



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

REPORT OF PUBLIC HEARING

February 8, 2021

10:00 A.M.

Via Conference Call

Division Staff Present:

Nadine Pfeiffer, Rule-review Manager
Diana Barbry, Rule-making Assistant
Tom Mitchell, Chief, OEMS
Chuck Lewis, Assistant Chief, OEMS
Wally Ainsworth, OEMS
SanJuan Timmons, OEMS
Robbie Amerson, OEMS
Tripp Winslow, OEMS
Mike Thomason, OEMS
Tonya Pool, OEMS

Others Present:

Jackie Gosnell, NC STAC Trauma Program
Kathy Rex, Atrium Health
Steven Johnson, Skyland Rescue
Tim Hinman, Skyland Rescue
Scott Wilson, Metrolina Trauma Advisory Committee
Sid Fletcher, Novant Health
Lori Gottlieb, Atrium Health
Kathy Haddix-Hill, Novant Health
Joe Penner, Mecklenburg EMS
David Jacobs, NC Committee on Trauma
Susan Macklin, Central Carolina Community College
Trevor Taylor, Mecklenburg EMS
Dee LaDuke, Novant Health Trauma Program
Mary Kaylor, Fayetteville Technical College, Curriculum EMS Program
Angela Clarkson, Novant Health Presbyterian
Britt Christmas, Atrium Health
Vickie Block, Atrium Health
Robbie Roberts, Wake Med
Chan Roush, Atrium Health
Megan Waddell, Atrium Health Living Children's

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

OFFICE OF THE DIRECTOR

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Others Present: (Continued)

Melissa Hall, Atrium Health

Kyle Cunningham, Trauma Atrium Health

Brian Simonson, State Trauma Advisory Committee, RAC Sub-Committee

Gail Shue, Wake Forest Baptist Health, RAC Coordinator for Triad Region

Angela Alexander, Atrium Health Cleveland

Scott Wade, Carolina Neurosurgery

Purpose of Hearing

This is the teleconference public hearing for the Emergency Medical Services and Trauma proposed rule amendments and fiscal note. These rules are 10A NCAC 13P .0101, .0102, .0222, .0501, .0502, .0504, .0507, .0508, .0510, .0512, .0601, .0602, .0904, .0905, .1101, .1401, .1403, .1404, .1405, .1505, .1507, and .1511. The purpose of this meeting is not to discuss or debate these rules but rather, to accept comments from the public on these proposed rules and fiscal note that was prepared for these rules. The Division will receive public comments through February 15, 2021. All comments, including those from this teleconference public hearing, will be considered prior to the Medical Care Commission adopting the proposed rules and submitting them to the Rule Review Commission for approval

Hearing Summary

The Public Hearing was opened via conference call by Nadine Pfeiffer at 10:00 a.m. Attending via conference call were twenty-six members of the public as listed above and in Appendix A attached. Each speaker was allotted a time limit of five minutes to present oral comments. A total of eight oral comments were recorded for the rule(s). The oral comments recorded are as follows:

1. **Jackie Gosnell, NC STAC Trauma Program:** [Ms. Gosnell read her comments verbatim that were submitted via email following the public hearing. See attached Appendix B for the comments read by Ms. Gosnell.]

2. **Tim Hinman, Skyland Rescue,** said the following: “Thank you for your time and thank you for the opportunity to share our thoughts on the new rule changes. Mine will be focusing basically on the continuing education institutions this morning. Skyland Fire Department, just to give you a little bit of background, we're probably one of the first EMS continuing education institutions in the State. We've been providing continuing education in house for our personnel since the early 1990's and have been doing that hopefully well since then.

I'll get right to the point then, our concern is just in our thoughts. And I guess it's major concern, just some clarification a little bit more. And we just want to make sure we're reading this right now that we're going to, despite looking at these new rules and regulations in 501 [Rule 13P .0501] under educational programs, it looks like that we're going to have to become an accredited institution. Down underneath 501 (12) [Rule 13P .0501, line 12] it says, *‘educational programs approved to qualify EMS personnel for*

a EMT and paramedic credentialing shall meet the requirements of Paragraph (b) of this rule and possess verification of accreditation or a valid letter of review for from the Commission on Accreditation of Allied Health Continuing Education Programs.’ So, I guess that's just, it's a little bit of concern for us. Here it's just kind of like another drop in the bucket of something we're going to have to expend time on. As well as I imagine we'll have to encumber a cost for that either annually or during that accreditation period. And so, we haven't totally been able to do our homework on this. This came out fairly quickly to us, but we are concerned about that for the future. I guess the good thing for us, our institution renewal comes up the end of March, so we'll be able to renew that. So hopefully this won't incur for us until four years down the road. But we are concerned about that as a small institution. I hope this works out for us, but I scratched my head that this is another little drop in the bucket that puts institutions, smaller institutions like us, to have to encumber more costs and time to keep our personnel educated.

