July 22, 2016

Celeste Philip, MD, MPH
Surgeon General & Secretary
Florida Department of Health
4052 Bald Cypress Way
Tallahassee, FL 32399

Dear Surgeon General Philip,

I am writing to submit comments related to the Department of Health (DOH) Office of Trauma proposed rules related to Chapter 64J. On behalf of Tenet Healthcare Florida, I want to thank you and your team for hosting the recent workshops related to the proposed rules. For over twenty-five years, our facilities in Palm Beach County have supported the response for and care of our community when trauma care is needed. Our two Level 1 trauma centers, Delray Medical Center and St. Mary's Medical Center, are committed to continued participation in and championing of the Florida Trauma System.

First, I would like to introduce myself as the new Regional Chief Nurse Executive for Tenet Healthcare Florida. With a background in Critical Care and Emergency/Trauma Services, I am familiar with the trauma programs of Florida, Georgia, and Tennessee and have worked with both the American College of Surgeons and State Trauma Boards in the past to obtain and maintain trauma certifications and programs. At the end of the day, the decisions set forth in this chapter effect our citizens, the community overall, and ultimately our families. To that end, we are providing the following comments related to the recent work on the development of Chapter 64J:

64J2.006 – Trauma Registry and Trauma Quality Improvement Program

1) Data Dictionary - Current Florida Trauma Registry Manual, Data Dictionary 2016 Edition is not aligned with the National Trauma Data Standard (NTDS). Since there is mandatory reporting to TQIP, this also goes into the National Trauma Data Bank (NTDB). The language in the Florida Trauma Registry Manual, Data Dictionary, needs to align with the national requirements. Due to the differences in the two data sets, extensive rework is done at the point of submission to the Florida Trauma Registry data bank in part due to differences between the two systems. If language changes are made such that the rule reflects that the "*current version of the National Trauma Data Standard"* is what is utilized in Florida, the need for future workshops and hearings would be significantly reduced in this specific area.
2) Reporting – Since reporting to TQIP is mandated by the rule, there should be direct reporting from all identified trauma centers to NTDB and in turn, TQIP. Reporting to the state trauma registry should be removed, allowing for the information to come back from the NTDB and TQIP to the state Office of Trauma. Time frames for reporting to NTDB are based upon admission date rather than the current Florida standard of discharge date. The NTDB also allows for updates of information should data need to be amended/corrected/added/changed. For example, receipt of an autopsy after the submission date has passed. The NTDB submission dates are a month earlier than the current Florida requirement. Information that is submitted

to NTDB is de-identified while the information submitted to the Florida Trauma Registry is not. This is a concern for potential release of data should reports be made available from the state registry back to hospital(s). All these differences have led to concerns in data submission from the trauma centers and in moving our Florida programs forward to national benchmarking standards.

Single source reporting to NTDB and TQIP by the trauma center(s) would lead to fewer errors in reporting. Mapping concerns from different vendors that have impacted individual trauma centers submission would be addressed through this mechanism. NTDB and TQIP would work to submit reports back to the state that would benchmark the data within the state as well as nationally. Given the identified issues of complications not being mapped correctly in the submission to NGTR, reports coming back from TQIP and NTDB would be more accurate with direct submission by each trauma center to those entities.

64J-2.010 – Allocation of Trauma Centers Among the Trauma Service Areas (TSAs)

1) Although it has been said by Ms. Colston in the hearings that current trauma centers will be grandfathered into the allocation, there is no language to that effect. This has been a concern expressed by many in the past and language should be added into the rule to put this issue to rest.
2) We would recommend that this change from a yearly assessment and scoring process to a 3 or 5 year process of scoring. We understand that Section 395.402 (3), F.S. refers to this as an annual process. As such, to the extent deemed necessary, we would encourage the department to seek legislative changes.
3) The process has looked at the impact of trauma centers throughout the state, according to the TSA breakdown. Our team would like to recommend we continue to utilize this methodology with some modification based on population growth and/or shifts.
4) Continued utilization of a points based system seems reasonable. We would like to recommend the following:
    a. Where existing trauma centers are present, a negative impact for the points system should be considered. Examples include:
        i. Pediatric Trauma Referral Center Present= minus 0.5 points
        ii. Level II Trauma Center Present= minus 1 point
        iii. Level II and Pediatric Trauma Referral Present= minus 1.5 points
        iv. Level I Present= minus 2.0-2.5 points
        v. 2 Level 1 Present= minus 3.0-3.5 points
    b. Community support letters are valuable and may be submitted; however, Community Support Letters are subjective and should not be included in point allocation.

64J-2.012 – Process for the Approval of Trauma Centers

1) The current application process is still heavily paper focused, with small components that are electronic. Since the ACS-COT members have acted as some of the surveyors that have come into the state, adoption of their application process would help to facilitate their reviews, would

not be as paper focused for submission to the state, and yet would still be available on site for the review team. Key information in the electronic format is still readily available for review and helps to identify areas for the surveyors focus during their visit. We would recommend an electronic submission model be implemented.

64J – 2.016 Site Visits and Approval

1) The current rule still references the Florida Trauma Center Standards. There needs to be a clarification and determination of what is going to be utilized in the future. Consideration for existing facilities to develop plans to meet current ACS-COT Optimal Resources Guidelines over a period of time will also need consideration.

In closing, the recommendations for the development of a Florida Trauma System Advisory Committee would serve all stakeholders in this dialogue. The committee needs to be multi-faceted. Some components are already in place in council/committees that directly impact the current processes. As has been the case in the past with participation by Julie Hilsenbeck, previous Tenet Healthcare Florida Chief Nurse Executive, we would like to commit to participating actively in the Advisory Committee. I as well as the teams currently serving the trauma needs of Palm Beach County are readily available to participate in such an Advisory Committee. We have served the Palm Beach County citizens in the past and are committed to continuing to serve them in this capacity by having a voice in trauma care across the State of Florida. Additionally, we have enjoyed a long and effective working relationship with the DOH and we wish to continue that relationship.

Warmest Regards,

Cathy Philpott, RN, BSN, MBA, NEA-BC
Chief Nurse Executive-Florida Region
tenet HEALTH
5810 Coral Ridge Drive
Coral Springs, Florida 33076
Office (954) 509-3600
Cell (954) 415-3035
Email cathy.philpott@tenethealth.com

SNHA Safety Net Hospital Alliance of Florida

Delivered Via Email
Leah.Colston@flhealth.govv

July 21, 2016

Celeste Philip, MD, MPH
Surgeon General & Secretary
FL Department of Health
4052 Bald Cypress Way
Tallahassee, FL 32399

RE: Comments rule development covering administrative rules 64J-2.006, 64J-2.010, 64J-2.012, 64J.2.013, and 64J-2.016

Dear Surgeon General Philip:

I am writing on behalf of the Safety Net Hospital of Alliance of Florida's (SNHAF) members to provide comments pursuant to DOH trauma rule workshops for administrative rules 64J-2.006, 64J-2.010, 64J-2.012, 64J-2.013, and 64J-2.016. SNHAF membership represents Florida's top teaching, public, children's, and regional perinatal intensive care hospitals. SNHAF members include the two (2) freestanding pediatric trauma centers, six (6) Level II trauma centers inclusive of a Level II/Pediatric trauma center, and seven (7) Level I trauma centers. Collectively, SNHAF trauma centers have more than 300 years of trauma care experience and includes the first two (2) trauma centers to be verified under Florida's trauma standards in 1982.

The Safety Net Hospitals have a long history of working collaboratively with the Department of Health including providing expertise through their participation on the Trauma Technical Advisory Panels established by Florida Legislature in the early 1980's; and the Florida Trauma System Plan Advisory Committee that successfully guided the statewide trauma system prior to its dissolution in 2011. We all share the same goal of ensuring citizens of Florida have access to high quality trauma care. We hope the Department will return to Florida's foundational collaborative approach to trauma planning and permit the trauma surgeons, program managers, and other trauma experts working in our trauma centers to lend their expertise to the Department staff in a collaborative environment to ensure a strong sustainable trauma system in Florida.

101 N. Gadsden Street · Tallahassee, FL 32301 · Office: 850 201 2096 · Fax: 850 201 2078
www.safetynetsflorida.org

Preamble for Rule Comments

The Safety Net Hospitals Alliance of Florida's membership are joined by our states finest trauma surgeons, trauma program managers, and other trauma experts in requesting the Department to return to working collaboratively with us to ensure a strong viable trauma system for all residents and visitors to the great state of Florida. We ask the Department to re-establish the Florida Trauma System Plan Advisory Committee with a membership inclusive of trauma surgeons, trauma program managers, and other trauma experts from Florida's Level I, Level II, and Pediatric trauma centers to work side by side with the Departments staff to develop sound trauma rules, standards, and develop a sound transparent objective data driven trauma system needs assessment tool measuring demand and capacity for each trauma service area (TSA). The SNHAF request for a return to a collaborative approach to trauma planning a proven method that worked for more approximately thirty (30) years in Florida is also a foundational principal included in the Committee on Trauma, American College of Surgeons (ACS) *Resources for Optimal Care of the Injured Patient (aka Orange Book)* which states "*Trauma center leaders need to take an active role in policy development for the trauma system. They should participate in oversight and advisory groups to ensure that rules and regulations are developed and implemented in a manner that supports the clinical aspects of injury care.*"[i] We again, ask the Department to work with us and other stakeholders to establish a multi-disciplinary Florida Trauma System Plan Advisory Committee, composed of trauma surgeons, trauma program managers, and other trauma experts from all levels of trauma centers, Level I, Level II, and Pediatric, ending the current dysfunction.

