BRENNAN, MANNA & DIAMOND, P.L.

27200 Riverview Center Blvd. ◆ Suite 310 ◆ Bonita Springs, FL 34134
Phone (239) 992-6578 ◆ Facsimile (239) 992-9328

Elinor E. Baxter
direct dial:
(239) 405-7863
ebaxter@bmdpl.com

June 5, 2015
(Via E-mail Only – Cindy.Dick@FLhealth.gov)

Cynthia Dick, Division Director for Emergency
Preparedness and Community Support
Florida Department of Health
4052 Bald Cypress Way, Bin A-04
Tallahassee, FL 32399-1705

Re: Comments Relating to the Trauma Workshop on May 27, 2015 / Proposed Rules

Dear Ms. Dick:

Thank you for the opportunity to comment on the rule workshop held May 27, 2015.

These comments represent the collective feedback from the Lee County Trauma Services District, Lee Memorial Trauma Services, and The Medical Care Council of Lee County (representing 5 Medical Directors, 20+ Fire Districts, and 5 EMS transporting agencies including 3 helicopter EMS programs).

1. Comments on Trauma Triage (64J-2.004, 64J-2.005)
RE: Adoption of CDC field Triage Criteria

We share the following feedback on changing the field triage criteria:

A. History:

- The current Florida Adult and Pediatric Trauma Triage Criterions have been in place since 12/2002.
- Prehospital providers have had extensive training and experience in utilizing the current triage methodology.
- As a system, we have experienced very clear destination guidelines, minimal under triage and minimal over triage.
- The existing combinations of anatomical and physiological characteristics have proven themselves effective in sensitivity and specificity to identify trauma center need.

- Provisions already exist to adapt criterion to local needs by allowing local trauma alert criteria.

B. Concerns:

i. CDC Field Triage Criteria raises the GCS (Glascow Coma Scale) threshold from < =12 to <14.

Potential effects of change:

- This would result in unnecessary triage and transportation to the trauma center for patients not demonstrating true trauma center need.
- There is known risk with emergent rotor wing and ground transportation coupled with very high costs for this type of transport.
- All local Emergency Departments maintain the ability to evaluate and treat mild traumatic brain injuries (Physical exam, radiographic evaluation etc).
- Evacuating minor injuries from the community to the trauma system will result in unnecessary resource utilization and expenses to the citizens of the community without concomitant reduction in morbidity / mortality, increased costs to the patient, and increased risk to the patient for unnecessary transport mode.

ii. Falls height increased from 10 feet (current FL Criteria) to 20 feet (CDC Field Triage).

Potential effect of change:

- Under triage of patients in falls less than 20 feet.
- Under recognition of significant mechanism of injury.
- Ground level falls is the #1 or #2 mechanism of injury seen at the trauma center.
- A 6 foot ladder is very good for business in the trauma center….
- We do not feel this criteria is sensitive enough for the mechanisms we see locally.

iii. Vehicle assessment in motor vehicle collision / speed assessment of motorcycle collision: CDC field triage gives parameters based on vehicle intrusion, occupant death, partial/complete occupant ejection, telemetry data for automobiles, and speed greater than 20 mph for

Jacksonville, FL ◆ 800 West Monroe Street ◆ Jacksonville, FL 32202 ◆ Phone: (904) 366-1500 ◆ Fax: (904) 366-1501
Akron, OH ◆ 75 E. Market Street ◆ Akron, OH 44308 ◆ Phone: (330) 253-5060 ◆ Fax: (330) 253-1977
visit us online at: www.bmdpl.com or www.probusinesslaw.org

motorcycle crash. Fl criteria are based specifically on anatomical and physiological characteristics of each individual patient.

Potential effect of change:

- We concur that the mechanism of injury and collision characteristics represent potential injury; however, patient specific criteria as determined by the pre-hospital provider isthe most sensitive in determining trauma center need.
- Automobiles accidents may indeed look bad, but ambulatory patients with minor / no complaint may not need to be strapped to a backboard and flown to the trauma center. This "automatic" criteria (CDC Field Triage) is based on the vehicle instead of the patient or the physiologic assessment of the patient by the attending pre-hospital provider.
- Evacuating minor injuries from the community to the trauma system will result in unnecessary resource utilization and expenses to the citizens of the community without concomitant reduction in morbidity / mortality, increased costs to the patient, and increased risk to the patient for unnecessary transport mode.

While we look nationally for guidelines and protocols, we must think locally on how it applies to the citizens we serve. National guidelines are just that, and not necessarily tailored to the specific characteristics of a region or community.

We do recognize the opportunity to strengthen the existing Florida Trauma Triage Criteria with updated language specific to the older adult and the physiologic changes of the aging process and welcome the opportunity to be part of the collaborative.

Recommendation: Maintain the current Florida trauma triage criterion, and adapt to local needs as determined by data. If we note weakness locally or statewide, we can update our current triage scheme and educate appropriately.

2. Comments on Trauma Center Standards (64J-2.011)
RE: Adoption of ACS Orange Book in place of existing Trauma Center Standards Pamphlet 150-9

We share the following feedback related to outright adoption of ACS Orange Book in place of the existing Florida Trauma Center Standards:

A. History:

- Florida has been a leader in trauma system development since the 1980's.

Jacksonville, FL ◆ 800 West Monroe Street ◆ Jacksonville, FL 32202 ◆ Phone: (904) 366-1500 ◆ Fax: (904) 366-1501
Akron, OH ◆ 75 E. Market Street ◆ Akron, OH 44308 ◆ Phone: (330) 253-5060 ◆ Fax: (330) 253-1977
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- Florida has maintained a State Designated Trauma System vs. American College of Surgeons (ACS) Trauma System.
- Florida Trauma System has consistently delivered good outcomes as measured by national benchmarks most of which are ACS systems.
- DOH Pamphlet 150-9 "Trauma Center Standards" implemented in 2010 was revised from 2008 150-8 "Trauma Center Standards".
- Elements of DOH Pamphlet 150-9 "Trauma Center Standards" supplemented by the precursor of the ACS Orange Book known as the ACS Green Book.
- ACS Green book was utilized as a reference to building DOH Pamphlet 150-9 "Trauma Center Standards" not simply adopted in its entirety, and modified to address the unique elements of the state of Florida.
- DOH Pamphlet 150-9 "Trauma Center Standards" represents the collective work and feedback of a broad group of Florida Trauma System stakeholders and experts.
- Existing trauma centers in the state of Florida have designed their systems based on DOH Pamphlet 150-9 "Trauma Center Standards", not the ACS Green or Orange Book or ACS standards.
- The ACS Orange Book is a reference that could/should be utilized to update the next generation of trauma center standards and adapted to our system.
- The ACS Orange Book is constantly being updated: This is science based on theory and as such is ever changing and evolving.
- The Trauma Center Standards are what has allowed Florida to excel in the delivery of lifesaving trauma care to the citizens and visitors of our state.

B. Concerns:

In February 2013, the American College of Surgeons (ACS) performed a trauma system consultation. Included in the priority recommendations from this consultation were to establish and appoint a new Florida Trauma System Advisory Council (FTSAC) to provide input to policy development for the trauma system and establish appropriate committees of the FTSAC to support key development and policy activities, such as data, performance improvement, and statewide trauma destination protocols. The FTSAC would feed directly from the expert bodies of the Florida Committee on Trauma, the Association of Florida Trauma Program Managers, and the EMS Advisory Council. This has not been formed to date, and instead we are using Florida DOH rulemaking to formulate the structure of the trauma patient's trauma care. What should be a clinical / optimal care discussion by experienced trauma clinicians is being worked through in a public forum not designed to address the needs of the existing system or the patient.

Jacksonville, FL ◆ 800 West Monroe Street ◆ Jacksonville, FL 32202 ◆ Phone: (904) 366-1500 ◆ Fax: (904) 366-1501
Akron, OH ◆ 75 E. Market Street ◆ Akron, OH 44308 ◆ Phone: (330) 253-5060 ◆ Fax: (330) 253-1977
visit us online at: www.bmdpl.com or www.probusinesslaw.org

Of special note, in the 2013 ACS trauma system consultation, it was never suggested that the state of Florida should become an ACS state for trauma care or completely adopt ACS criteria. Instead, Florida was recognized as a leader in trauma care in its own right, and the recommendations set forth to strengthen our existing system, not adopt an entirely new one.