The other one I had a little concern about, a little head scratcher, I also notice that we're trying to ramp up and we have one person right now. We have some Level I instructors, and that was the requirements right now for the continuing education institutions. But we see in the future that requirements are going to be for a Level II educational instructor for the future on that. And in the past, and we've been trying to dump one person right now who has met all the requirements as of the 1st of January 2020, with the exception of a OEMS Instructor workshop. That was all that person has been waiting on since January 2020. OEMS has not had an Instructor workshop this year so she is still waiting on that to get her Level II. I also noticed now that if that person has an Associates Degree and does not have a Bachelor's Degree as of July 1, requirement will be for that person to have the Bachelor's Degree. So, I guess my question is kind of a twofold, if that person does not get their Bachelor's degree by July 1, which they probably will not, will they be grandfathered since they've been trying to get that since 2020 and the only thing they lack is an instructor workshop? And how and why hasn't instructor workshop now not been offered through Noodle since all the nation has been going to either a phone conference like this one to make that available to that person?

So those are my two questions: one, and just to recap there just a concern on the educational program for continuing education institutions like us. Two, requires us to be accredited. I think it's a little much, but that's our opinion here locally.”

[Time limit of five was minutes reached before the remainder of the oral comments were provided.]

- 3. Scott Wilson, Metrolina Trauma Advisory Committee**, said the following: “Hello, I'm Scott Wilson, Regional Trauma Coordinator from Metrolina Trauma Advisory Committee, one of the eight Trauma Regional Advisory Committees (RACs) in the state and a key stakeholder in the trauma system. I'm also making these comments with the support of Gail Shue, Coordinator for the Triad RAC.

After reviewing proposed rule changes for EMS and trauma systems and holding discussions about these changes with the other RAC coordinators across the state, members of our RACs consisting of EMS agencies and trauma centers in civilian members of community, the proposed changes will negatively impact the care of trauma patients in North Carolina by altering the trauma landscape and jeopardizing the safeguards that help maintain the highest level of patient care.

The proposed changes to .904B-3 [Rule 13P .0904(b)(3)] removal of the 1200 patient volume prerequisite for a trauma center to change their status to Level II may benefit that hospital, but it ultimately takes away from the patient. Level I and II Trauma Centers should clinically offer the same trauma care to patients. They should also be held the same standards when judging whether they are eligible to upgrade their status.

The two reasons for this change that were listed in the DHHS fiscal note were alignment with the ACS orange book that was about the change, and to assist military hospitals in their efforts to increase the level of care provided. While I generally support aligning trauma standards to the College, which some may say is considered a higher standard, by removing the hard requirement, we're actually lowering the standard of care for our patients. As for the rationale of assisting military hospitals in their process, this impacts all 17 trauma centers in the state. And if the true reason for the change, it would benefit only two trauma centers in North Carolina. Additionally, the way the military medical system is designed, this change would not benefit the average citizen in North Carolina as they're not able to seek care on the military base. If for some highly unlikely case that they did receive initial care at these two trauma centers, they would then be transferred to a civilian hospital after initial stabilization.

As part of the same section, an important portion is completely removed. This being that the criteria should be met without compromising the quality of care or cost effectiveness of any other trauma center in that catchment area. The addition of a trauma center with no qualifying standards or approving need will inevitably impact other trauma centers. Its estimated that additional trauma centers will impact existing centers by decreasing their volume by up to 40%. If anything, this section should be strengthened through a needs assessment, not weakened by the removal.

In rule [13P] .0904(c), (d), and (e), data submission requirements to the State, RAC, and County Commissioners are removed. We use this data to analyze trends and identify opportunities for improvement. Without making this information available, we limit our ability to improve the care given to our patients. The decision to literally change the trauma landscape should be data driven with evidence to show that the need is truly there. Why would we not want the opportunity for outside organizations to have information and the opportunity to review changes to the care providers of the community, and in this case, by the Commissioners who are elected by their citizens to represent them in decisions such as this and the RACs that serve as quality control? The same argument

goes against the proposed removal of section (f) [Rule 13P .0904(f)] which would not notify either the hospital's RAC or their County Commissioners of a trauma center application moving forward in the process. Hospitals are mandated by the same rules to work with the RACs. Why would we not want to notify them?