Pending the re-establishment of a broad based Trauma System Plan Advisory Committee, we ask the Department to temporarily suspend or pause all rule development and approval of new trauma center applications. Pausing will not cause harm to Florida's trauma system or citizens. There are no trauma administrative rules where the absence of action (update/revision/repeal) will cause harm to a single trauma patient. There are no TSA's were the data remotely indicates urgent need for one more trauma center, in fact Florida exceeds the national average for access to trauma care with the available data show 97% of Florida's population have access to trauma care within the "golden" hour (60 minutes).[ii] However, moving forward with business as usual, promulagating rules that don't support the clinical aspects of trauma care as defined by the American College of Surgeons, or approving new trauma centers based on a seriously flawed methodology that does not accurate measure demand and capacity to determine each trauma service areas (TSAs) "need", does cause harm.

64J-2.006 Trauma Registry and Trauma Quality Improvement Program:

The Department did not provide draft language nor state a goal for why administrative rule 64J-2.006 is being considered for rule development therefore, our comments are to the current rule. However, first we would like to paint a bigger picture of trauma center data reporting to

101 N. Gadsden Street · Tallahassee, FL 32301 · Office 850.201.2096 · Fax 850.201.2078
www.safetynetsflorida.org

help provide context to some of our recommendations. Florida trauma centers report trauma data to:

1. American College of Surgeons *Trauma Quality Improvement Program* (ACS TQIP®)[iii],
2. American College of Surgeons National Trauma Data Bank[iv] (NTDB)[v],
3. FL Agency for Health Care Adminstration (AHCA) hospital inpatient, ambulatory/outpatient, and emergency discharge data (AHCA discharge data), and
4. Department of Health (DOH) state trauma registry (a/k/a Next Generation Trauma Registry (NGTR).

The data reported by trauma centers to the ACS TQIP and NTDB is de-identified data, meaning the individual patient's identity is protected and not transmitted outside the care facility. The AHCA discharge data set and the state trauma registry require the reporting of patient identification, HIPAA[vi] protected health information. ACS TQIP and NTDB provide participating trauma centers with reports and provide state-wide reports to states. AHCA produces reports and provides an interactive tool for consumers, health care providers, and researchers to access and use their data in a de-identified format. DOH state trauma registry data is not used to produce public reports and no de-identified data set is available.

The current rule was adopted in January 2016. The 2016 rule adopted by references the ACS National Trauma Data Bank (NTDB) data dictionary and the Florida Trauma Registry Manual, Data Dictionary 2016, as well as, includes a provision requiring Level I and Level II verified trauma centers to report data to the ACS Trauma Quality Improvement Program (ACS TQIP). The goals of the 2016 rule revisions included aligning the state trauma registry with ACS TQIP reporting requirements. Algining reporting requirements is a sensible goal given the Department requirement that trauma centers report data to the state trauma registry and to ACS TQIP. Unfortunately, the alginment fell short in ways that have significantly complicated and increased the reporting staffing burden for trauma centers. For example the Department in the new state trauma registry reporting requirements adopted the CMS[vii] two-midnight rule in its inclusion criteria, meaning the state trauma registry is limited to trauma patients who are inpatients for two-midnights[viii]. TQIP's inclusion criteria is the standard trauma 24 hour rule. Two different reporting requirements means extra staff time and more importantly means the state trauma registry does not capture all the trauma patients treated in Florida's trauma centers. Compounding the state trauma registry reporting problems is the failure of the state trauma registry to use it's own data dictionary submission rules to validate the data submissions of Florida trauma centers, meaning valid state trauma registry data submissions fail. Trauma center's are in a no-win situtation, they are required to report trauma data as a part of verification despite herculian efforts, the data will not go through because the state trauma registry's validation software doesn't match the state trauma registry submission requirements. The average trauma center is using two (2) to three (3) times more staff resources in their efforts to report to the state trauma registry than they use to report to both TQIP and NTDB. Specific details regarding the tremendous resources expended by trauma

101 N. Gadsden Street · Tallahassee, FL 32301 · Office 850.201.2096 · Fax 850.201.2078
www.safetynetsflorida.org

centers attempting to comply with the state trauma registry reporting requirements can be found in the transcript of the July 11, Orlando rule development workshop in the testimony of SNHAF members Lee Memorial and Orlando Health.

The reporting of patient identification to the state trauma registry is an unnecessary risk. When ask recently why the Department needed the patient identifiers, we were told the Department hopes one day to be able to match EMSTAR data (EMS transport data) to trauma registry data. The collection of patient identification based on the hope of one day matching voluntary EMSTAR data to trauma registry data does not justifiy the risk. The trauma program managers have been questioning the need for patient identifers for several years.[ix] Neither ACS TQIP or NTDB require reporting of patient identification.

We think it's time to consider the viablity and value of the state trauma registry. ACS TQIP and NTDB provides trauma centers with intrastate and interstate quality and performance comparisons based on national standards. The state trauma registry does not provide reporting trauma centers with feedback or reports. ACS TQIP and NTDB work with state trauma regulatory agencies to provide quality and performance data necessary for regulation. A unique state trauma registry requiring exordinary trauma center staff resources for submission from which no meaningful state-wide or trauma center specific reporting is available verses NTDB and TQIP seems a clear choice.

We recommend:

- Administrative rule 64J-2.006 be revised to require all trauma centers as a condition of provisional or verified status to report their trauma data directly to the National Trauma Data Bank® (NTDB®),
- Repeal the requirement for trauma centers to report data to the state trauma registry, close the state trauma registry unit, create a secure de-identified data set[x] from the records reported to date, and securely dispose of the historical identified data set avoiding the accidential disclosure of protected health information (PHI).
- Expand the requirement for Level I and Level II verified trauma centers to participate in ACS TQIP to include Pediatric verified trauma centers.
- The Department should contract with the ACS NTDB and ACS TQIP for statewide risk adjusted trauma reports and quality data reports necessary to effectively fulfill its regulatory requirements for Trauma.
- The Department should continue to use AHCA discharge data in a de-identified format for research and for data required for a new objective data driven trauma system needs assessment that accurately measures demand and capacity to determine need.
- Repeal the requirement for non-trauma acute care hospitals to report trauma data to the state trauma registry, as the reporting is duplicative of the AHCA discharge data reporting requirements.

101 N. Gadsden Street · Tallahassee, FL 32301 · Office: 850.201.2096 · Fax: 850.201.2078
www.safetynetsflorida.org

- Should the Department wish to pursue matching EMSTAR transport files to specific trauma patients, the Department should work collaboratively with the EMS Advisory Committee and the Florida Trauma System Plan Advisory Committee to develop a methodology for matching EMSTAR data to AHCA discharge data.
- Seek legislative authority to revise s. 395.404 F.S. removing the requirement for trauma centers to report data to the state trauma registry and substitute language permitting the Department to use data from NTDB and TQIP to monitoring patient outcome and ensuring compliance with the standards of approval.
- Pending legislative authority, suspend the state trauma registry-reporting requirement alleviating the burden created by the problems outlined above with the state trauma registry.

Our recommendations will provide Florida trauma centers and the Department of Health with a higher quality trauma system data inclusive of quality, as well as, intrastate and interstate benchmarking reporting.

64J-2.010 Allocation of Trauma Centers Among the Trauma Service Areas (TSAs):

The Department did not provide draft language for including administrative rule 64J.2.010 in rule development. However, the Department staff did verbally state at each workshop the Departments goal of repealing the statutory statewide cap of 44 trauma centers, as well as, elimination the individual TSA caps. Therefore, our comments are to the current rule language and the Departments stated goals. The current rule fails to measure the two key components of need; demand and capacity. Failure to accurately measure demand and capacity results in the allocation of trauma centers to TSA's where there is no need and weakens Florida's trauma system. The current rule includes the subjective criteria of community support, which measures "desire" not demand. The SNHAF membership have provided numerous comment letters detailing the deficiency of the current trauma system methodology, to permit us to focus on how we move forward we have attached a copy of our most recent analysis of the deficiencies of administrative rule 64J-2.010 and the trauma system needs assessment methodology/criteria. A point of clarification, at the rule development workshops, many in the audience thought there were statements made that implied the American College of Surgeons (ACS) had adopted a mirror of the Florida needs assessment as defined in the current rule 64J-2.010 as the ACS standard for trauma system needs assessment. We have confirmed that ACS has not adopted the Florida methodology.