Recommendation: We believe we are ahead of the national curve, and this is due to the existence of the collaboratively derived Florida Trauma Center Standards Pamphlet 150-9. We urge the DOH to establish the FTSAC in accordance with the ACS trauma system consultation recommendations, and allow the trauma care experts serving our population to update the existing trauma center standards, protect an exclusive trauma service, and continue to lead the nation in delivery of quality trauma care.

If you have any questions or concerns regarding the above comments, please feel free to contact me.

Very truly yours,

Brennan, Manna & Diamond, P.L.

Elinor E. Baxter

Elinor E. Baxter

cc: Leah Colston, Bureau Chief, Emergency Medical Oversight
(Leah.Colston@Flhealth.gov)

Jacksonville, FL ◆ 800 West Monroe Street ◆ Jacksonville, FL 32202 ◆ Phone: (904) 366-1500 ◆ Fax: (904) 366-1501
Akron, OH ◆ 75 E. Market Street ◆ Akron, OH 44308 ◆ Phone: (330) 253-5060 ◆ Fax: (330) 253-1977
visit us online at: www.bmdpl.com or www.probusinesslaw.org

From:	Dick, Cindy
To:	Dyal, David
Cc:	Dan Harshburger (dharshbu@martin.fl.us); DDonatto@TownofPalmBeach.com; a-emsp@yahoogroups.com; Colston, Leah; Bulecza, Susan R
Subject:	RE: Comments: 64J-2.004
Date:	Monday, June 01, 2015 9:18:51 AM

Thanks Chief

From: Dyal, David [mailto:ddyal@ci.stuart.fl.us]
Sent: Wednesday, May 27, 2015 9:33 AM
To: Dick, Cindy
Cc: Dan Harshburger (dharshbu@martin.fl.us); DDonatto@TownofPalmBeach.com; a-emsp@yahoogroups.com
Subject: Comments: 64J-2.004

Hi Chief:

Subsequent to this morning's comments, wanted to amend my comments and send them to you for consideration.

Rule 64J-2.004 (2). "… the patient shall be *considered* a trauma alert patient."

Subsequent to a lawsuit recently ruled against a provider, nowhere in the law or rule does it actually REQUIRE the paramedics to transport Trauma Alert patients to a Trauma Center except under their TTP's designed locally by the EMS Medical Director. As the patient was transported to a trauma center at further distance than the local hospital, the jury found that without a law that REQUIRED such transport, the EMS agencies were allowed to vary from TTP's that are not in law or rule but are locally designed. At the very least, the rule should state that such patients shall be transported to a Trauma Center unless TTP's specifically allow a variation from this rule. In this case, the airway was maintained by a supraglottic device and patient was transported to a trauma center. In this case, the jury was convinced that the supraglottic device was not a secured airway, therefore needed to be transported locally and there was not law in place to require the transport to a Trauma Center.

Suggest that a legal expert be consulted to improve the language, such as "shall be identified (or classified) as a TA patient" instead of the subjective term, "considered".

Rule 64J-2.004(5): "TTP approval process" in light of the above example seems to need some more teeth in the review process to better assist local agencies in their attempts to be proactive to assure TA patients are taken to Trauma Centers. Can the term "TTP approval process" be better defined? Seems there are ample measures in the rule to include patients, but not much to protect the paramedic when such a call is made to include patients in the destination decision.
Is there some means to give TTP's the power of rule once they are state approved?

Rule 64J-2.004 (3)(d): "… or has sustained a GSW to the extremities of the body."
Rule 64J-2.004 (3)(f): "Age: The patient is 55 years of age or older."

Seems to be overly aggressive in combination. A person aged 55 years of older who is shot in the

hand and has no other comorbidity issues certainly does not need to be transported to a Trauma Center urgently. It could be better constructed if the GSW was proximal to the axillary or groin where a tourniquet is impractical and where major blood vessels may be involved. Generally, no single bullet GSW distal to the elbow or knee without any other factors should rate a ride to a Trauma Center. I defer to much higher authorities than I, but a single GSW (especially small caliber) to an extremity without other physiological signs seems to be overly aggressive and could be easily assessed locally and then transferred if needed.

One of the problems with including such injuries is their impact on the EMS Providers that have no choice but to transport such patients out of county as they meet TA criteria, when they most likely could have been treated locally and referred later at much less cost to the patient and the community. When there is limited resources, it would be a disservice to the community to expend scarce resources to transport out of county and take that transport resource away from its community and the opportunity costs that it implies by being out of service for such a long time during transport. As not all communities are equal in resources, this may not be a problem in major population centers, but most certainly is a problem for less populated areas.

Rule 64J-2.005 Pediatric Scorecard
"(2)…the patient shall be considered a pediatric trauma alert patient". As above, being considered a TA patient and being required to transport to a Trauma Center are not the same. Whatever, if anything, is done to the adult scorecard rules, needs to be copied to the pediatric methodology as well.

Again, perhaps "identified or classified" as a TA patient is stronger than "considered".

Dave Dyal
Fire Chief
Stuart Fire Rescue
800 S.E. Martin Luther King Jr. Blvd
Stuart, Fl 34994
Office: 772-600-1287
Mobile: 561-662-9714
email: ddyal@ci.stuart.fl.us

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From: Dick, Cindy
To: Bulecza, Susan R; Colston, Leah
Subject: FW: EMS/Trauma Rule Workshop
Date: Thursday, May 28, 2015 12:58:09 PM
Attachments: ACS Trauma Center 2_2015.pdf

OOPS, with attachment.

From: McIntyre, Chad [mailto:chad.mcintyre@jax.ufl.edu]
Sent: Wednesday, May 27, 2015 4:14 PM
To: Dick, Cindy
Subject: EMS/Trauma Rule Workshop

I want to thank you for leading the workshop today and keeping everyone on track and moving forward.

I would like to submit the press release attached to this email from the American College of Surgeons pertaining to allocation of Trauma Centers.

Thank you.

Chad E. McIntyre, BS, NRP, FP-C
Manager, Trauma & Flight Services
UF Health Jacksonville
904-244-4548 Office
904-244-7929 Fax
chad.mcintyre@jax.ufl.edu

From:	Dick, Cindy
To:	Karen Macauley
Cc:	Colston, Leah; Bulecza, Susan R
Subject:	RE: Trauma Rules Workshop
Date:	Monday, June 08, 2015 1:18:11 PM

Thank you for your participation and input. We look forward to continuing to work with our community partners towards the best product.

Cindy E. Dick, MBA, EFO
Division Director
Emergency Preparedness and Community Support
Phone (850) 245-4864
Cell – (850) 688-2204
Fax – (850) 921-8162

How am I doing? Please let me know by taking this short survey. Thank you!
Director's Office
Please consider the environment before printing this email.

From: Karen Macauley [mailto:karen.macauley@jhmi.edu]
Sent: Friday, June 05, 2015 4:52 PM
To: Dick, Cindy
Subject: Trauma Rules Workshop

Dear Ms. Dick,

It is clear the Florida Department of Health is committed to excellent care of the trauma patient across the entire trauma system. All Children's Hospital is especially committed to care of our smallest and most vulnerable trauma patients and respectfully requests that the DOH seeks expert pediatric input before finalization of the CDC triage guidelines. We are concerned that the guidelines addressing the needs of these patients is not adequately defined in the CDC standards as written and careful and thoughtful review of the needs for triage of the pediatric patient requires some additional thought and input.

Thank you for allowing us to provide input. We look forward to working with you. Please do not hesitate to contact us if we can any questions or provide further input.

Sincerely, Karen Macauley

Karen Macauley, DHA, MEd, BSN
Director, Pediatric Trauma Program
All Children's Hospital
727 767 4926
Karen.macauley@jhmi.edu

AMERICAN COLLEGE OF SURGEONS

Inspiring Quality: Highest Standards, Better Outcomes

American College of Surgeons Releases Position Statement Stressing Importance of Trauma Center Designation Based Upon Population–Based System Need

New statement developed to support state and local agencies in making designation decisions that advocate for optimal care of injured patients

NEWS FROM THE AMERICAN COLLEGE OF SURGEONS | FOR IMMEDIATE RELEASE

CHICAGO (February 6, 2015): The American College of Surgeons (ACS) recently released a statement emphasizing that the allocation of trauma centers should be based upon the needs of the population, rather than the needs of individual health care organizations or hospital groups. The position statement, developed by the ACS Committee on Trauma's (COT) Trauma Systems Evaluation and Planning Committee, was approved by the ACS Board of Regents last fall and recently published in the January issue of the *Bulletin of the American College of Surgeons.*

Trauma systems have long been of concern to the ACS and the COT. "Historically, the ACS has taken the lead in establishing standards and promoting quality in trauma care, and has long supported the principle that trauma centers should be allocated on the basis of need; ensuring that the welfare of injured patients remains the primary goal," said statement coauthor Robert J. Winchell, MD, FACS, Chair of the ACS Trauma Systems Evaluation and Planning Committee, and professor of surgery and chief of trauma at the University of Texas Health Science Center, Houston.