In section (j) of .0904 [Rule 13P .0904(j)] the requirement for a site visit within six months after review and approval of the initial application was removed. By removing this time frame, the process could be dragged on indefinitely and allows for additional preparation plan for a site visit. A hard stop deadline should remain in place but with exemptions on as needed basis. Additionally, this rule [13P .0904] directly conflicts with rule [13P] .0905, which governs renewal trauma center status and states a defined time frame first site visit. The trauma centers should ready for their site visit the moment they submit their paperwork.

As mentioned, rule [13P] .0905 deals with renewal trauma center status, and I share the same concerns in this section with the lack of notification of local government representatives in section (c) 3 [13P .0905(c)(3)]. This decreases the oversight and opportunity for input from those who are impacted the most by any changes.

Rule .1101 section (c) [13P .1101(c)] removes OEMS from reporting of a RAC alliances. Why? This method works and no problems with this reporting system has been reported. OEMS is an integral part of the trauma network and should remain as currently designated.

Section (d) [Rule 13P .1101(d)] reverses the process by requiring the RAC Coordinator to reach out to each EMS agency and hospital in their region to confirm their RAC affiliation. However, in the same rule it also asks those same agencies and hospitals to do the reverse and report the State if they intend to change RACs. This is conflicting and adds confusion to the process, especially when the requirements to provide written notification to the State is also proposed.”

[Time limit of five was minutes reached before the remainder of the comments were provided.]

4. **Dr. Sid Fletcher, Novant Health**, said the following: “My name is Dr. Sid Fletcher and I'm the Senior Vice President and Chief Clinical Officer for Novant Health in Charlotte. By way of background, I'm an Emergency Medicine physician and practice in Charlotte for 17 years. I'm here today on behalf of Novant Health which is North Carolina's second largest healthcare system. We serve patients across North Carolina and we're committed to bringing remarkable access to high quality care for each community in which we have the privilege to serve.

Thank you for the opportunity to provide our support for the proposed changes to the trauma center initial designation rule currently being considered. We are in strong support of the proposed changes. North Carolina's existing trauma regulations around initial designation has long been misaligned with the American College of Surgeons and national guidance related to their gold standards and trauma management.

As it currently stands, the rule requires a hospital to provide care for 1200 trauma cases or 240 with an ISS score greater than 15 annually in order to apply for Level II trauma center status. In most other states this is typically reserved for Level I trauma centers as recommended by the American College of Surgeons. We support removing this volume ISS criteria. These volumes are difficult to achieve as trauma designation protocols require ambulances to transport many trauma patients only to existing Level I or II centers. For those desiring Level II designations, the circular problem, you cannot get the volumes needed without designation and you cannot get designation without the volumes is creating a barrier to patients receiving the care that they deserve.

As we consider all communities across our statewide footprint it's particularly problematic here in the Charlotte region. The Charlotte region has an economy that continues to grow, and many companies, businesses, and events are coming to the area. We believe the need for additional trauma capacity continues to grow. At this moment in the largest metropolitan area in the state, we have just one high level trauma center. The care options should really be consistent across the state. The catchment area for trauma services in the Charlotte region is 2.3 million people, and our region makes up 22% of the state population with an average growth rate of 15% since 2010.

Across the United States many metropolitan areas have multiple high-level centers. The population in Raleigh, Durham, and Chapel Hill as well as Winston-Salem and Greensboro are smaller than Charlotte, as a reason, and yet they have multiple high-level trauma centers. The Raleigh-Durham, Chapel Hill region has three high level trauma centers that are all Level I centers. The Winston-Salem, Greensboro area has two high level trauma centers, a Level I and a Level II. In large metropolitan areas like Charlotte, we also believe redundant high-level centers protect communities by preventing a singular very high functioning Level I trauma center from being overwhelmed during disasters and unexpected surges.

Trauma mortality rates are impacted by availability of trauma centers. Statistical analysis and comparison of state census trauma center destination and age adjusted mortality rates reveal an inequitable distribution of trauma services across the US. This study listed North Carolina in the bottom 5 in the US for number and density for its population of trauma centers, surgical critical care providers, and surgical critical care fellowships.