Regarding the Departments stated goal of removing the statutory state-wide cap of 44 trauma centers and the elimination of the individual TSA trauma center caps, it's helpful to look to the Committee on Trauma, American College of Surgeons, the national trauma experts, for guidance regarding how to ensure a strong statewide trauma system. The Committee on Trauma, American College of Surgeons (ACS) *Resources for Optimal Care of the Injured Patient*

101 N. Gadsden Street · Tallahassee, FL 32301 · Office: 850.201.2096 · Fax: 850.201.2078
www.safetynetsflorida.org

(aka ACS Orange Book), has been referenced previously by the Department as the authoritative guide or gold standard for trauma. The *ACS Orange Book* includes language advocating an approach to trauma planning placing limitations on the number and level of verified trauma centers in a given area to ensure resources are used appropriately to achieve the goal of optimal care for injured patients[xi]. *The ACS Orange Book* also links trauma patient volume to quality outcomes, and the core competency of each Level of trauma care. For example the *ACS Orange Book* includes the following guidance for Level I trauma centers (a) a minimum of at least 1,200 trauma patient admissions annually or 240 admissions with an Injury Severity Score (ISS) of no more than 15 to ensure that an adequate number of injured patients are cared for at the institution to support the required educational programs in training future trauma care providers and to fulfill the required research activities to advance the care of trauma patients; (b) that the trauma system concentration certain injuries that occur infrequently in the Level I trauma centers, to ensure these patients are properly treated and studied; and (c) that the development of Level II trauma centers should not compromise the flow of patients to existing high volume Level I trauma centers.[xii] Florida's current approach to trauma system needs assessment and trauma center allocation does not (a) ensure trauma centers meet the *ACS Orange Book* or the Florida Statutory minimums for severely injured patients; (b) attempt to concentrate infrequent or specific injuries to a TSAs Level I trauma center; (c) consider the potential impact to existing Level I or Level II trauma centers when approving new trauma centers in a TSA; and (d) include Pediatric trauma centers. The elimination of the individual TSA caps is contrary to the Committee on Trauma, American College of Surgeons guidance and is essential to building a strong sustainable trauma system. The approach to trauma system planning and allocation of trauma centers among TSA's must change to an objective data driven trauma system need assessment measuring demand and capacity to determine need, if Florida is to maintain a strong trauma system.

The statutory state-side cap of 44 trauma centers found in s.395.402(4)(c) F.S. was established in the early trauma system development process. The statewide cap is arbitrary and contrary to an objective data driven needs assessment methodology. However, the cap on number of trauma centers allocated to a TSA is not arbitrary and is an essential element in ensuring resources are used appropriately to achieve the goal of optimal care for severely injured patients. The current trauma system needs assessment tool has serious flaws therefore, the current allocation of trauma centers to TSAs is most likely overstated in some TSAs. It is essential that the Department move forward with re-establishing the Florida Trauma System Planning Advisory Committee and begin to work collaboratively with the Committee to develop and adopt an objective data driven trauma system needs assessment methodology that measures demand and capacity to determine need. An objective data driven trauma system needs assessment methodology will provide a TSA by TSA look at whether demand exceeds capacity or capacity exceeds demand. The consistent use over time of a sound objective data

101 N. Gadsden Street · Tallahassee, FL 32301 · Office 850.201.2096 · Fax 850.201.2078
www.safetynetsflorida.org

driven trauma system methodology that accurately measures demand and capacity will naturally change each TSAs allocation of trauma centers.

We recommend:

- The Department temporarily suspend revisions to all trauma rules, preparation of the 2016/2017 trauma needs assessment based on current rule, and acceptance of new trauma center applications.
- Re-establish the Florida Trauma System Planning Advisory Committee
- Working collaboratively with the Florida Trauma System Planning Advisory Committee develop and test an objective data driven trauma system (EMS and Trauma Center) needs assessment methodology to measure demand and capacity for each TSA, inclusive of Level I, Level II, and Pediatric trauma centers and all trauma patients, with consideration given to adopting Geospatial Evaluation System of Trauma Care methodology[xiii],
    - The following issues should be addressed in the development of the objective data driven trauma system needs assessment methodology:
        - Adoption of guiding principles consistent with ACS *Orange Book* specifically (a) an approach to trauma planning placing limitations on the number and level of verified trauma centers in a given area to ensure resources are used appropriately to achieve the goal of optimal care for injured patients, (b) do not compromise the existing trauma centers high volume of trauma patients when developing new trauma centers in a TSA, and (c) an approach that recognizes the role all levels of trauma centers.
        - Define a trauma patient consistent with the definition in the NTDB data dictionary to include an ISS score of no more than 15.
        - Determine the geospatial area of need
        - Define demand, define how to measure demand and identify data required to measure
        - Define capacity – define how to measure capacity and identify data required to measure
    - Ensure the trauma system needs assessment is a transparent methodology using de-identified data sets, permitting stakeholders (a) access to the data sets, (b) risk scoring methodology, (b) assumptions, and (c) formulas to enable stakeholders the opportunity to validate the Departments needs assessment report.
- Develop draft language for a revised administrative rule 64J-2.010 to include the new objective data driven trauma system needs assessment methodology recommended by the Florida Trauma System Planning Advisory Committee and include the baseline TSA trauma center allocation report and allocation table developed using the new proposed methodology that is inclusive of identification of EMS needs as well as trauma center needs.

101 N. Gadsden Street · Tallahassee, FL 32301 · Office 850.201.2096 · Fax: 850.201.2078
www.safetynetsflorida.org

- Include language in the rule "grandfathering" the continued operation of existing verified trauma centers in TSA's where operating trauma centers exceed the number of trauma centers (needed) allocated under the new methodology.
- Limit trauma center application acceptance and approval to those TSAs where the new trauma system needs assessment shows demand exceeds capacity.

Trauma system planning is built on a sound trauma system needs assessment methodology. The re-establishment of the Florida Trauma System Planning Advisory Committee and the collaborative development of a new objective data driven trauma system needs methodology should be the Departments number one priority. The SNHAF membership includes recognized experts in trauma system needs assessment who are eager to work with the Department to development a new objective data driven trauma system needs assessment methodology.

64J-2.012 Process for the Approval of Trauma Centers:

The Department did not provide draft language or state specific goals for including administrative rule 64J-2.012 in rule development therefore, our comments are to the current rule. The Process for the Approval of Trauma Centers rule was last updated in 2010 to include the revisions made to *DOH Pamphlet 150-9 Trauma Center Standards* which demonstrates the need to coordinate rule revisions in a more comprehensive holistic approach. The recommendations below include the provisions included in the comment letter preamble regarding the temporary suspension of rule development and trauma center application approval pending the re-establishment of the Florida Trauma System Plan Advisory Committee and the collaborative development of an objective data driven trauma system needs assessment methodology measuring demand and capacity to determine need.

We recommend:

- The Department working collaboratively with the Florida Trauma System Plan Advisory Committee after the development of a transparent objective data driven trauma system needs assessment methodology measuring demand and capacity to determine need:
  - Review the *ACS Orange Book* to identify the appropriate updates to *DOH Pamphlet 150-9 Trauma Center Standards*
  - Draft revisions to administrative rules 64J-2.012, 64J-2.010, 64J-2.011, 64J-2.016
- Pending the re-assessment of the trauma system need using an objective data driven trauma system needs assessment methodology the Department should not approve any new provisional trauma centers.
- Notify all hospitals in the TSA's where the objective data driven methodology has identified need for additional trauma centers that "letters of intent" will be accepted.
- Revise "Letter of intent" language in 64J-2.012 (1) (a) to include language permissive of:
  - Acceptance of Trauma Center "Letters of Intent", in electronic format (email attachment) or by US Postal Service no earlier than September 1 and no later than midnight October 1 from an acute care general or pediatric hosptial in a TSA where the Department has published pursuant to the objective data driven

101 N. Gadsden Street · Tallahassee, FL 32301 · Office: 850.201.2096 · Fax: 850 201 2078
www.safetynetsflorida.org

needs assessment tool developed collaboratively with stakeholders a need for a new trauma center exist.