The statement notes, "The importance of controlling the allocation of trauma centers, as well as the need for a process to designate trauma centers based upon regional population need, has been recognized as an essential component of trauma system design since the 1980s. Nonetheless, few trauma systems are able to operationalize these concepts, especially when faced with real or potential challenges that stem from powerful health care institutions or providers."

At their core, trauma systems are developed to achieve care that is optimal for injured patients. Ronald M. Stewart, MD, FACS, Chair of the COT, and professor and chair of the department of surgery at the University of Texas (UT) Health Science Center, San Antonio, said that in the beginning of trauma system development, the problem was a lack of trauma centers. However, some areas are now seeing a perceived oversupply of trauma centers because the provision of trauma care can in some instances become highly profitable. "We believe it is very important to the injured patient to get this balance right, thus the need for this

position statement," Dr. Stewart said. Further, Dr. Winchell said, "History has shown that market forces are insufficient to guarantee a stable system. Police, fire and EMS services are not provided based on market profitability; the same criterion must be held true for trauma services."

The statement lays out guidelines for optimal trauma system function. Among these is the principle that designation of trauma centers is the responsibility of the governmental lead agency with oversight of the regional trauma system. Furthermore, the lead agency should be guided by the local needs of the region(s) for which it provides oversight, and trauma center designation should be guided by the regional trauma plan based upon the needs of the population being served, rather than the needs of individual health care organizations or hospital groups.

The intent of developing this statement is to support state and local agencies in making designation decisions and to develop policy at the state and national level that ensures the focus on centers being allocated on the basis of need, according to Dr. Winchell. "At a high level, the intent is to reach leaders and policy makers at the regional, state, and national level, to raise awareness and to stimulate the comprehensive development of public health policy and supporting legislation that establishes trauma care securely as a basic public health component."

Trauma systems today are based upon the understanding that injury is a public health problem. As A. Brent Eastman, MD, FACS, past-President of the ACS, noted in the 2009 Scudder Oration on Trauma delivered before the Clinical Congress of the American College of Surgeons , the concept of injury as a public health problem was integral to the 2006 document "Model Trauma System Planning and Evaluation" from the U.S. Department of Health and Human Services. This 2006 document was in turn influenced by the 1992 document "The Model Trauma Care System Plan." Dr. Eastman noted, "Do trauma systems make a difference?...they do and they must make a difference. If we are to decrease the unacceptably high death rates...we must establish trauma systems."*

The new trauma systems statement sets forth this premise, and goes on to note, "The problem arises when a lead agency passively allows health care organizations and hospital groups to establish new trauma centers in areas that yield an economic advantage, while ignoring areas of true need."

In looking to the future of trauma systems in the U.S., Dr. Stewart said, "My hopes are that we, all the elements of the trauma system, are committed to doing the right thing and doing things right for our patients and our fellow citizens—this includes all patients and all regions of the country."

The new trauma systems statement is available at http://bulletin.facs.org/2015/01/statement-on-trauma-center-designation-based-upon-system-need/.

*Eastman AB. Wherever the Dart Lands: Toward the Ideal Trauma System. *Journal of the American College of Surgeons*. August 2010; 211(2): 153-168.

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About the American College of Surgeons

The American College of Surgeons is a scientific and educational organization of surgeons that was founded in 1913 to raise the standards of surgical practice and improve the quality of care for surgical patients. The

College is dedicated to the ethical and competent practice of surgery. Its achievements have significantly influenced the course of scientific surgery in America and have established it as an important advocate for all surgical patients. The College has more than 80,000 members and is the largest organization of surgeons in the world. For more information, visit www.facs.org.

Contact:

Dan Hamilton
312-202-5328
or
Sally Garneski
312-202-5409
pressinquiry@facs.org

MIAMI LODGE
FRATERNAL ORDER OF POLICE

710 Southwest 12th Avenue. Miami, Florida 33130
Phone (305) 854-5019 Ortiz@fopmiami.com

Javier Ortiz
PRESIDENT

Thomas Reyes
SECRETARY

May 27, 2015

Florida Department of Health
C/O Ms. Cynthia Dick, Division Director
4052 Bald Cypress Way, Bin A-22
Tallahassee, Florida 32399-1701
Sent Via Email to: Cindy.Dick@flhealth.gov

Re: Trauma Chapter 64J-2 Rule Workshop

Dear Ms. Cynthia Dick,

Thank you for giving me the opportunity to speak at today's rule workshop in Tallahassee. As you are aware, your team's decision will directly affect the level of care Floridians will receive when they are injured in our state.

It is refreshing to know that the Division Director for Emergency Preparedness and Community Support is a retired City of Tallahassee Fire Chief. With that said, you have firsthand knowledge that when it comes to rendering first aid, that rules are just guidelines and sometimes deviation is necessary in order to ensure that the final result of a critical incident is positive.

In regards to Rule 64J-2.004, the Fraternal Order of Police is respectfully requesting for the trauma scorecard methodology to include CDC guidelines for field triage and to also give the EMS provider for that area the authority to make a judgment call when they feel it's necessary to take the patient to the highest level trauma center. If you were seriously hurt, wouldn't you want to go to the highest level trauma center?

A HCA representative made a poor argument stating that level one and two trauma centers are similar. If that is the case, why do we have different levels? In the case of trauma centers in South Florida, there is a **significant difference.** JMH Ryder Trauma has a trauma neurosurgeon 24 hours a day on staff. HCA hospitals like Kendall Regional can't say the same. The argument that bypassing a lower level center to go to the highest level center would overload EMS services is also a farce. As stated by the Trauma One Helicopter representative, those that are providing pre-hospital care know where their patient would get the best care especially since they are physically assessing the individual at the incident scene. If there are sufficient resources and the EMS provider can safely transport that patient to the higher level trauma center, they should be allowed to do that. **Hospital administrators shouldn't be calling the shots at a rescue scene in which they aren't even in control of**.

At today's hearing regarding this rule, everyone in that room had a direct affiliation (because they are all employees) with a hospital. In my case, I have no hidden agendas or affiliation. Most of today's speakers have a financial interest in how these rules are implemented since they are for- profit hospitals. We solely want the best care given to our first responders when they are seriously injured.

As police officers, we put our lives on the line to protect our communities. You have the power to show that the Department of the Health has our back when we are injured. We are asking for you to do what is morally and ethically correct for Floridians. Please enact the CDC field triage guidelines that will take you to the **highest** level trauma center. Please let paramedics have the authority to take us to the best facility based on those guidelines. When you have a serious injury, there isn't a substitution for #1.

When I'm hurt, I want to be taken to Ryder Trauma Center, the only level one trauma center in South Florida.

Sincerely,

Javier Ortiz

Lieutenant Javier Ortiz, President
Miami Fraternal Order of Police, Lodge #20
Ortiz@fopmiami.com
(786) 290-1183

ORLANDO HEALTH
1414 Kuhl Ave.
Orlando, FL 32806
tel 321.843.7000
OrlandoHealth.com

June 5, 2015

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

Ref: Workshop 64J-2.001-20

Dear Ms. Cindy Dick,

On behalf of Orlando Health, I am responding to the request for comments on the proposed changes to the trauma rule discussed during the May 27 workshop. Orlando Health is grateful for the opportunity to listen to the rule workshop and found the feedback from others in the trauma community very helpful. As Central Florida's only Level I Trauma Center, please consider our feedback below as the Department of Health (the Department) finalizes its rule.

In regards to 64J-2.001, 64J-2.004 and 64J-2.005, the Centers for Disease Control and Prevention (CDC) guidelines for Field Triage will allow Emergency Medical Services to make quick decisions and decrease delays in patients reaching a destination of definitive care. This change will help to standardize care throughout the nation, which will improve care and drive best practices in healthcare. During the workshop there was discussion regarding further definition of the highest level of care. This is already defined by the CDC and American College of Surgeons (ACS) in the CDC's foot notes of the Field Triage Decision Scheme in the CDC Guidelines for Field Triage of Injured Patients: Recommendations of the National Expert Panel on Field Triage. It notes, "Trauma centers are designated Level I-IV, with Level I representing the highest level of trauma care available." While Level II Trauma Centers provide excellent care for injured patients, there is a difference in the requirements of Level I and Level II Centers which are listed in the ACS Resources for the Optimal Care of the Injured Patient. Although some Level IIs may go beyond the in-house service requirements, there is still a fear that patients in need of specialized trauma services may arrive at a center that only meets the minimum requirements. Orlando Health supports the Department's decision to adopt the proposed CDC guidelines as a substitute for the current Adult Trauma Scorecard Methodology.