Novant Health Presbyterian Medical Center already provides remarkable trauma care as a Level III center in the Charlotte community. At the appropriate time, this facility could

consider becoming a Level II center to fill the current gap created by the barriers inherent in the existing rules.

We urge you to change the rules as proposed and thank you for working to enable a more integrated sufficient trauma system for all citizens across North Carolina.”

5. **Dr. David Jacobs, NC Committee on Trauma** – said the following: [Dr. Jacobs read excerpts of his comments verbatim (italicized below) that were submitted via email following the public hearing. See attached Appendix C for these excerpts read by Dr. Jacobs and additional comments not read.] “Thank you for giving me the opportunity to speak this morning. I am speaking on behalf of the North Carolina Committee on Trauma. There’s been a lot of talk this morning already about aligning with national standards, so we’re going to try to limit comments this morning to those that will directly reflect comments and position statements that have been issued by the American College Surgeons. We’re going to base our comments on two documents primarily the Statement on Trauma Center Designation Based upon System Need from 2015 and the Resources for Optimal Care for the Injured Patient from 2014. *In the interest of time, I won't go through all those principles with you specifically, but they are going to be in our written response.*

I will say at the COT believes that the designation of trauma centers is the responsibility of the governmental lead agency and that this lead agency should be guided by the local needs of the region for which it provides oversight rather than the needs of the individual health care organizations or hospital groups. The North Carolina Committee on Trauma believes that the net effect of the proposed rules we are discussing today is to diminish this fundamental role of the OEMS and thus we do not endorse these proposed changes. Instead we propose a thorough review of all the current existing trauma rules with the goal of better defining our state’s trauma system’s purpose and function, and the OEMS’ role in that trauma system. This refinement process is necessary to ensure timely access to state-of-the-art trauma care for 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 comments today will be on the proposed changes, our review also revealed some internal inconsistencies within the rules document that we feel further provides justification for our argument to undertake a thorough review and update of all the trauma rules.

Getting to the trauma rule changes specifically, we have identified four areas of concern these being:

- Number 1: the proposed trauma rules would *remove the applicant’s hospitals obligation to provide, in its letter of intent to OEMS, any evidence that it’s designation as a trauma center might compromise the quality of care or cost*

effectiveness of any other designated Level I or Level II trauma center sharing all or part of its catchment area, that's number one.

- Number 2: would be that the proposed rule changes *remove the obligation on the part of the OEMS to review the regional Trauma Registry data from both the applicant as well as the existing trauma centers to be sure that the applicant's ability to satisfy the justification of need required in Paragraph (b).*
- Third: concern is that these proposed changes would *remove the obligation on the part of OEMS to provide to the RACs the regional data submitted by the applicant in Paragraph (b).*
- And then finally that these rule changes would *remove the obligation on the part of OEMS to notify the respective Board of County Commissioners that's for both the Initial as well as the Renewal designation process.*

We believe that these proposed changes would:

- a) impair the OEMS' responsibility to ensure that the optimum number and type of trauma centers exist in a given geographic region and would deny them all of the information necessary for them to determine that the development of Level II trauma centers will not compromise the flow patients to existing high volume Level I trauma centers.*
- b) We also believe the proposed changes would impair the RAC's ability to have significant and timely input into the designation and re-designation processes and would similarly deny the Board of County Commissioners their opportunity for input.*

Furthermore, as we lay out in our written comments these proposed changes would set up some internal inconsistencies between Rules .0904 [Rule 13P .0904(d)] and Rule .1102 [Rule 13P .1102(3)], and also inconsistencies between Rule .0905(c)(3) and .0905(b)(1). We provide further details about these concerns in our written comments.

We've refrained here from commenting on two other proposed rule changes having to do with elimination of volume requirements for Level II trauma centers and elimination of specific North Carolina Trauma Registry data elements as reporting requirements for the initial designation process. We have done so because it's not been specifically endorsed by the COT."

[Time limit of five was minutes reached before the remainder of the oral comments were provided.]

- 6. Dr. Britt Christmas, Atrium Health:** [Dr. Christmas read his comments verbatim that were submitted via email following the public hearing. See attached Appendix D for the comments read by Dr. Christmas.]