- Retain the current language stating letters of intent are non-binding, preserve the submitting hospitals right to complete a new trauma center applications by the due date including language that failure to submit an application voids the hospitals letter of intent

- Revise "Application" language in 64J-2.012 (1) (c) to include language:
  - Requiring submission of electronic trauma center application on or before the deadline of April 1 from those hospitals who submitted a letter of intent in TSAs where a need has been identified.[xiv] (Electronic defined as pdf containing all required information defined in rule delivered by email or CD delivered to the Department by deadline.) Delete all references to paper applications.
  - Requiring electronic submission of applications to the local trauma agency with recommendations back to applicant and the Department within a reasonable time frame to be determined in collaboration with the Trauma System Advisory Committee and local trauma agencies.
- Revise language in 64J-2.012 (1) (d) last sentence to read:
  - "...The standards of critical elements for provisional review for Level I, ~~and~~ Level II, and Pediatric trauma center applications are specified in *DOH Pamphlet 150-9 Trauma Center Standards,* which is incorporated by reference in Rule 64J-2.011, F.A.C. ..."
- Work collaboratively with the Florida Trauma System Plan Advisory Committee to create a transparent [xv]application evaluation and scoring process. The criteria should not automatically rank a Level I application above a Level II or Pediatric trauma center application or a Level II application above a Pediatric trauma center application.
- Publish letters of intent as received on the DOH Trauma Webpage
- Publish names of hospitals submitting a new trauma center application on DOH Trauma Webpage with the date of receipt, level of trauma center for which the hospital is applying, and the TSA in which the trauma center would be located.
- Provide an option for new trauma center applicants to include community support letters with their application. Community support is not an objective criteria and should not be included in the annual TSA needs assessment therefore, inclusion in the application provides an opportunity for community input.
- The Department shall publish on the Trauma webpage on or before May 1, the names and trauma center level of each trauma center applicant granted provisional status and the names of the applicants whose application was denied along with the score of each application.
- Seek legislative authority if necessary to permit adoption of the recommended rule revisions.

Creating a collaborative environment for stakeholders and the Department to address in a comphrensive manner how need is assessed, what standards a trauma center is required to meet by level, the application process, the application evaluation process, the selection methodology, and the approval process is the most effective and efficient path forward.

101 N. Gadsden Street · Tallahassee, FL 32301 · Office 850.201.2096 · Fax 850.201.2078
www.safetynetsflorida.org

64J-2.013 Extension of Application Period:

The Department did not provide draft language nor state specific goals for including administrative rule 64J-2.013 in rule development therefore, our comments are to the current rule. The Extension of Application Period rule was first adopted in 1992, a period when Florida was struggling to provide trauma care in each trauma service area (TSA). The rule has been updated over the years with the last update in 2010. Florida is no longer struggling to provide trauma care in each TSA, the available data show 97% of Florida's population have access to trauma care within 60 minutes (the golden hour).

- We recommend the repeal, in it's entireity, of administrative rule 64J-2.013 *Extension of Application Period*

The administrative rule made sense in 1992 when there were TSAs with no trauma center, however, today all the data shows Florida exceeding the national average for population access to trauma care and the rule is no longer necessary.

64J-2.016 Site Visits and Approval:

The Department did not provide draft language nor state specific goals for including administrative rule 64J-2.016 in rule development therefore, our comments are to the current rule. The Site Visits and Approval rule was last updated in 2010 following the update of the DOH Pamphlet 150-9 trauma standards. Language in administrative rule 64J-2.016 (7) and (11) demonstrates the recognizes by the Department that the current TSA needs assessment methodology does not accurately measure need. The language in 64J-2.016 (7) lays out the situation where in the final verification of a provisional trauma center DOH recognizes there are more trauma centers operating in the TSA than available trauma center slots in the TSA, while the language in 64J-2.016(11) would prioritize the approval of a provisional Level I over a Level II or a Level II over a pediatric trauma center when the TSAs operating trauma centers exceed the TSAs allocated trauma centers. The two sections are addressing a situation where in year 1 the Department approved provisional trauma centers for a TSA then 12 months later when the Department is considering final verification the data shows there are more verified and provisional trauma centers than trauma centers allocated to the TSA, a clear indicator that the needs assessment methodology is ineffective at measuring need. Florida has a mature trauma system and has not experienced a massive population migration of the sort that would justify erratic swings in TSA need year to year. The cause of such erratic swings is a failure to objectively measure demand and capacity to determine a TSA's need for a new trauma center. The one size fits all ranking of Level I's above Level II's and Pediatric trauma centers demonstrates a failure to understand trauma systems are regional and shoud be structured to to serve the unique requirements of the regions population and efficiently use the regions available health care resources. We must reverse the course documented by the two work

101 N. Gadsden Street · Tallahassee, FL 32301 · Office: 850.201.2096 · Fax: 850 201 2078
www.safetynetsflorida.org

arounds in this rule and we must work collaboratively to develop a sound transparent objective data driven trauma system needs assessment methodology and approval process.

We recommend:

- The Department working collaboratively with the Florida Trauma System Plan Advisory Committee after the development of a transparent objective data driven trauma system needs assessment methodology measuring demand and capacity work collaboratively to develop recommended revisions:
    - to *DOH Pamphlet 150-9 Trauma Center Standards* based on the current *ACS Orange Book*.
    - to administrative rules 64J-2.010, 64J-2.011, 64J-2.012, and 64J-2.016
- Reference 64J-2.016 (2), the Department working collaboratively with the Florida Trauma System Plan Advisory Committee should consider the cost effectiveness of the Department's current contract for out-of-state trauma center site reviewers verses the Department contracting directly with ACS for trauma center site reviewers.
- Revise the language in administrative rule 64J-2.016 to:
    - Delete all language arbitrarily prioritizing Level I trauma centers over Level II and Pediatric trauma centers, as well as, language prioritizing Level II trauma centers over Pediatric. The needs of the population and availability of existing resources should drive the level of trauma center not an arbitrary hierarchy. All levels of trauma care are essential to a strong trauma system.
- Delete language in 64J.2016 (7) and (11). Adoption of an objective data driven methodology for determining trauma center need within a TSA will eliminate the circumstances anticipated by the current language in (7) and (11).

We ask the Department to re-establish the Florida Trauma System Plan Advisory Committee. The Department has statutory authority to re-establish the Florida Trauma System Plan Advisory Committee and to work collaboratively with stakeholders. We encourage the Department to make the development of an objective data driven trauma system needs assessment methodology that measures demand and capacity to determine need for each TSA the first priority of its work with the re-established Florida Trauma System Plan Advisory Committee.

We recognize some of our recommendations may require statutory changes, however, the Department staff at each workshop indicated the goal was to develop revised rules and then seek statutory changes required for adoption of the revised rules. We ask the Department to hold rule development workshops after the Department prepares revised rule language for any of the five rules included in this comment letter. The rule development workshops held in June and July provided limited insight into the Departments goals for the rules being work-shopped and no draft language. Moving forward with adoption of a proposed rule for any of the referenced rules would not constitute stakeholder input on the rule as no language was provided. We thank the Department for opportunity to provide written comments and look

101 N. Gadsden Street · Tallahassee, FL 32301 · Office: 850.201.2096 · Fax: 850.201.2078
www.safetynetsflorida.org

forward to collaboratively working with the Department to develop an objective data driven trauma system needs assessment methodology to ensure citizens of Florida have access to high quality trauma care

Sincerely,

Lindy Kennedy

Lindy Kennedy
Vice President

Attachment

101 N. Gadsden Street · Tallahassee, FL 32301 · Office 850.201.2096 · Fax 850.201.2078
www.safetynetsflorida.org

Endnotes

[i] Committee on Trauma, American College of Surgeons *Resources for Optimal Care of Injured Patient 2014 (aka ACS Orange Book) Chapter 1, Page 12, 3rd paragraph.*

[ii] All TSA's have at least one verified trauma center, excluding TSA 17 (Collier County), where officials have repetitively voiced they are not interested in opening a trauma center. Pointing to their strong working relationship with Lee Memorial the trauma center in neighboring TSA 15 which provides Collier residents with ready access to trauma care.

[iii] See attached ACS TQIP PowerPoint

[iv] The NTDB is the largest aggregation of U.S. trauma registry data ever assembled and is the leading performance improvement tools of trauma care

[v] See Attached 2015 NTDB Report Overview

[vi] HIPAA _ Health Insurance Portability and Accountability Act, a 1996 Federal law that restricts access to individuals' private medical information

[vii] CMS – Centers for Medicare and Medicaid Services

[viii] Meaning a trauma patient who expires at 11:55 p.m. before the second midnight is not included in the Florida Trauma Registry.

[ix] See June 24, 2013 letter to Janet Collins from the Association of Florida Trauma Coordinators which includes comments on reporting patient identification and other trauma registry issues.

[x] AHCA Hospital Discharge Data Unit has a proven methodology for creating de-identified health data and should be consulted.