There seems to be a lack of clarity in the CDC guidelines related to the pediatric population which Orlando Health believes needs to be addressed by keeping the current 64-J2.005, Pediatric Trauma Scorecard Methodology. These patients manifest a different physiology than adults and

ORLANDO HEALTH
1414 Kuhl Ave.
Orlando, FL 32806
tel 321.843.7000
OrlandoHealth.com

decompensate quickly. Thus, the need for a pediatric trauma center as the initial and definitive destination is vital. If not initial for the purpose of extremis in the field, transferring to a trauma center with verified pediatric capabilities should occur after stabilization. This should be clarified in the rule.

There is ambiguity surrounding Section 3a of 64-J2.010 of the rule regarding community support. It states, "city and county commissions" while 3b states "city or county commissions". The ambiguity of the letters for community support allows for misinterpretation. Orlando Health feels that this should be excluded from calculations of TSA allotments. The remaining variables of the calculation are inclusive of an objective needs assessment of the community.

As mentioned above, Orlando Health is in support of the adoption of the ACS's Resources for the Optimal Care of the Injured Patient 2014 as proposed in the rule change for 64-J2.011 and appreciates the Department striving to align with the national standard of trauma care. The timeline of one year from date of the rule being amended is too short to ensure that the revised standards are properly and effectively implemented across the state. We believe two years to effectively implement the standards is an adequate timeframe.

In regards to the 10 mile halo proposed in 64-J2.012, Orlando Health believes that trauma centers should be spread out in order to provide services throughout the state. Orlando Health is uncertain of the evidence supporting the proposed halo mileage and would recommend removing this from the proposed rule. If it were to remain, the consideration of median transport time should be included which might result in the need to expand the halo area.

There are several definitions included in the proposed rule 64-J2.019, and we appreciate that "verified" is included as this clearly defines the trauma centers that have fully met the requirements for state approval. We have some hesitation to the deletion of definitions in this section, specifically the definitions of the words, "verified trauma patient" and "caseload volume." Although there are definitions available in statute 395.4001, we believe the definitions should remain as in the current rule, in order to ensure Florida's trauma system has a unified understanding of these definitions.

ORLANDO HEALTH

1414 Kuhl Ave.
Orlando, FL 32806
tel 321.843.7000
OrlandoHealth.com

Thank you again for the opportunity to provide written feedback regarding the proposed rule changes. Orlando Health looks forward to collaboration within the trauma system to provide the optimal care for trauma patients in our communities. Over the past couple of months, I have seen several steps to improve the collaboration among the trauma community by the Department, and Orlando Health thanks you.

Sincerely,

John Promes, MD, FACS
Trauma Program Medical Director

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
BankAmerica Building, Third Floor
3600 North Federal Highway
Fort Lauderdale, Florida 33308
(954) 390-0100 Fax (954) 390-7991
Please reply to Fort Lauderdale Office

MIAMI-DADE
Two Alhambra Plaza
Suite 102
Coral Gables, FL 33134

June 5, 2015

Florida Department of Health
c/o Ms. Cynthia Dick, Division Director
Emergency Preparedness and Community Support
Florida Department of Health
4052 Bald Cypress Way, Bin A-22
Tallahassee, FL 32399-1701
Sent Via Email to: Cindy.Dick@flhealth.gov.

Dear Ms. Dick:

On behalf of Jackson Memorial Hospital ("Jackson") we, thank the Department of Health for the opportunity to provide feedback on the proposed revisions to the administrative rules relating to Trauma Centers. We recognize that the Florida Trauma system provides critical medical services to many citizens, and the rules will impact their care when injured in Florida.

Trauma Agency Formation

Regarding Proposed Rules 64J-2.007, 64J-2.008, and 64J-2.009, Florida Administrative Code, Jackson respectfully requests clarification from the Department of Health regarding the implications on the status quo. First, what will happen in regions where Trauma Agency's currently exist? Will those Trauma Agencies be grandfathered in under the new rules or would they be required to reapply and undergo the certification process anew? Second, do the proposed rules allow for more than one trauma agency in a single region? How would multiple trauma agencies collaborate with one another?

Regarding the jurisdictional boundaries of trauma agencies, Jackson believes that alignment with the existing Trauma Service Areas is more prudent than alignment with the Florida Regional Domestic Security Task Force, as proposed in Rule 64J-2.007(1). Jackson requests that the Department reconsider the alignment of the trauma agency boundaries.

Next, much of the information required of a trauma agency plan is proposed to be removed from Rule 64J-2.007(2). This leaves uncertainty as to what is required to be included in a Trauma Agency Plan, what is required of its organizational structure, and what is required of the Trauma System structure and of the individuals charged with leading these agencies.

Jackson is uncertain whether the Department intends to include this information in the form application that trauma agencies will be completing in the future. If this is the case, Jackson requests that the Department make the proposed form application available for public comment as part of the rulemaking process. If this is not the case, Jackson requests that the Department provide insight into how applicants will be reviewed when submitting applications to the Department for consideration.

Jackson also has concerns regarding the use of the term "entity" in proposed Rule 64J-2.007(2). This term is undefined in the rule and is open to broad interpretation. Must the entity be a non-profit or could it be a for-profit entity? Must it be affiliated with a governmental agency or body? How will the definition of "trauma agency" as set forth Florida Statute 395.4001(11) be incorporated into the rules? The Statute defines a "trauma agency" as a "department approved agency established and operated by one or more counties, or a department approved entity with which one or more counties contract, for the purpose of administering an inclusive regional trauma system." Because the term "entity" as used in the rule appears to be ambiguous and potentially in conflict with Florida Statute 395.4001(11), Jackson respectfully requests additional guidance regarding the definition of "entity." Without additional guidance, Jackson believes that this ambiguity could lead to highly biased trauma agencies, potentially organized by those whose financial interests would conflict with the interests of the entire region.

Jackson also has concerns with the proposed removal of the requirement for a trauma agency to obtain the formal authority to create a trauma agency from each of county commissions in each of the counties in which the agency intends to operate. Local governments have a vested interest in the health and care of its citizens and removing their input from the formation process will have an adverse effect on the trauma system as a whole.

Trauma Center Allocation

Jackson would ask that the Department consider requiring all Trauma Center Applicants to file a needs assessment as part of its application and should make a determination that the proposed location ensures reasonable access to high-quality trauma services for the residents of the Trauma Service Area. Today applicants are suggested to file a needs assessment, but it is not required.

Trauma Center Selection

Jackson supports the proposed revisions to Rule 64J-2.012, which moves the preference criteria from Rule 64J-2.016 to Rule 64J-2.012.

However, Jackson respectfully requests that the Department remove the proposed language in 64J-2.012(1)(d), regarding the implementation of a 10-mile "halo" around existing trauma centers. This has been the source of much debate in the recent past, and Jackson requests that the Department instead base the location of new trauma centers on the given need in Trauma

Service Areas rather than on an arbitrary radius that may have no bearing on the actual need for a particular Trauma Service Area. The needs of the community will best be served by making a reasoned analysis of need for a given area rather than making arbitrary halo zones for existing trauma centers.

Finally, Jackson respectfully notes that it appears that the preference criteria that are being moved from Rule 64J-2.016(11)(c)-(e) to Rule 64J-2.012 have been misnumbered in the process. As a result, they appear to be part of the consideration of the level of service an applicant proposes to provide, rather than free-standing preference criteria as intended. The preference criteria should be numbered as sections (2)(c)-(e) instead.

Jackson thanks the Department for the opportunity to provide feedback on the proposed rule changes and looks forward to working with the Department on developing these rules further.

Sincerely,

THOMAS F. PANZA, ESQ.

TFP/ELP/cd

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

SOUTH FLORIDA HOSPITAL DISTRICT
d/b/a MEMORIAL REGIONAL HOSPITAL,

Petitioner,

vs. Case No. 14-1033RP

DEPARTMENT OF HEALTH,

Respondent,

And

OSCEOLA REGIONAL HOSPITAL, INC. d/b/a
OSCEOLA REGIONAL MEDICAL CENTER,

Intervenor,

_____/

STIPULATION

The South Broward Hospital District d/b/a Memorial Regional Hospital ("Memorial") and the Florida Department of Health ("the Department") (collectively "the Parties"), through their respective undersigned counsel, enter the following Stipulation:

The renewal of trauma center certifications will be unaffected by the adoption of Rule 64J-2.010, Florida Administrative Code, related to trauma center allocation among Trauma Service Areas. The procedure for renewal of a trauma center certification shall be as provided in Rule 64J-2.015, Florida Administrative Code.