7. **Brian Simonson, State Trauma Advisory Committee, RAC Sub-Committee**, said the following: “I’m here this morning and a representation of the RAC Subcommittee of the State Trauma Advisory Committee. My comments this morning will be limited to our support to what has already been stated by the Trauma Program Manager Subcommittee, to the point of that we feel like there should be a delay in the rules as stated just simply due to lack of information. There’s been a burden placed on what is now the orange book as far as guidance for a trauma designation in the state of North Carolina. That book, guidelines, <inaudible> therefore we really don’t know exactly what these rules will look like with that particular material being referenced so often. The RAC is defined by geography in the state of North Carolina, it does not sub-define the entire system. We do agree it needs a space assessment and make our decisions based on that and top-quality care and safety for our patients in North Carolina. The STACs committees <inaudible> and the trauma program management.”

8. **Angela Alexander, Atrium Health Cleveland**, said the following: “I wish to back what Dr. Christmas said and to agree with them on holding on the rule changes.”

Adjournment

These comments will be taken into consideration by the Agency. The hearing was adjourned at 10:51 a.m.

Respectfully Submitted,



Nadine Pfeiffer, Rule-review Manager
February 17, 2021

Attachments

Public Hearing Teleconference Attendance
Office of Emergency Services and Trauma Rules
10A NCAC 13P .0101, .0102, .0222, .0501, .0502, .0504, .0507, .0508, .0510, .0512,
.0601, .0602, .0904, .0905, .1101, .1401, .1403, .1404, .1405, .1505, .1507, and .1511
February 8, 2021 10:00 a.m.

Attendee Name	Representing	Speaking Yes(Y)No(N)
Jackie Gosnell	NC STAC Trauma Program	Y
Kathy Rex	Atrium Health	N
Steven Johnson	Skyland Rescue	N
Tim Hinman	Skyland Rescue	Y
Scott Wilson	Metrolina Trauma Advisory Committee	Y
Sid Fletcher	Novant Health	Y
Lori Gottlieb	Atrium Health	N
Kathy Haddix-Hill	Novant Health	N
Joe Penner	Mecklenburg EMS	N
David Jacobs	NC Committee on Trauma	Y
Susan Macklin	Central Carolina Community College	N
Trevor Taylor	Mecklenburg EMS	N
Dee LaDuke	Novant Health Trauma Program	N
Mary Kaylor	Fayetteville Technical College, Curriculum EMS Program	N
Angela Clarkson	Novant Health Presbyterian	N
Britt Christmas	Atrium Health	Y
Vickie Block	Atrium Health	N
Robbie Roberts	Wake Med	N
Chan Roush	Atrium Health	N
Megan Waddell	Atrium Health Living Children's	N
Melissa Hall	Atrium Health	N
Kyle Cunningham	Trauma Atrium Health	N
Brian Simonson	State Trauma Advisory Committee, RAC Sub-Committee	Y
Gail Shue	Wake Forest Baptist Health, RAC Coordinator for Triad Region	N
Scott Wade	Carolina Neurosurgery	N

Attendee Name	Representing	Speaking Yes(Y)No(N)
Angela Alexander	Atrium Health Cleveland	Y
Staff Attendee Name	Representing	Speaking
Nadine Pfeiffer	DHSR	Y
Diana Barbry	DHSR	N
Tom Mitchell	OEMS	N
Chuck Lewis	OEMS	N
Wally Ainsworth	OEMS	N
SanJuan Timmons	OEMS	N
Robbie Amerson	OEMS	N
Tripp Winslow	OEMS	N
Mike Thomason	OEMS	N
Tonya Pool	OEMS	N

Pfeiffer, Nadine

From: Jaclyn.Gosnell@HCAHealthcare.com
Sent: Monday, February 8, 2021 10:54 AM
To: Rulescoordinator, Dhhs
Subject: [External] Re:comment for proposed changes to EMS and Trauma Rules

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Please see below for public comment that was presented at this morning's public hearing, again on behalf of the NC Trauma Program Manager Committee

Thanks,

Jackie Gosnell MSN, RN, TCRN, CEN
NC State Chair, Trauma Program Committee
828-713-4019

From: Gosnell Jaclyn
Sent: Friday, February 5, 2021 1:59 PM
To: 'DHSR.RulesCoordinator@dhhs.nc.gov' <DHSR.RulesCoordinator@dhhs.nc.gov>
Subject: comment for proposed changes to EMS and Trauma Rules