[xi] *ACS Orange Book*, Chapter 2, Page 16, Paragraph 2

[xii] *ACS Orange Book*, Chapter 1, page 3, Level II Section, Paragraph 1,

[xiii] Geospatial Evaluation of Systems of Trauma Care methodology is a mathematical modeling of a population-based data set, to optimize trauma system location of trauma centers considering population, injury profile, available resources and travel time optimization. See attached article - *Jan* O. Jansen, FRCS, FFICM, Jonathan J. Morrison, MRCS, Handing Wang, BSc, Robin Lawrenson, MCPara, FASI, Gerry Egan, QAM, DipIMC, RCSEd, Shan He, PhD, and Marion K. Campbell, PhD, ***"Optimizing trauma system design: The GEOS (Geospatial Evaluation of Systems of Trauma Care) approach"***, Trauma Acute Care Surgery, Volume 76, Number 4 (January 2014)

[xiv] Current language requires 3 paper copies, prior drafts by DOH revised to 2 electronic and 1 paper.

[xv] Transparent defined as an approach or methodology with clearly defined criteria and scoring such that any person reviewing the new trauma center application in accordance with the Departments published criteria would arrive at approximately the same score for each application.

ORLANDO HEALTH

July 20, 2016

Leah Colston
Emergency Preparedness Division
Florida Department of Health
4052 Bald Cypress Way
Tallahassee, FL 32399-1705

Ref: Rule development covering administrative rules 64J-2.006, 64J-2.010, 64J-2.012, 64J.2.013, and 64J-2.016

Dear Ms. Colston,

On behalf of Orlando Health, we are grateful for the opportunities to participate in the three rule workshops held throughout the state. We were pleased to attend the July 11 workshop in Orlando and found the feedback from others in the trauma community very helpful. As Central Florida's Level I Trauma Center serving the community for the past 33 years, please consider our feedback below as the Department of Health (the Department) drafts these proposed rules.

In regards to rule 64J-2.006, the Trauma Registry and Trauma Quality Improvement Program (TQIP) rule currently requires that all Florida trauma centers participate in risk adjusted benchmarking through TQIP. Several centers have signed the Florida Collaborative TQIP agreement in order for the Department to receive our quality data as it compares to trauma centers across the nation. We have signed the agreement to participate in this collaborative agreement in an effort to improve trauma care across the state of Florida by sharing best practices and developing our system's areas of opportunity. We met in November 2015 regarding our desire to move forward with this agreement, but we understand that there have been some changes in the Department staff that were helping to lead these efforts. However, we feel that the utilization of this data received by the Department from TQIP can replace the utilization of the Florida Next Generation Trauma Registry (NGTR).

Beyond the ability of the National Trauma Data Bank (NTDB) and TQIP to replace and enhance the Florida NGTR, there are other issues with the registry which utilize unnecessary resources at the Department and trauma centers. Our team is charged with utilizing two data dictionaries and sets of inclusion criteria due to the variation between the NTDB and the Florida NGTR. In addition to this, data submission and acceptance is different from the NTDB in that patient records are submitted by discharge date for the Florida NGTR and admission date for the NTDB. This has caused an extensive amount of time spent on data submission and configuration for an

ORLANDO HEALTH

additional registry submission. For our most recent submission of the 2016 1st quarter data, it took from the first week of June until the July 1 deadline to have a successful submission after having a successful submission to the NTDB in May. This takes away from trauma data analysis for quality improvement initiatives and data abstraction for the trauma registrars.

Below we have included our recommendations on other trauma rules to ensure a robust trauma system that does not duplicate requirements and services we currently provide to the Central Florida community:

- Re-establish the Florida Trauma System Planning Advisory Committee.
- Work collaboratively with the Florida Trauma System Planning Advisory Committee to develop and test an objective data driven trauma system (inclusive of EMS) needs assessment methodology to measure demand and capacity for each trauma service area (TSA), inclusive of Level I, Level IIpediatric trauma centers and patients.
- Ensure the trauma system needs assessment is a transparent methodology using de-identified data sets, permitting stakeholders access to data sets, risk scoring methodology, assumptions, and formulas to enable stakeholders the opportunity to validate the Department's needs assessment report.
- Develop draft language for a revised administrative rule 64J-2.010 to include the new objective data driven trauma system needs assessment methodology recommended by the Florida Trauma System Planning Advisory Committee. Include language in the rule "grandfathering" the continued operation of existing verified trauma centers in TSA's where operating trauma centers exceed the number of trauma centers (needed) allocated under the new methodology.
- Seek legislative authority if necessary to permit adoption of the new objective data driven trauma system needs assessment methodology or required to update the rule.

Thank you again for the opportunity to provide written feedback following the recent rule workshops. Orlando Health looks forward to collaboration within the trauma system to provide the optimal care for trauma patients in our communities. Over the past year, Orlando Health has seen several steps to improve the collaboration among the trauma community by the Department. Orlando Health thanks you.

Sincerely,

Joseph Ibrahim, MD, FACS
Trauma Program Medical Director

Donald Plumley, MD
Pediatric Trauma Program Medical Director

RUTLEDGE ECENIA
PROFESSIONAL ASSOCIATION
ATTORNEYS AND COUNSELORS AT LAW

STEPHEN A. ECENIA
DIANA M. FERGUSON
MARTIN P. McDONNELL
J. STEPHEN MENTON
CRAIG D. MILLER
R. DAVID PRESCOTT

POST OFFICE BOX 551, 32302-0551
119 SOUTH MONROE STREET, SUITE 202
TALLAHASSEE, FLORIDA 32301-1841

TELEPHONE (850 681-6788
TELECOPIER (850) 681-6515
www.rutledge-ecenia.com

MARSHA E. RULE
GARY R. RUTLEDGE
MAGGIE M. SCHULTZ
TANA D. STOREY
GABRIEL F.V. WARREN

GOVERNMENTAL CONSULTANT
JONATHAN M. COSTELLO

OF COUNSEL
HAROLD F. X. PURNELL

July 21, 2016

Via Email

Ms. Leah Colston
Department of Health
4052 Bald Cypress Way, Bin A-22
Tallahassee, Florida 32399
Leah.Colston@flhealth.gov

Re: Amendment of Rule 64J-2.010

Dear Ms. Colston:

We are writing as the authorized representatives of the USF/HCA Trauma Network hospitals to address the Department of Health's rule development efforts regarding Rule 64J-2.010, which allocates trauma center need. We commend the Department of Health on its efforts to review trauma regulation to help move Florida's trauma system forward. To that end, we have compiled our comments below on how to ensure any proposed rule reflects the trauma system mission and best allows Florida trauma centers to provide timely, life-saving care to trauma patients statewide.

Amendments to Rule 64J-2.010

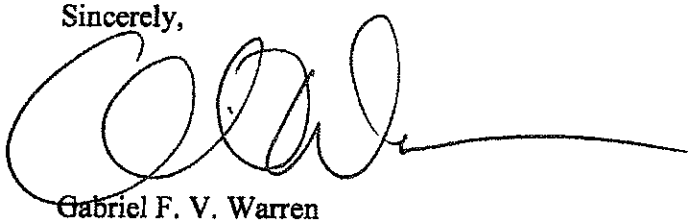
We understand and appreciate the Department's recent efforts to reassess how trauma center need is currently allocated in Florida. However, a number of hospitals have developed trauma programs in reliance on the Department's current allocation methodology and are now well into the application process to become verified trauma centers. It would be grossly unfair to these hospitals, which are currently operating as provisional trauma centers, to not immediately implement rules that address their programs.

In that regard, we strongly urge the Department to adopt the proposed Rule 64J-2.010, which was released on February 4, 2016. A copy of the proposed rule is attached for reference. That proposed rule was based on the Department's 2015 Amended Trauma Service Area Assessment, as well as letters of community support which the Department received. A copy of the 2015 Amended TSA Assessment is also attached for reference.

Once the hospitals who have built trauma programs complete the application process, we will be happy to work with the Department to determine if a new approach to trauma center allocation is warranted.

The USF/HCA Trauma Network hospitals remain committed to providing excellent care and look forward to working with the Department to reach the best solution for the citizens and visitors of Florida that depend on us.

Sincerely,



Gabriel F. V. Warren

PANZA, MAURER & MAYNARD P.A.
ATTORNEYS AND COUNSELORS AT LAW

TALLAHASSEE
215 South Monroe Street
Suite 320
Tallahassee, Florida 32301
(850) 681-0980
Fax (850) 681-0983

FORT LAUDERDALE
Coastal Towers | Suite 905
2400 East Commercial Boulevard
Fort Lauderdale, Florida 33308
(954) 390-0100 Fax (954) 390-7991
Please reply to Fort Lauderdale Office

CORAL GABLES
The Alhambra Building
Two Alhambra Plaza
Suite 102
Coral Gables, FL 33134
(305) 906-0155

July 21, 2016

Via Email: leah.colston@flhealth.gov
Ms. Leah Colston
Bureau of Emergency Medical Oversight
Florida Department of Health
4052 Bald Cypress Way, Bin A-22
Tallahassee, Florida 32399-1722

Re: Written Comments on Trauma Rule Development Workshops Concerning Rules 64J-2.006, 64J-2.010, 64J-2.012, 64J-2.013, and 64J-2.016
Our File No.: 2154/16-21652

Dear Ms. Colston:

We are submitting these written comments on behalf of the Public Health Trust of Miami-Dade County, Florida, which oversees and operates the Jackson Health System. The Public Health Trust thanks the Department of Health (the "Department") for re-visiting existing rules 64J-2.006, 64J-2.010, 64J-2.012, 64J-2.013, and 64J-2.016 and holding three rule development workshops with the purpose of receiving public comment and improving the Florida trauma system as a whole. The Public Health Trust agrees that a collaborative process with the Department and trauma stakeholders will provide the best outcome for the trauma system and the trauma patients that it serves.