Counsel for Memorial and the Department have reviewed and approved this Stipulation on behalf of their clients.

Respectfully submitted this 24th day of March, 2014.

Filed March 24, 2014 12:26 PM Division of Administrative Hearings

F. Philip Blank
Florida Bar No. 190812
F. Philip Blank, P.A.
204 S. Monroe Street (32301)
Post Office Box 11068
Tallahassee, FL 32302
Telephone: (850) 681-6710
Facsimile: (850) 681-6713
Email: phil@blanklaw.com

Counsel for South Broward Hospital District d/b/a Memorial Regional Hospital

Caryl Kilinski
Chief Legal Counsel
Florida Bar No. 4806649
Chadwick R. Stevens
Assistant General Counsel
Florida Bar No. 15758
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin A02
Tallahassee, Florida 32309-1703
Telephone: (850) 245-4005
Facsimile: (850) 413-8743
Email: Caryl.kilinski@flhealth.com
Email: Chad.stevens@flhealth.com

Counsel for Florida Department of Health

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 24th of March, 2014, the foregoing has been electronically filed with Clerk of the Division, Division of Administrative Hearings, The DeSoto Building, 1230 Apalachee Parkway, Tallahassee, Florida 32399-3060; and a true and correct copies have been furnished by electronic mail to the following addressees:

Stephen A. Ecenia
R. David Prescott
J. Stephen Menton
Rick M. Ellis
Rutledge, Ecenia and Purnell, P.A.
119 South Monroe Street, Suite 202
P.O. Box 551
Tallahassee, FL 32302
steve@rutledge-ecenia.com
david@rutledge-ecenia.com
smenton@rutledge-ecenia.com
rellis@rutledge-ecenia.com

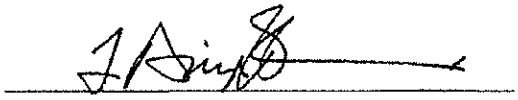
Eduardo Lombard
Vezina, Lawrence and Piscitelli, P.A.
413 East Park Avenue
Tallahassee, FL 32301
(850) 224-6205
elombard@vlplaw.com
Counsel for Osceola Regional Hospital, Inc.

Jeffrey L. Frehn
Angela D. Miles
Radley, Thomas, Yon and Clark
301 South Bronough Street, Suite 200
Tallahassee, FL 32301
(850) 425-6654
jfrehn@radleylaw.com
amiles@radleylaw.com
Counsel for Bayfront HMA Medical Center, LLC and Florida Health Sciences Center

Karen A. Putnal
Robert A. Weiss
Moyle Law Finn, P.A.
118 N. Gadsden Street
Tallahassee, FL 32301
kputnal@moylelaw.com
rweiss@moylelaw.com
Counsel for St. Joseph's Hospital, Inc.

Seann M. Frazier
Jonathan L. Rue
Parker, Hudson, Rainer & Dobbs, L.L.P.
215 South Monroe Street, Suite 750
Tallahassee, Florida 32301
sfrazier@phrd.com
jlr@phrd.com
Counsel for Shands Teaching Hospital & Clinics, Inc. d/b/a UF Health Shands Hospital

Eugene Shy, Jr.
Christopher Charles Kokoruda
Miami-Dade County Attorney
Jackson Memorial Hospital
1611NW12th Avenue
West Wing, Suite 109
Miami, Florida 33136
eshy@miamidade.gov
kokorud@miamidade.gov
Counsel for The Public Health Trust of Miami-Dade County



F. Philip Blank

SNHA Safety Net Hospital Alliance of Florida

Teaching Hospitals

Broward Health

Jackson Health System

Mount Sinai Medical Center

Orlando Health

UF Health Shands Hospital

UF Health Jacksonville

Tampa General Hospital

Public Hospitals

Halifax Health

Lee Memorial Health System

Memorial Healthcare System

Sarasota Memorial Health Care System

Children's Hospitals

All Children's Hospital

Nicklaus Children's Hospital

Regional Perinatal Intensive Care Center

Sacred Heart Health System

Anthony Carvalho

President

June 5, 2015

John H. Armstrong, MD, FACS
Surgeon General & Secretary
FL Department of Health
4052 Bald Cypress Way
Tallahassee, FL 32399

Dear Surgeon General Armstrong:

I am writing to submit comments regarding the Department of Health (DOH) Office of Trauma proposed draft revisions to Florida Administrative Code (F.A.C.) 64J-2.001, 64J-2.004 through 2.013, 64J-2.016, 64J-2.019, and 64J-2.020.

These comments are submitted on behalf of the Safety Net Hospital Alliance of Florida's (SNHAF) 14 members representing Florida's top teaching, public, children's, and regional perinatal intensive care center hospitals. SNHAF members shoulder a disproportionate share of Florida's hospital care responsibilities while providing highly specialized medical care and innovation. While SNHAF members account for only 10% of the state's hospitals they provide 100% of all pediatric level one trauma care, over 88% of all level one trauma care, 72% of graduate medical education programs, 41% of all charity care, 40% of all Medicaid days, and 25% of all hospital admissions. In fact, we provide almost 2½ times more charity care days than all of the for-profit hospitals in the state combined.

The SNHAF membership and the department share a common goal of ensuring Florida has a sustainable high quality trauma system for our citizens. The recommendations and justification provided herein are in addition to those provided by our members during the May 27, 2015 workshop.

<u>64J-2.004 Adult Trauma Scorecard Methodology</u> F.A.C, revision and deletion of 64J-2.005 Pediatric Trauma Scorecard Methodology - also referred to as adoption of CDC Guidelines for Field Triage of Injured Patients Recommendations of the National Expert Panel on Field Triage, 2011, (CDC Triage Guidelines).

- **Support the CDC triage guidelines & recommend including pediatric trauma.** The CDC Triage Guidelines do not define or differentiate between adult and pediatric trauma victims. The Department should include language addressing the pediatric trauma victim inclusive of pediatric trauma alert criteria and language requiring the transport of pediatric trauma victims to the closest pediatric trauma centers.
- **Review & report needed**. The department should also conduct a study within 24 months of adoption of the CDC Triage Guidelines, to analyze: (a) increase in trauma alerts for patients who fail to meet the ACS Standards definition of a trauma patient; and (b) volume driven increase in trauma activation fees.

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

64J-2.007 Trauma Agency Formation, Plan Approval, and Denial Process Continuation, and Plan Requirements, F.A.C. revision creating regional trauma agency pursuant to s. 395.4015 F.S.:

- **Consistency with regional domestic boundaries needed**. The rule should include clear specific language defining the regional trauma agency boundaries will be consistent with the regional domestic security task forces established under s. 943.0312. F.S.,
- **Definition of authority & responsibilities needed.** The rule must include language defining the membership eligibility criteria, leadership, authority, responsibilities, and accountability of regional trauma agencies.
- **Representative membership needed.** The membership of the regional trauma agency should be inclusive of representatives of all trauma stakeholders within the regional domestic security task force boundaries.
- **Define & differential roles needed**. The rule as drafted fails to define clearly the role of the local trauma agency verses the regional trauma agency. Clarifying language is required to avoid duplicity of effort and to prevent marginalizing those effective local trauma agencies.
- **Identification of funding needed.** The rule does not include language defining how regional trauma agencies will be funded.

64J-2.010 Allocation of Trauma Centers Among the Trauma Service Areas (TSAs) F.A.C.

- **Assessment tool must be improved**. The methodology and the resulting 2015 Assessment continues to be seriously flawed by failing to consider the excess capacity of existing verified and provisional trauma centers, population specific needs, pre-transport staging improvements, and how improvements in EMS transport resources impact trauma access.
- **Community support irrelevant for quantifiable needs determination**. Letters of community support are subjective desire driven not objective data driven and therefore, should be removed from the rule.
- **Transparency needed**. The annual needs assessment process should be transparent and all data used in determining need should be publically available, the current process lacks transparency.

64J-2.011 Trauma Center Requirements F.A.C revisions to adopt the American College of Surgeons (ACS) Resources for Optimal Care of the Injured Patient 2014 (6th edition),

- **Current nursing & personnel standards retention needed**. Adoption of the ACS standards, which are nationally recognized and updated continually, is laudable; however, the current FL Trauma Center Standards for Nursing and Ancillary personnel exceed the proposed ACS Standards and should be retained.