NCOEMS:

As the Chair of the NC State Trauma Program Manager Committee, I am submitting the following proposal to the trauma amendment changes on behalf of all the NC State Trauma Program Managers:

As a committee we would like to suggest holding on proposed changes until release and review of new ACS standards, "Resources For Optimal Care of the Injured Patient" (gray book) which will be released in March 2021. In the meantime, we would like to request NCOEMS to develop a formal subcommittee with adequate RAC and trauma center representation from all areas within NC, to complete a needs based assessment (NBAT or geospatial) as suggested by the 2004 ACS NC site review. The NC State TPM committee unanimously agrees quality of care and cost to patients should not be jeopardized through amendments. We also would like to request that pediatric trauma and burn become a NC state designation.

If the decision is made to not await publication of the new updated "Resources For Optimal Care of the Injured Patient" (gray book) we would like to suggest the following specifics.

- "NCAC.13P .0904 B3: Request to have a needs based assessment and to leave following statement "Criteria shall be met without compromising the quality of care or cost effectiveness to patients."

- NCAC13P.0904 C, request amendment from weekly submission to quarterly submission to align with NTDB data submissions. Also requesting no amendments to defined data points or defined as by the NC COT. Group concern for not submitting these data points is related to the inability to specifically assess injury burdens of catchment areas.

- NCAC13P .1101: Requesting no change to the current NCOEMS process for obtaining RAC affiliations. We feel this process works well now and fear the proposed amendments would jeopardize RAC relationships and unnecessary politics within our state and the pre-hospital agencies.

Respectfully,

Jackie Gosnell MSN, RN, TCRN, CEN

NC State Chair, Trauma Program Committee

828-713-4019

NC-COT Response to Proposed Changes to Trauma Rules-2021

Spoken Response

Good morning. Once again, I am speaking on behalf of the North Carolina Committee on Trauma.

Since the stated purpose of these rule changes was to provide greater alignment with guidelines put forth by our parent organization, the American College of Surgeons Committee on Trauma (which I will refer to from here on out as “the COT”), our comments will be limited to an assessment of how closely aligned these proposed rule changes are to COT positions and principles. Those positions and principles that inform our response come from 2 sources:

- 1) **ACS-COT “Statement on Trauma Center Designation Based upon System Need-2015”**
- 2) **“Resources for Optimal Care of the Injured Patient 2014”**

In the interest of time, I will not review these principles individually with you today, but they are referenced in our written response. Suffice it to say that the COT believes that the designation of trauma centers is the responsibility of the governmental lead agency, and that this lead agency should be guided by the local needs of the region for which it provides oversight rather than the needs of individual health care organizations or hospital groups. **The NC-COT believes that the net effect of the proposed rule changes we are discussing today is to diminish this fundamental role of the OEMS, and thus we do not endorse these proposed changes.** Instead, we propose a thorough review of all the currently existing Trauma Rules, with the goal of better defining our state trauma system’s purpose and function, and OEMS’s role in that trauma system. This refinement process is necessary to ensure timely access to state-of-the-art trauma care for 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 today 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 document 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 of our Trauma Rules would be a valuable investment for us at this time. Regarding the proposed rule changes, we have six specific observations:

- 1) The Trauma Rules changes proposed for would:
 - a. remove the applicant’s hospital obligation to provide, in its letter of intent to OEMS, any evidence that its’ designation 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”.
 - b. remove 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.”

- c. remove the obligation on the part of OEMS to “provide [to the applicant's primary RAC] the regional data submitted by the applicant in Paragraph (b) of this Rule for review and comment”
 - d. remove 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]. This would be for both the Initial as well as the Renewal Designation Process
- 2) We believe these proposed changes would:
- a. Impair OEMS’s responsibility to ensure that the optimum number and type of trauma centers exist in a given geographic region”, and would deny them all 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.
 - b. Impair the RAC’s ability to have significant and timely input in the designation and re-designation processes, and would similarly deny the Board of County Commissioners their opportunity for input.
- 3) *Furthermore*, as we lay out in our written comments, these proposed changes would set up some internal inconsistencies:
- a. The changes proposed for **Rule.0904 (d)** would directly contradict language in **Rule .1102 (3)**
 - b. The changes proposed for **Rule .0905 (c) (3)** would directly contradict the process outlined in **Rule .0905 (b) (1)**.
- 4) We have refrained here from commenting on 2 other proposed rules changes having to do with 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 endorsed by the COT, and, as we stipulated at the outset of this document, our intent in responding to the proposed rules changes was to limit our comments to an assessment of how closely aligned these proposed rule changes are to 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 espoused by other trauma organizations here today that while adherence to, and alignment with, COT positions and principles is desirable, there may well be circumstances and situations where it is equally desirable, and even necessary, to move beyond 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 to not 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 concerns raised above regarding the proposed rules changes, and the areas of internal inconsistency that we have identified with the Trauma Rules document, we have identified several areas of external consistency between the document and established OEMS practices. In the interest of time,