We also laud the Department's proposed formation of a trauma advisory council and recommend that it be formed as soon as practicable. This way the advisory council can participate in the drafting of the proposed rules and provide invaluable insight on the needs of the trauma system and how best trauma outcomes may be achieved.

Rule 64J-2.010

A well thought out and transparent allocation rule, along with any assessment tools that inform the rule, lays the foundation for an integrated trauma system. The goal should be that it assesses the need for trauma centers in the most efficient way possible, and is tailored to the specific trauma service area ("TSA") in question. As the Department can appreciate, not all TSAs are created equally. Some encompass many counties while others are only comprised of one or two counties. Some are made up of dense, largely urbanized areas while others serve sparsely populated, rural areas. Because of these differences, it may not make sense for a one-

rule-fits-all approach. Instead, a better approach may be to craft a process similar to the Certificate of Need approval that is currently in place for general hospitals and other health care specialties, as provided in Chapter 408, Florida Statutes.

In whatever methodology the Department ultimately adopts, the process should be as transparent as possible. The current allocation rule, particularly the TSA assessment that informs the rule, resides in the unknown. Due to the confidential nature of the data and methodology underlying the allocation inputs, the public is not in a position to replicate or confirm the calculations by the Department. As the Department is keenly aware, the Public Health Trust on two separate occasions attempted to challenge the annual update to the allocation rule, but the rule was withdrawn twice at the eve of trial. It should not be necessary for the public to commence litigation every time someone from outside the Department seeks to verify the allocation rule. The methodology, including the data and calculations that derive the final results, should be included in the rule itself, so that everyone knows exactly how the Department is determining the need for trauma centers in a particular TSA.

Finally, the Public Health Trust also recommends that the Department not only assess the need for the number of trauma centers in a TSA, but also determine the best location for trauma centers in a particular location within the TSA. As a number of commentators have expressed during the rule workshops, the current allocation rule is silent on geography within a TSA. As it currently stands, a trauma center could open across the street from an existing trauma center, just as long as there is a stated need for one in the TSA. This does not make sense practically and does not serve the needs of the trauma system, especially of the needs for trauma patients in a particular TSA. Two trauma centers in close proximity to one another does little to serve the population in other areas of a TSA. Any proposed rule should factor in the specific geography of proposed trauma centers in the particular TSA. This way the Department can ensure that trauma centers are in the best possible location within a TSA so that trauma patients can receive care as efficient and quickly as possible.

Rules 64J-2.012, 64J-2.013, and 64J-2.016

The Public Health Trust urges the Department to consider the great time and expense that hospitals must spend during the provisional stage of the application process. As Rule 64J-2.012 is currently set up, a hospital must devote enormous amounts of capital on equipment, infrastructure, and staff without any guarantee that they will secure a provisional license. Moreover, even should a hospital obtain provisional licensure, that provisional licensure is probationary subject to revocation. That is, if the number of applicants vying to become trauma centers is more than the number of trauma slots available in a particular TSA, then, by default, one of those provisional trauma centers will lose its licensure at the conclusion of the application process. This means that a hospital will expend millions of dollars with a substantial probability that it will be wasted. What's more troubling is that during this probationary period, the public grows accustomed to having access to the provisional trauma center but then must look to other options should it not be the winning applicant.

There must be a better alternative. What may be better is to have a provisional review where applicants undergo a "paper" application before having to devote the considerable amount of time and resources of purchasing costly equipment, constructing a helipad, and hiring highly specialized surgeons and staff. This would be different than the "paper" provisional review that is currently in place, which requires the applicant to have all of the equipment, infrastructure, and staffing in place as a prerequisite to filing an application. Again, this could potentially be achieved through a process similar to the Certificate of Need licensure for general hospitals and other health care specialties.

With respect to the application itself, the Public Health Trust also urges the Department to adopt a more objective process for measuring an applicant hospital's ability to provide trauma care. The current system allows for too much subjective interpretation by the Department's internal and external evaluators, especially during the provisional review stage. This is partially due to many of the Trauma Standards being vague and ambiguous. Though the Public Health Trust recognizes that there will always be some measure of subjectivity in evaluating trauma center applications, there should be objective parameters in place to ensure that all applicants are on the same level playing field.

There is also uncertainty with respect to the scoring system and standard that evaluators use to measure the application as a whole. The rules should conform to the trauma statutes' directive of measuring applications through the lens of substantial compliance. It is impracticable to expect applicants to submit perfect applications and that every single one of the components of the Trauma Standards to be in perfect compliance. Some measure of leniency should be permitted, especially considering the great time and expense applicants dedicate to their applications and the relatively short provisional review period that evaluators have to review them.

Conclusion

The Public Health Trust thanks the Department again for welcoming public comment and reconsidering the trauma administrative rules. It is apparent that the rules can be improved, particularly with respect to the allocation of trauma centers in TSAs and the application process for becoming trauma centers in general. We believe that the trauma advisory council will be invaluable in this endeavor and can provide the necessary expertise in establishing an efficient and transparent trauma system for the future.

The Public Health Trust stands ready to offer any further assistance to the Department in the drafting of proposed rules and is open to providing further comment as necessary.

Sincerely,

THOMAS F. PANZA, ESQ.

TFP/BSV

MIAMI CHILDREN'S HEALTH SYSTEM

April Andrews-Singh, Esq.
General Counsel and
Senior Vice President for Legal & Public Affairs

July 21, 2016

Celeste Philip, MD, MPH
Surgeon General & Secretary
FL Department of Health
4052 Bald Cypress Way
Tallahassee, FL 32399

Re: Comments on Rule Development Covering Rules 64J-2.006, 64J-2.010, 64J-2.012, 64J.2.013, and 64J-2.016, Fla. Admin. Code

Dear Surgeon General Philip:

On behalf of Nicklaus Children's Hospital ("NCH") please accept these comments on the Department's recent workshops as to the current trauma program Rules 64J-2.006, 64J-2.010, 64J-2.012, 64J-2.013, and 64J-2.016.

NCH currently is a licensed Class III Specialty Children's Hospital providing world class medical care for children in South Florida, and serves as the largest pediatric teaching and research hospital in the southeast United States. NCH has long served the community by providing lifesaving services to injured children. Established in 1950, NCH (formerly Miami Children's Hospital) is South Florida's only licensed specialty hospital exclusively for children, with more than 650 attending physicians and 130 pediatric subspecialists providing services to children at its 289-bed hospital, 16,400-square foot ambulatory surgical center, physician practice and affiliated network of eight outpatient services.

NCH is one of only two dedicated freestanding pediatric trauma centers ("PTCs") in the state of Florida and the only dedicated freestanding pediatric trauma center in South Florida. NCH's Trauma Center serves approximately 550 children annually and has outstanding performance and outcomes. NCH provides state of the art equipment and also has highly qualified physicians who are Board certified. The Trauma Teams include multidisciplinary health care professionals throughout NCH, and many NCH physicians have national and international reputations and consult in the care of the most complex cases. In addition to being designated by DOH as a pediatric trauma center in TSA 19, NCH is also licensed to provide acute care services to Miami-Dade County. NCH has full LifeFlight transportation and provides helicopter and fixed wing transport services between hospitals to ensure transport of children quickly for the care they need, with a volume of approximately 3,000 LifeFlight transports per year. NCH also has the largest pediatric residency program in the southeastern United States, including fellowships and GME programs including in each of the following program areas: (1) Pediatric Neurosurgery; (2) Pediatric Surgery; (3) Pediatric Emergency Medicine; (4) Pediatric Critical Care that has a required

Mailing Address: 3100 S.W. 62nd Avenue, Miami, Florida 33155-3009 / (305) 666-6511
Visit us online at MiamiChildrens.com

component to be at a hospital with a pediatric trauma program; and (5) Trauma training program for Nurses.

Summary

The current rules do not take into consideration the highly unique and special role of stand-alone dedicated PTCs in the state-wide trauma system, and the important public policy interests they serve in treating and serving catastrophically injured children. This unique role and the underlying public policy considerations dictate that the rules be modified to fully take into consideration such PTCs, and especially that the needs assessment and allocation methodologies specifically include and fully take into account PTCs. This is already required by the statutory language and legislative intent. But it should be made specific and clarified in the Allocation Rule's methodology. Failure to include PTCs in the allocation methodology will continue to ignore the clear legislative intent and the unique role of PTCs in the trauma system. It will also inevitably have a devastating impact when any Level I or Level II/pediatric trauma centers are approved in a geographic location that is in close proximity with a preexisting approved PTC.