- **Verification & timelines needed**. The rule needs to be revised to clarify the verification method and timeline, questions include will FL continue its 7-year review cycle or adopt the ACS 3-year cycle.
- **Reviewer credentialing needed.** The rule should include the requirement that on-site reviewers have completed the ACS COT Verification and Review training program to ensure reviewers remain objective and adhere to the standards.
- **Adoption compliance period extension needed**. The rule should be revised to extend the adoption compliance period from one year from date of rule adoption to a minimum of two years from date of rule adoption for existing verified trauma centers.
- **Provisional TC verification standards needed**. What standards will be applied to newly approved provisional trauma centers during their 2016 verification process?

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

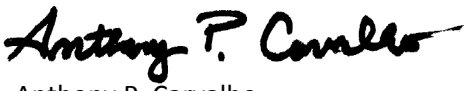
- **'Halo' not needed if objective needs criteria are applied**. Adoption of a needs determination based on objective data such as population density, injury epidemiology, etc, would eliminate the need for arbitrary requirements such as the proposed 10-mile halo.
- The DOH 'halo' proposal is inconsistent with previous department actions. A review of the factors precipitating this policy change would be appropriate.

64J-2.019 Funding for Verified Trauma Centers:

- **Definitions & caseloads should be retained**. The definition for Public hospital and caseload volume are essential to the accuracy of the funding formula in 64J-2.019 F.A.C.
- Retention of the definitions for public hospital and caseload volume voids the necessaity and resulting confusion resulting from the revisions to the formula portion of 64J-2.019 F.A.C.

As the organization with the state's largest providers of level one trauma care, we thank you in advance for your consideration of our recommendations.

Sincerely,



Anthony P. Carvalho
President

VIA EMAIL TO
Cindy.dick@flhealth.gov

Cynthia Dick
Division Director, Emergency Preparedness
& Community Support
Florida Department of Health
4052 Bald Cypress Way, Bin #A 23
Tallahassee, Florida 32399-1738

Re: Trauma Chapter 64J-2

Dear Ms. Dick:

I am the Regional Chief Nurse Executive for the Florida Region of Tenet Healthcare Corporation. In that role, I work with the ten Tenet hospitals located in Miami-Dade, Broward and Palm Beach Counties, including St. Mary's Medical Center and Delray Medical Center which are both Level I trauma centers. At various points in my career, I have provided direct patient care to trauma patients at both Jackson Memorial and Delray Medical Center. I have also offered comments at prior hearings and participated on the panel selected to contribute to the process last year. Along with Maggie Crawford from Delray Medical Center, I attended the Department's workshop on May 27, 2015. We appreciate the work that you and the Department are doing to improve these rules and the Florida trauma system. The purpose of this letter is to supplement Ms. Crawford's comments at the workshop regarding the draft rule changes.

Definitions- Rule 64J-2.001

Florida Administrative Code Rule 64J-2.001 (13) defines "Trauma Alert." We would suggest that term be changed to "Trauma Alert Notification" because definition only covers EMS initiated notices informing a hospital that EMS is en route with a patient meeting trauma alert criteria. However, trauma patients don't always arrive via EMS and trauma hospitals often initiate "trauma alerts" for patients that arrive by private vehicle.

Non-Trauma Designated Acute Care Hospital Trauma Registry- Rule 64J-2.020

At the outset, we want to state that we believe that trauma patients should be treated in designated trauma centers whenever and wherever possible. We understand and support the goal of gathering data to try to identify trauma patients that are currently being treated in non-trauma acute care hospitals. However, we are concerned that the new reporting requirements being imposed on non-trauma acute care hospitals as set forth in the Acute Care Trauma Registry Manual needs significant work. Let me begin by identifying the issues and then suggest a framework for a solution.

First, the requirements of that Manual impose obligations on non-trauma acute care hospitals that they are simply not equipped to properly handle. The language of trauma patient data is different and non-trauma acute care hospitals do not have the trauma experts to properly gather and report this information, especially when judgment based on this unique body of knowledge is required. Becoming expert at this skillset will remain out of reach for non-trauma

reporters working with low volumes. Having the acute care data dictionary reference other documents will not be sufficient for hospitals not used to dealing with these patients. The acute care dictionary should have its own set of clear definitions. In other words, the non-trauma acute care hospitals need clear and simple direction that either rules in or rules out someone as a trauma patient (i.e. did the patient live or die; were they assigned an ICD-9 CM code between 800-959.9; were more minor injuries excluded, etc.)

Coding for trauma is not the same as coding for other types of patients. These non-trauma acute care hospitals typically don't have a sufficient volume of these types of patients to develop expertise and judgment for this unique specialty. Expecting non-trauma acute care hospitals to hire, train and retain personnel competent to do this type of reporting is simply not efficient and you will likely end up with data that is of little value.

Second, we believe that if one of the goals of this reporting is to try to incentivize non-trauma acute care hospitals to appropriately transfer these patients to trauma hospitals, this reporting system is not likely to help achieve that result. For those non-trauma acute care hospitals that persist in treating trauma patients, allowing them to self-report may well just allow them to mask these patients. A non-self reporting system would enhance the Department's goal.

We are also concerned about the possibility of double counting of some patients. If non-trauma hospitals must provide detailed data on trauma patients treated and then transferred, these requirements not only impose a high reporting burden on the non-trauma hospital, there is also duplication as a result of the reporting done the by the trauma hospital (which is uniquely equipped to do this reporting).

We have several thoughts regarding possible solutions. First, we think there should be a clear threshold for detailed reporting. For example, if patients were transferred to a trauma center, then only very limited data should be required from the non-trauma acute care hospital. The more detailed data should be reported by the trauma hospital. This helps avoid needless duplication and supports the expert reporter concept.

Rather than asking non-trauma acute care hospitals to self-police by self-reporting of trauma patients, we would also suggest that consideration be given to developing methodology to identify trauma patients via the Agency for Health Care Administration's detailed patient data base. AHCA has one of the most extensive data bases on hospital patients in the country. All acute care Florida hospitals are accustomed to submitting this data on a regular basis. If there are some 'tweaks' that could be made to that AHCA reporting in order to allow the Department to query that data base to identify possible trauma patients, then you would no longer be dependent on non-trauma acute care hospitals to try to self-identify trauma patients when they are often poorly equipped to do so. If the Department can then identify possible trauma patients via the AHCA data base, the Department could then send requests for more detailed information (possibly along the lines of what is in the Acute Care Trauma Registry Manual) to those hospitals for more extensive information about that smaller subset of patients.

The initial reports under the Acute Care Trauma Registry Manual are due by July 1, 2015. I have been working closely with our hospitals and can tell you that these requirements are

causing significant problems, even though we have highly talented people as well as the resources of experts at two trauma hospitals to call on for help. If our hospitals are facing the issues described above, we have to believe that many others are as well. We are therefore strongly recommending and respectfully requesting you to suspend the non-trauma acute care hospital reporting while we work together to find a better system.

Trauma Center Requirements- Rule 64J-2.011

We support the use of ACS standards as the Department is suggesting in its draft of Rule 64J-2.011. However, we are still concerned about the interplay between Rules 64J-2.011, 2.012 and 2.015. The ACS certification process operates on a 3-year cycle whereas Florida trauma center certification runs on a 7-year cycle. At present, when a trauma center goes through its renewal process, it is essentially submitting the same extensive data and certifications as a new trauma center applicant. The ACS system is largely handled through electronic data. The Florida system is still heavily reliant on paper. The ACS standards have been added to this rule but all of the various DH forms (with associated documentation) are still part of the process. If trauma hospitals are complying with ACS standards while also having to submit all of the paper that Florida requires, we are concerned about the possible duplication of effort and inefficiency. In other words, the current draft looks like the Department is moving toward requiring compliance with both ACS standards and the Florida Trauma Care Standards without regard to areas of duplication or even inconsistency. The two systems are not entirely consistent. For example, we don't believe the ACS recognizes the concept of a "provisional" trauma center. We would suggest this needs more clarification and work.

What is also not clear is whether the Department is looking to substitute ACS certification for state survey and oversight. We would ask for clarification as to the Department's plan regarding the respective roles of ACS certification and Department oversight. In other words, would violations of ACS standards be policed by ACS, the Department or both?

