and support the position expressed by other responding trauma organizations that while adherence to, and alignment with, ACS-COT positions and principles is desirable, there may well be circumstances and situations where it is equally desirable, and even necessary, to move beyond ACS-COT positions and principles, to establish even higher standards of care, particularly if these higher standards are based upon the unique needs of a particular state or community. These 2 additional proposed rules changes that we have chosen not to specifically address at this time may well represent such a circumstance where adoption of a higher standard of care is necessary.

Additional Concerns:
In addition to the 6 discrete concerns raised above regarding the proposed rules changes, the NC-COT has several additional concerns with the Trauma Rules that add further justification to our recommendation that the currently proposed rules changes be tabled pending a more complete review and revision of the rules.

1) **SECTION .0900 - TRAUMA CENTER STANDARDS AND APPROVAL**. The rules in this section do not make it clear whether currently designated trauma centers seeking to "upgrade" their designation

level (to Level II or Level I) should utilize the .0904 process (initial designation process) or the .0905 process (renewal designation process). This issue should be clarified.

2) **10A NCAC 13P .0904 (l)** and **.0905 (c) (6). INITIAL & RENEWAL DESIGNATION PROCESSES. T**he composition of a Level I, II, or III site survey team as required in these rules does not appear to be consistently followed. The composition of these teams is frequently determined by the ACS-COT itself, and not by OEMS. Teams are typically comprised of 2 out-of-state trauma surgeons, as opposed to 1, as specified in the state rules. Our state rules should be modified to acknowledge the prerogative of the ACS-COT to determine the composition of the site survey team.

3) **10A NCAC 13P .0905 (b) (10)** and **(c) (14): RENEWAL DESIGNATION PROCESS**. The process for correction of cited deficiencies described in these rules does not seem to consider the ACS-COT's decision process. These rules suggest that if a trauma center fails their ACS-COT site visit, that OEMS could do a focused review and re-verify that center, without the input or consent from the ACS-COT. This issue should be clarified.

4) **10A NCAC 13P .1101: STATE TRAUMA SYSTEM**. The design and function of our State Trauma System, as defined in these rules falls short of the vision put forth by the ACS-COT that a trauma system recognize "the importance of controlling the allocation of trauma centers, as well as the need for a process to designate trauma centers based upon regional population need". Our current rules read "the state trauma system shall consist of regional plans, policies, guidelines, and performance improvement initiatives by the RACs to create an Inclusive Trauma System monitored by the OEMS." There is no reference to OEMS' responsibility to "ensure that the optimum number and type of trauma centers exist in a given geographic region". According to our current rules, this responsibility appears to have been relegated to the RAC's. Indeed, 2 of the "challenges" identified during our ACS-COT NC Trauma Systems Consultation in 2004 were:
    a. Lack of a comprehensive statewide trauma plan, and
    b. Divergent expectations for trauma system regulation between centralized (state) versus de-centralized governance (RAC/county, etc.)

   A comprehensive state Trauma Plan should be developed, and then reflected in the state's Trauma Rules.

Conclusion: The NC-COT welcomes the opportunity to partner with OEMS to develop guidelines and standards to ensure that we have an inclusive and collaborative state trauma system, with appropriate oversight and monitoring provided by OEMS. In making this recommendation, we do not mean to imply, in any way, that the North Carolina OEMS has been derelict in its responsibility to the citizens of North Carolina to provide and ensure a robust, and fully functional state trauma system. Indeed, in our NC Trauma Systems Consultation in 2004, in addition to specifically listing "Strong and consistent state OEMS leadership" as one of our strengths and assets, our site surveyors went on to say:

> "The State EMS and trauma systems have flourished under the expert and consistent leadership of dedicated individuals who have committed themselves to the improvement of trauma care and EMS in North Carolina (NC). The stability of the leadership over long spans of time has permitted continued progress towards goals that have resulted in NC becoming a leader in the

nation in trauma care. One of the strengths of the OEMS is its ability to identify and collaborate with a multitude of stakeholders for trauma and EMS".

We recognize that the task of updating and strengthening our state trauma system's processes and rules will not be an easy one, but we also recognize that we have a great partner in OEMS with whom to carry out this most important work. Updating and strengthening our trauma system might involve conducting another statewide trauma systems evaluation, or simply assembling a task force to address the recommendations made in the 2004 survey. However, simply adopting the proposed changes to our current rules would be short-sighted, and not move us, as a state, closer to achieving our overall goal of providing optimal trauma care to all the citizens of North Carolina.

Thank you for the opportunity to comment. Should you have any questions, comments, or concerns, or require any clarification or further information, please do not hesitate to contact me at any time. My contact information is listed below.

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