As explained further below, these dire consequences are illustrated by the current situation faced by NCH, wherein the Department has recently issued a provisional approval (which approval is under challenge and pending at DOAH) of a Level I trauma center in the same county (Miami-Dade County) and the same Trauma Service Area (TSA 19) which is only a mere 6.7 miles from NCH's stand-alone dedicated pediatric trauma center. Generally speaking, any final approval of a Level I in such close proximity will inevitably and severely impact the preexisting PTC, including by greatly limiting its ability to continue to provide high quality health care services to pediatric patients, creating an unnecessary duplication of pediatric health care services, and causing a severe decrease in the volume of pediatric patients served by the PTC resulting in a material loss of revenue, and more – all of which will equate to a virtual revocation of the PTC's preexisting approval.

The Unique Position of PTCs in the Trauma System

In treating and serving children who have been catastrophically injured, PTCs serve important public policy interests and hold a highly specialized, important, and unique role in the trauma system.

Injury is the number one killer of children in the United States. Numerous studies and articles show that injuries result in more deaths in children than all other causes combined. The deaths caused by injuries, intentional or unintentional, account for more years of potential life lost under the age of 18 years than do deaths attributable to sudden infant death syndrome, cancer, and infectious diseases combined. It has been estimated that 1 in 4 children sustain an unintentional injury that requires medical care each year, with resultant costs that exceed many billions of dollars per year nationwide. Moreover, it has been estimated that for every child who dies from an injury, 40 others are hospitalized and 1,120 are treated in emergency departments, and that an estimated 50,000 children acquire permanent disabilities each year, most of which are the result of closed head injuries. In short, pediatric trauma continues to be one of the major threats to the health and well-being of children.

Because of the unique and specialized needs of children, a coordinated trauma system must recognize and support the unique role of pediatric trauma centers. The above factors and the underlying public policy interests dictate that any well-designed statewide trauma system and the applicable rules fully take into consideration the unique role of freestanding dedicated PTCs and include PTCs in all aspects of the rules where appropriate, especially in determining the needs assessment methodology for each TSA. If the trauma system rules do not recognize and take into account this special role, then it places the system as well as the PTCs in jeopardy resulting in devastating impacts to the PTCs and consequently to the system as a whole. *See* "Impact" discussion below.

As compared to PTCs, Level I and Level II/pediatric trauma centers simply do not have the highly specialized resources to care for all of the injured children within their referral area. Thus, the most seriously injured children typically need to be stabilized and transported to facilities, such as NCH, which have these highly specialized resources and which continue to make extraordinary efforts to provide highly specialized care for these children.

The Legislature has recognized the highly unique and important place in Florida's trauma care system including by specifically designating pediatric trauma as a specialized service. And in fact the care of pediatric trauma patients is highly specialized and requires the presence at the facility of unique and highly trained specialists and sub-specialists that see a high volume of pediatric patients annually. For this reason, the American College of Surgeons Orange Book, Ch. 2 p. 5, addresses "Adult Trauma Centers Treating Injured Children" and states as follows (emphasis added):

> **Pediatric trauma centers should be used to the fullest extent feasible**. However, pediatric resources for trauma care are scarce in many communities. In such areas, adult trauma centers, of necessity, may serve as the primary pediatric resource for the region and, therefore, may need to provide initial care for injured children

The studies and data also show a direct relationship between volume and quality of care at trauma centers – the higher trauma patient volumes and a wider variety of trauma cases correlate to higher quality of patient care in a trauma setting. A dedicated PTC such as NCH has the higher volume (NCH serves approximately 550 children annually) and the corresponding quality, in contrast to a Level I or Level II/Pediatric which lack the required depth of special expertise, volume, and experience. NCH's high volume is further illustrated by the fact that its emergency department has a volume of approximately 91,000 patients per year, which is the fourth busiest in the nation for a children's hospital. A stand-alone dedicated trauma center also has a better cost and quality component because NCH's Trauma primary goals are entirely focused on serving the children and maintaining a center of excellence to pediatrics.

The current rules do not recognize this unique role of highly specialized and dedicated PTCs like NCH and the important public policy interests at stake, nor do they implement the legislative intent. In fact the current rules have been interpreted in a manner that is detrimental to the two freestanding existing pediatric trauma centers in the State, and harmful to the important goal of ensuring available trauma services to children.

The Rules should be amended to recognize and clearly articulate the unique role and importance of pediatric trauma services. The Allocation Rule should note that in TSAs with an already approved pediatric trauma program, no additional provisional trauma programs should be approved to provide trauma services to children. The Rules should further specify that transport of children with trauma injuries should go first to any designated pediatric trauma center within a an appropriate transport time to be determined by the agency.

The Needs Assessment Methodology Must Include PTCs

The legislative intent indicating that PTCs must be included in any needs assessment methodology is illustrated by the statutes which indicate the Department should deny an applicant hospital unless it is located in a trauma service area that has a need for an additional trauma center. For example, section 395.4025(5), Florida Statutes provides as follows (emphasis added):

> In addition, hospitals being considered as provisional trauma centers shall meet all of the requirements of a trauma center and shall be located in a trauma service area that has a need for such a trauma center.

Similarly, section 395.402(2)(c), Florida Statutes, provides that the Department is tasked with establishing criteria for determining the number and level of trauma centers needed to serve the population in a defined trauma service area or region. In doing so, it must consider "the geographical composition of an area to ensure rapid access to trauma care by patients," the "[h]istorical composition of patient referral and transfer in an area," the "inventories of available trauma care resources, including professional medical staff," "population growth characteristics," and the "actual number of trauma victims currently being served by each trauma center," among others. See 395.402(3), Fla. Stat. In addition, section 395.402(2)(g), Florida Statutes further specifically requires the Department to take into consideration "the need to maintain effective trauma care in areas served by existing centers, ..."

Thus the Department is tasked with taking into consideration need when it reviews applications, and section 395.4025(1) specifically requires the Department to "establish the approximate number of trauma centers needed to ensure reasonable access to high-quality trauma services."

Integral to this analysis is the contemplation of the specific geographic location of a trauma center inside a particular TSA. Rule 64J-2.016 establishes preference criteria for the selection of trauma centers in a specific trauma service area. Virtually all of these criteria relate to geographic location. For example, the first criterion is measured by the geographic location that is most conducive to access by the greatest number of people to be served within a TSA. The second criterion is measured as the hospital representing the best geographic distribution with respect to terrain, population served, and projected service population in a given TSA. These are but two examples of how geographic location is pertinent to the licensure analysis for trauma centers. The Department should not ignore this legislative mandates and must consider these criteria when it made its decision to approve a trauma center's provisional status.

Additionally, Florida rules provide for a specific number of trauma centers in each trauma service area. The current Allocation Rule 64J-2.010 provides, for example, for a determination of need for *three* trauma centers in TSA 19 (which includes Miami-Dade and Monroe Counties). However, the Department's recent provisional approvals of May 6, 2016 would result in *five* trauma centers in TSA 19 -- three Level I trauma centers and two Level II trauma centers:

- NCH – dedicated pediatric Trauma Center
- Kendall Regional – Provisional Level I (includes Pediatric)
- Jackson Health System/Ryder Trauma Center – Level I
- Aventura – Provisional Level II
- Jackson South – Provisional Level II.

Accordingly, these provisional approvals are in excess of and facially violate the Department's own Rule 64J-2.010.

Moreover, the current rules do not clearly specify where, within each TSA, there is a need. As explained further below (see Impact section), the location of an additional Level I or Level II/pediatric trauma center in close geographic location to an existing PTC will inevitably have devastating consequences on the PTC. There is no shortage of pediatric resources in the area closely proximate to an existing PTC, and so no necessity to have a Level I or Level II/Pediatric provider in close proximity to a specialized dedicated PTC.

Simply put, such a location does not harmonize with the existing true needs, nor with overall trauma system to provide the best trauma care and serviceability in the particular TSA. Any final approval of such a program would so severely impact the existing pediatric trauma program that it would amount to a constructive revocation and closure of the pediatric trauma program.

Impact of Not Considering PTCs in the Allocation Methodology

Any proposed approval of a Level I or a Level II/Pediatric facility in close proximity to a PTC, without properly including the PTC in the methodology of determining need, will cause a substantial and severe impact on the nearby existing pediatric Trauma Center.

The current Allocation Rule has been interpreted in at least one recent administrative case (erroneously) to exclude consideration of pediatric trauma programs in determining need for additional trauma programs in a trauma service area. This type interpretation results in unnecessary proliferation of trauma programs generally, including programs with ability to offer only an inferior level of care to pediatric patients that is not specialized for children only.