Allocation Rule-Letters of Support

During the workshop, it was pointed out that Rule 64J-2.010 contains a small inconsistency. In subsections (1)(a)3.a. and b. with regard to letters of support, it states "…city *and* county…" in one paragraph and "…city *or* county…" in the other. We agree those two paragraphs should be made consistent. It is our suggestion that the phrase should be "…city *and* county…" in both subsections. The establishment of an additional trauma center is a major commitment for not only the hospital, but the entire county and both city *and* county commission views should be considered. If the word "*or*" is used, then one or the other could be completely eliminated from the equation.

Additional Workshops

Again, we sincerely appreciate the effort that is being put into these rules and also the open positive atmosphere of the hearing. While I know that you are new to the Department, I believe that those with the Department that have been there longer will tell you that we at Tenet worked constructively with your agency during the earlier efforts to develop rules and that we are bringing that same spirit to this process and want to work with you to find solutions. We stand ready to serve on any workgroups you might want to form. We also believe there is still

much work to be done. Rather than proceed immediately to rulemaking, we believe one or more additional workshops are warranted as you begin to develop new drafts.

Please let me know if you or anyone at the Department has any questions.

Sincerely,

Dr. Julie Hilsenbeck

Julie Hilsenbeck, RN, DNS, CNRN

Cc: Michael Glazer, Esq.

RUTLEDGE ECENIA
PROFESSIONAL ASSOCIATION
ATTORNEYS AND COUNSELORS AT LAW

MICHAEL J. BARRY
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
GABRIEL F.V. WARREN

GOVERNMENTAL CONSULTANT
JONATHAN M. COSTELLO

OF COUNSEL
HAROLD F. X. PURNELL

June 5, 2015

Via Email

Ms. Cynthia Dick
Director
Division of Emergency Preparedness and Community Support
Department of Health
4052 Bald Cypress Way, Bin A-22
Tallahassee, Florida 32399-1701
cindy.dick@flhealth.gov

Re: Draft Amendments to Trauma Chapter 64J-2

Dear Ms. Dick:

We are writing as the authorized representatives of the USF/HCA Trauma Network hospitals to address the Department of Health's efforts to amend the trauma-related rules contained in Florida Administrative Code Chapter 64J-2. We commend the Department of Health on its efforts to update its trauma rules to help move Florida's trauma system forward. To that end, we have compiled our comments below on how to make sure the draft amended rules reflect the trauma system mission and best allow Florida trauma centers to provide timely, life-saving care to trauma patients statewide.

Amendments to Rule 64J-2.004

The current amendments to Rule 64J-2.004 propose to discard the old trauma scorecard methodology and adopt the CDC Guidelines for Field Triage of Injured Patients. While we generally support this change, we have some major concerns with its implementation.

The CDC Guidelines recommend transporting certain patients to the facility that provides "the highest level of care" within the defined trauma system. The patients identified by the CDC Guidelines include patients with the following injuries: (1) all penetrating injuries to head, neck,

torso, and extremities proximal to elbow or knee; (2) chest wall instability or deformity (e.g. flail hest); (3) two or more proximal long-bone fractures; (4) crushed, degloved, mangled, or pulseless extremity; (5) amputation proximal to wrist or ankle; (6) pelvic fractures; (7) open or depressed skull fractures; or (8) paralysis. Additionally, the CDC Guidelines recommend transporting patients to the "highest level of care" if they meet one of the following physiologic criteria: (1) Glasgow Coma Scale ≤ 13; (2) systolic blood pressure < 90 mmHg; or (3) respiratory rate of < 10 or > 29 breaths per minute. Patients with these injuries or meeting these criteria make up the vast majority of trauma patients currently treated at Level I and II trauma centers in Florida.

The Department of Health should amend Rule 64J-2.004 to expressly define "highest level of care" as a Level I or II trauma center. In Florida, the current clinical standards and resource requirements for Level I and II trauma centers in Florida are nearly identical, as identified in Figure 1 below. The Department proposes to adopt new trauma center standards set forth by the American College of Surgeons in Resources for Optimal Care of the Injured Patient 2014 (the "Orange Book"). The standards outlined in the Orange Book for the provision of clinical care to injured patients for Level I and Level II trauma centers are identical. Level I trauma centers are only distinguished from Level II trauma centers in that they must do the following: (1) Meet the admission volume requirements; (2) Maintain a surgically directed critical care service; (3) Participate in the training of residents and be a leader in education and outreach activities; and (4) Conduct Trauma center research. See Orange Book 2014, Chapter 2, Page 17. The primary differences between Level I and II trauma centers in Florida are the educational mission and research requirements for Level I trauma centers.

These additional requirements do not necessarily result in better patient care or outcomes at Level I trauma centers as compared to Level II trauma centers. In Florida, clinical research shows that low volume trauma centers can have the same, if not better, patient mortality rates as high volume trauma centers, even when such data is adjusted for patient risk. See Figure 2 below. Further, patient mortality rates at both Level I and II trauma centers around the state uniformly fall within the state's 95% Confidence Interval for trauma mortality. See Figure 3 below.

Some trauma system stakeholders have advocated that the CDC Guidelines be interpreted to require the transport of these patients only to Level I trauma centers. However, such an interpretation would prevent patients from being transported to the nearest trauma center, as required by Florida law, and drastically curtail the patient volumes Level II trauma centers, which are vital to the continued training and education of physicians and staff. We strongly urge the Department to define "highest level of care" as a Level I or II trauma center to ensure the CDC Guidelines are not interpreted in a manner which negatively impacts Florida's trauma patients or patient care.

The draft rule amendments also fail to define "trauma system" for the purposes of identifying the

"highest level of care" or even what entity is charged with defining the "trauma system". The CDC Guidelines recognize that the highest level of trauma care should be determined by the state trauma system authority. In Florida, this authority is the Department of Health and we encourage the Department to identify itself in the rule amendments as the sole entity charged with defining the "trauma system", as well as the "highest level of care".

Amendments to Rule 64J-2.007

The current amendments to Rule 64J-2.007 simplify and reconfigure the requirements to form a trauma agency and approve a trauma system plan submitted by a trauma agency. However, the amendments vaguely permit any "entity" to form a trauma agency. This broad term could allow individual trauma centers or other stakeholders to create exclusive trauma agencies with self-serving ends that usurp the inclusive intent behind local and regional trauma agencies. Rule 64J-2.009 grants trauma agencies a great deal of authority, including reviewing trauma center applications and conducting performance evaluations. Rule 64J-2.012 also lists trauma agency recommendations as the first tiebreaker in cases where multiple provisional trauma center applications are submitted for one TSA allocation slot. The current amendments also fail to carefully identify how entities go about creating trauma agencies and their boundaries. The significant authority assigned to trauma agencies makes it imperative that the Department specifically identify what entity or entities may form a trauma agency, the process by which that entity or entities may create a trauma agency, and how trauma agency boundaries are delineated to ensure that that Florida's local and regional trauma agencies are inclusive and operating in the best interest of Florida's trauma patients.

Amendments to Rule 64J-2.012

The current amendments move the trauma center application tiebreaker provisions to Rule 64J-2.012. These provisions determine which applications are approved in the event that multiple provisional trauma centers apply for less TSA allocation slots than applicants. Echoing the concerns above, the first tiebreaker favors the hospital recommended by the local or regional trauma agency. Trauma agency input should not be a determining factor in approval of trauma center applications. There has been too much dysfunction and it is too easy for self-serving interests to dominate the trauma agencies to allow them a deciding role in ultimate application approval. This role is ideally suited for the Department, as an impartial arbiter, using the objective criteria listed in the Rule as tiebreakers, such as patient access and geographic considerations. We encourage the Department to amend the application tiebreakers to remove trauma agency endorsement and give primary consideration to patient access and geographic factors.

If the 10-mile halo provision is to be adopted, the Department should clearly indicate in the Rule that this amendment will only operate prospectively. The Department has already stated this position, but, as discussed below, we strongly urge the Department to include this clarification in

the Rule.

Prospective Application of the Amended Rules

The Department has indicated on numerous occasions that any amendments to Chapter 64J-2 would operate prospectively. Given the contentiousness that has plagued Florida's trauma system, we believe it is imperative that the Department affirmatively state its intent in Chapter 64J-2 for the prospective application of these amendments. There are a number of draft rule amendments, including the TSA allocations of Rule 64J-2.010 and the 10-mile halo provision of Rule 64J-2.012, which, if adopted and applied retrospectively, could negatively impact the ongoing applications of currently operating provisionally approved trauma centers. Retrospective operation of these rules could result in the denial of pending applications and closure of these provisional trauma centers, denying Florida's residents access to the life-saving care that these centers currently provide. In accordance with the Department's stated intent to avoid such a scenario, we strongly urge the Department include a provision in the Chapter 64J-2 amendments clearly asserting the prospective application of these amendments.