we will simply list them here, although these areas are described in greater detail in our written response. These areas of inconsistency include:

- 1) State Trauma Rules 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 *initial* designation process or the *renewal* designation process.
- 2) The composition of a Level I, II, or III site survey team as stipulated in our Trauma Rules does not appear to be consistently followed in renewal site surveys.
- 3) The process for correction of deficiencies identified during trauma center site surveys as described in our Trauma Rules does not seem to consider the COT’s decision process.
- 4) The design and function of our State Trauma System, as defined in these rules falls short of the vision put forth by the 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”.

Conclusion: The NC-COT welcomes the opportunity to partner with the 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 the 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 NC 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 changes to our current rules proposed here today 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.

David G. Jacobs, MD FACS
Chair; NC-COT

Ladies, Gentleman, Members and Guests:

Thank you for the opportunity today to comment on the proposed rule changes in relation to the designation of North Carolina Trauma Centers.

I am Dr. Britt Christmas, the Chief of Trauma and Trauma Medical Director at Atrium Health – Carolinas Medical Center...a nationally recognized Level I Trauma Center that serves the Charlotte region.

The public is largely unaware that most hospitals are not trauma centers. The assumption is frequently made that every hospital with an emergency department is equipped to optimally manage trauma patients. State designated and verified trauma centers undergo a rigorous process to ensure adherence to rules and standards for verification 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.

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 during their most crucial hours.

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 considering the designation of new trauma centers is absolutely essential.

We are opposed to several of the proposed rule changes for the North Carolina state trauma center designation process which seemingly contradict the widely-accepted national recommendations for trauma systems infrastructure. These proposed changes introduce a level of subjectivity that would effectively allow any hospital to become a trauma center, without the due diligence of quality

assurances for state verification 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 trauma centers applications.

With regard to the proposed rule changes in .904 section B:

If the goal is to better align with ACS Committee on Trauma Standards, then why do these changes regarding impact on existing trauma centers seem to directly contradict those standards as stated in the Resources for Optimal Care of the Injured Patient through removal of key phrases regarding impacts on existing trauma centers? “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.**” This has become a significant issue, in states such as Florida, jeopardizing the viability of several existing Level I trauma centers in the absence of quality driven motives. Of note, a 2020 study by Dooley and colleagues states, “additional urban centers only provide additional care to 1% of population but decrease volume at existing centers by 40%”. Trauma system needs should be assessed and guided by measures of access for our communities, the quality of patient care provided, population mortality rates and overall trauma system efficiency.

With regard to Sections C&D:

The ultimate goal must be the adherence to appropriate standards for the optimal care of the trauma patient. There must be assurances to include appropriate infrastructure and personnel, the assimilation of high- quality data for performance improvement, and review and verification processes for quality outcomes. The proposed changes effectively limit, or eliminate, the ability to perform a true quality assessment of any new trauma center applicant prior to designation.

With regard to Section E:

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** in accordance with the framework of national standards, such as ACS-COT verification, as soon as possible. We would advocate for additional OEMS resources – as opposed to decreased quality standards— if we are truly considering the best interest of the community.

Finally, while we support the effort of a state trauma system to align with the American College of Surgeons Committee on Trauma standards for verification, we would be remiss if we did not recognize that the North Carolina trauma system is highly regarded in the nation as a best practice model largely due to the collaborative efforts of our trauma centers, leadership, and care providers over these many years. It is important to recognize that even the ACS standards represent the **minimum requirements...we are better than that**. It is my belief, and hope, that the state of North Carolina should always strive to far exceed minimum standards...because that is what I know our providers do every time they cross the threshold to care for the patients of our respective communities.

Thank you for your time and consideration today and please feel free to contact me with any further information or inquiries.

A. Britton Christmas, M.D., FACS

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