This is best illustrated by NCH's current situation in Miami, where the Department has provisionally approved a Level II/pediatric Trauma Center located only 6.7 miles from NCH's dedicated PTC. If finally approved, the inevitable result will be devastating to NCH including in each of the following ways, all of which will equate to a virtual revocation of the PTC's preexisting approval:

- A severe reduction in NCH's "geographic" service area within TSA 19, because it changes NCH's current allowed geographic area to a greatly reduced area which in turn will result in a greatly reduced number of pediatric trauma cases at NCH;

- A severe reduction in NCH's Trauma cases -- approaching a 90% reduction -- so as to amount to a constructive revocation and closure of NCH's excellent and leading pediatric trauma program and replacing it with a much less qualified general Level I program that essentially only dabbles in pediatric trauma services;

- A devastating impact on graduate medical programs (GMEs) and residency programs at NCH, which has the largest pediatric residency program in the southeastern United States, including substantial impact on fellowships and GME programs in each of the following program areas: (1) Pediatric Neurosurgery; (2) Pediatric Surgery; (3) Pediatric Emergency Medicine; (4) Pediatric Critical Care that has a required component to be at a hospital with a pediatric trauma program; and (5) Trauma training program for Nurses;

- Undermine and defeat the purpose of enormous capital and operational investments made to develop trauma services specifically for children, including investments funded through millions of dollars in philanthropic donations made specifically for this purpose;

- Disruption and substantial alteration of existing patient flows to NCH, which will compromise NCH's ability to continue to meet the needs of the trauma patients it serves;

- Trauma patients that would otherwise receive trauma care at NCH will be diverted to the nearby Level I for trauma care, which is detrimental to the inclusive trauma system and to NCH in particular;

- Economic and non-economic impacts, including a decrease in volume and revenues which in turn leads to a loss of expertise, proficiency and experience available to the highly qualified trauma team otherwise in place at NCH.

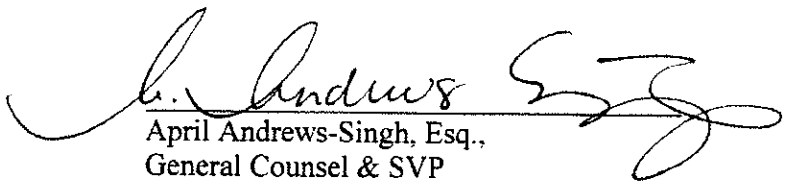
Conclusion

As part of the fix being considered by the Department, we strongly urge that the rules be modified to fully take in to account the unique role of PTCs, and that the needs assessment and allocation methodology be modified to specifically and fully factor in consideration of PTCs, as is already required and contemplated by the statutory language, the legislative intent, public policy considerations, and the best interests of children.

We also request that additional workshops, and perhaps a specific workshop on a portion of an Agenda, be devoted to the issue of pediatric trauma services.

Thank you for the recent workshops and the opportunity to provide these comments. We look forward to working with the Department in the coming months.

Sincerely,



April Andrews-Singh, Esq.,
General Counsel & SVP
Miami Children's Health System

Cc: Leah Colston, Leah.Colston@flhealth.gov
Michael Leffler, Michael.Leffler@flhealth.gov

Leffler, Michael

From: Colston, Leah
Sent: Friday, July 22, 2016 9:08 AM
To: Leffler, Michael
Subject: FW: Trauma rule comments

Leah A. Colston, PMP, CPM, FCCM
Chief, Bureau of Emergency Medical Oversight
Office: 850.245.4693
Mobile: 850.528.5036

How am I doing? Please let me know by taking this short survey. Thank you!
http://survey.doh.state.fl.us/survey/entry.jsp?id=1389303062486

From: Shouppe, Clint [mailto:Clint.Shouppe@baycare.org]
Sent: Friday, July 22, 2016 8:54 AM
To: Colston, Leah <Leah.Colston@flhealth.gov>
Subject: Trauma rule comments

July 22, 2016

Dear Leah,

Thank you for the opportunity to provide written comment as part of the trauma rule development workshops the Department of Health recently held in Tallahassee, West Pam Beach, and Orlando. Please accept these comments on behalf of St. Joseph's Hospital and BayCare Health System.

BayCare Health System is the leading community-based health system in the Tampa Bay area. Composed of a network of 14 not-for-profit hospitals, outpatient facilities, and services offerings such as imaging, lab, behavioral health, and home health, BayCare provides expert medical care throughout a patient's lifetime. St. Joseph's Hospital is BayCare's largest facility and also a level II/pediatric trauma center that treats more than 2,500 trauma patients each year.

First and foremost, we want to thank you for your commitment to restart the Department's Trauma Advisory Council. By reinstituting the Council, it increases the chance for the industry to return to the consensus-driven approach to trauma policy that allowed our state to become a national leader in trauma care. In putting together the Council, we encourage you to:

1. Select members representing a broad range of stakeholders from across the trauma system, including prehospital, hospital, trauma surgeons, and trauma program managers. Having a representative

membership will ensure the Council provides useful advice to the Department that represents a consensus from across the state.

2. Convene the Council before moving forward with rule promulgation. Providing policy guidance is the chief responsibility of the Council and also the best way to develop consensus on new policy changes. Moving forward on substantive rule changes before the Council is operating would undercut the very purpose of reconvening the Council.

64J-2.006 Trauma Registry and Trauma Quality Improvement Program

While we appreciate the improvements made to the trauma registry, there remain significant compliance burdens that increase cost without improving patient outcomes.

1. The two midnight inclusion threshold is problematic and we encourage the Department to remove it from the data dictionary. The arbitrary standard has no bearing on whether a patient is truly a trauma patient. Moreover, the two midnight inclusion threshold is inconsistent with the TQIP submission requirements and potentially disincentivizes reducing length of stay for trauma patients.

2. Submissions to the Florida Trauma Registry are duplicative of the existing submission process for TQIP. It would be significantly more efficient to instead have DOH contract directly with TQIP to receive the necessary data from the national registry. Doing so would reduce cost while still giving DOH access to the necessary trauma data.

3. The existing DOH requirement to submit identified patient data unnecessarily puts patient privacy at risk. By adopting the national database, this issue would also be resolved.

64J-2.010 Apportionment of Trauma Centers Among the Trauma Service Areas (TSA)

As the Department considers potential changes to the allocation process, we would ask you to think through how the rule can best measure the true demand for trauma services measured against the capacity of existing facilities. We are fortunate that almost every Floridian has had access to a trauma center within the golden hour for many years. As coverage becomes less of a challenge, we hope the Department will shift its focus to ensuring quality trauma care across the state. In trauma, volume matters. It is far better to tap the existing capacity of legacy trauma centers rather than unnecessarily increase the total number of new trauma centers. To that end, we would make the following suggested improvements:

1. Remove the community support component from the allocation calculation. Trauma demand should be a quantitative measurement. Community support might be an appropriate measure when considering the relative merits of competing trauma center applications, but it does little for scientifically evaluating the level of care needed to improve patient safety.

2. Lower the relative weight of population in the calculations. Population is at best an inexact measure of trauma demand and ignores the differences in population density between large metro areas and more rural or suburban communities.

3. Incorporate the impact of provisional trauma centers in the allocation calculation. It is our understanding that the Department only uses verified trauma centers for the existing capacity evaluations. This ignores the patients being seen by provisional trauma centers and tips the scale in favor of allocating new trauma center slots. Any time a new trauma center opens, it will take time for prehospital trends to alter.

4. Finally, we encourage the Department to be more transparent in providing not only the final calculations for the allocation scorecard but also the underlying data that is used to develop the figures.

64J-2.012 Process for the Approval of Trauma Centers

1. Consider that trauma demand is not spread around the existing trauma service areas (or the larger regional domestic task force regions) equally. The existing rules do not distinguish whether a proposed trauma center is as far from an existing trauma center as possible or across the street. Evaluating trauma center applicants based on their proximity to existing trauma centers would be a significant improvement and provide better coverage for the patients in that area.

2. The Department should develop a more formal process for the approval of provisional trauma centers. Increasing the clarity around this process and creating more firm units of measurement when evaluating provisional applicants will only increase the likelihood of new trauma centers becoming successfully verified.

3. We appreciate the statements that reinforce no existing trauma centers are at risk due to changes in the allocation rule. We encourage you to give this statement the force of rule by making clear that any allocation changes will not impact existing trauma centers either immediately or when those centers are up for reverification.

Thank you again for the opportunity to provide comment. If you have any questions, please do not hesitate to reach out.

Sincerely,
Clint Shouppe

Clint Shouppe
State Government Relations Manager
BayCare Health System
727-519-1885 office
813-767-0550 cell
Clint.Shouppe@baycare.org

of the contents of this message is prohibited. If you have received this electronic message in error, please notify the sender and destroy the original message and all copies.