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,

Stephen A. Ecenia

cc: Susan Bulecza (via email)

Figure 1: Comparison of Clinical Standards for Level I and Level II Trauma Centers in Florida. (http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/traumacntrstandpamphlet150-9-2009rev1-14-10.pdf)

Requirements	Level 1	Level 2
5 Trauma Surgeons 24 hours a day coverage	YES (in-house requirement)	YES
Surgical subspecialists immediately available 24 hours a day: Neurosurgery, Orthopedics, Plastics Surgery, Oral Maxillo Facial, ENT, Urology, Pediatric Surgery, Ophthalmology, Plastics, Obstetrics/Gynecology, Thoracic	YES	YES
Neurosurgery Services	YES (in-house neurosurgeon or in-house 2nd year neurosurgical resident)	YES (Neurosurgeon arrives within 30 minutes of consult)
Pediatric surgical services	YES (board certified or eligible Pediatric surgeon, or qualified trauma surgeon)	YES (trauma surgeons will perform pediatric surgery if necessary and stabilize for transport to nearest pediatric hospital)
Inpatient Pediatric Services requirement	YES	NO (stabilize patient and transfer agreement in place)
Operating Room immediately available for Trauma 24 hours a day	YES	YES
Medical subspecialists immediately available 24 hours a day	YES	YES
Gastroenterology 24-hour coverage	YES	NO
ATLS certified ED physicians	YES	YES
Burn Center: Either in-house or transfer agreement	YES	YES
Research	YES	NO
In-house microsurgery capabilities	YES	NO

Figure 2: Risk Adjusted Mortality O/E versus Trauma Center Patient Volume in Florida: No difference in patient mortality between high and low volume centers. (Accepted for Publication in the **Journal of Surgical Research 2015**, Ang et al.)

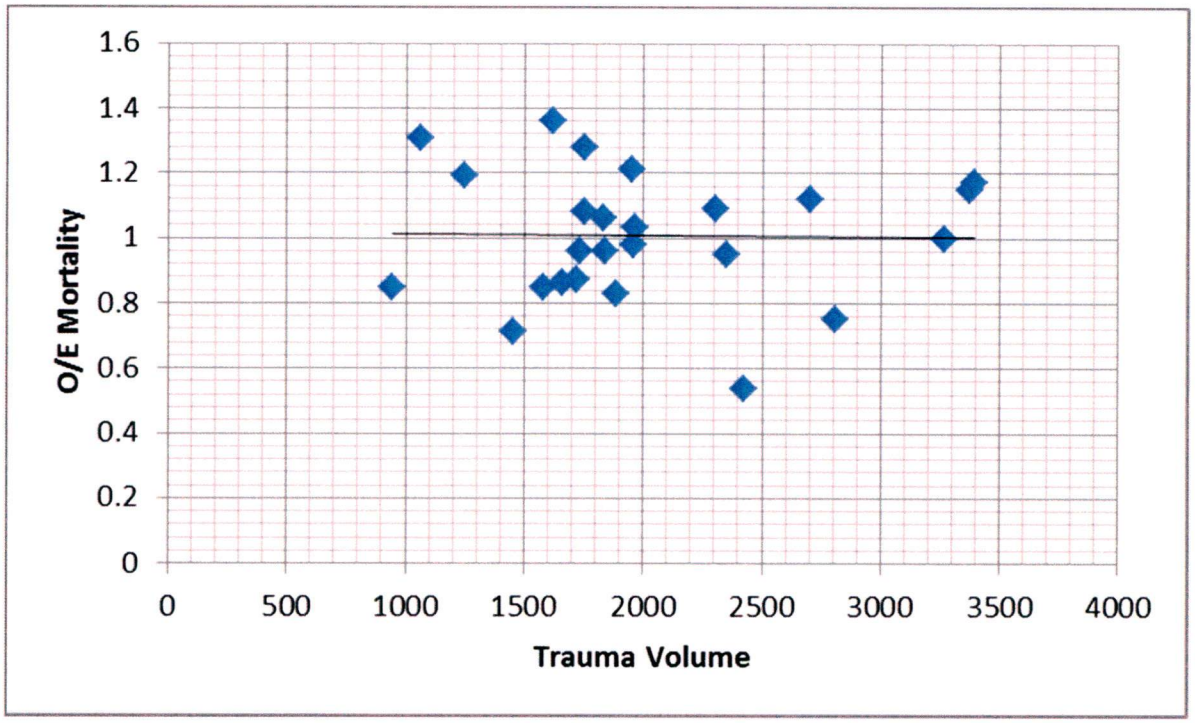
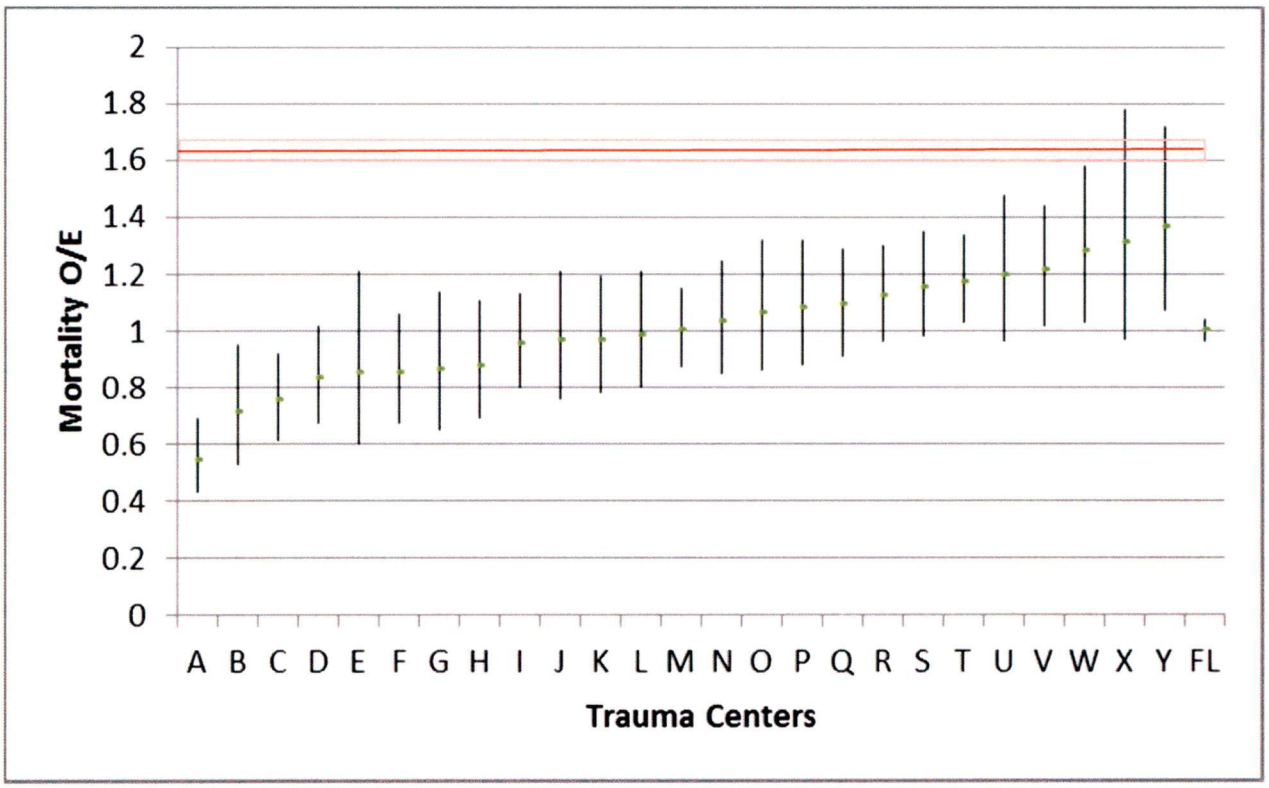
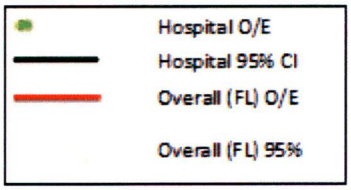



Figure 3: Adjusted Mortality Index with 95% CI by Trauma Center (Sorted from Low to High in alphabetical order) Compared to Average hospital mortality and its 95% CI range. Nearly all trauma centers whether level 1 or 2 fall within the State's 95% Confidence Interval for trauma mortality (Accepted for publication **2015 Journal of Surgical Research**, Ang et al.)