#### The Florida Senate

**COMMITTEE MEETING EXPANDED AGENDA** 

#### HEALTH POLICY Senator Young, Chair Senator Passidomo, Vice Chair

MEETING DATE:	Wednesday, March 22, 2017
TIME:	1:00—3:30 p.m.
PLACE:	Pat Thomas Committee Room, 412 Knott Building

**MEMBERS:** Senator Young, Chair; Senator Passidomo, Vice Chair; Senators Benacquisto, Book, Hukill, Hutson, Montford, and Powell

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION		
1	Presentations on Physician Supervision of C	Presented			
	- Lori E.H. Killinger, Florida Association of				
	- Brence Sell, M.D., Anesthesiologist				
2	Presentations on the Trauma System:		Presented		
	- Cindy Dick, Department of Health				
	- Robert J. Winchell, M.D., FACS, American College of Surgeons				
	- David Ceisla, M.D., Trauma Surgeon, Ta	mpa General Hospital			
3	Workshop on SB 406 (Compassionate Use of filed Senate bills to implement Amendment 2 Conditions.	of low-THC Cannabis and Marijuana), and other - Use of Marijuana for Debilitating Medical	Discussed		
	Other Related Meeting Documents				
	PUBLIC COMMENT WILL BE CONSIDEREI THE TIME ALLOTTED FOR EACH TOPIC.	D ON A TOPIC IF TIME PERMITS WITHIN			

### Lori E. H. Killinger

Lewis, Longman & Walker, P.A. Executive Shareholder

Ms. Killinger's law and lobbying practice spans 29 years during which she has been a private practitioner, worked as Assistant General Counsel for the Florida Department of Environmental Protection and then as Chief Attorney for the Florida House of Representatives, Committee on Judiciary. Ms. Killinger spear-headed the Late Governor Chiles' Building Codes Study Commission and worked as an in-house lobbyist for a major trade association.

Ms. Killinger is a shareholder in the law firm of Lewis, Longman & Walker where her practice focuses on Legislative, Administrative, and Governmental representation. She is Chairman of the firm's Legislative, Lobbying and Governmental Affairs Practice Group and represents clients before the legislative and executive Branches of government, regulatory agencies at the state and local levels, the Florida Cabinet, and legislative and gubernatorial Commissions.

Ms. Killinger is a founding member and current Board Member of the Florida Association of Professional Lobbyists and holds a certification as a "Designated Professional Lobbyist" from that organization. Ms. Killinger is also an AV-rated attorney, a certified mediator and a member of United States District Court, Southern and Middle Districts of Florida. Ms. Killinger is also the Past-Chairman of the Florida Construction Coalition.

Ms. Killinger earned a Bachelor of Arts degree in English Literature from the University of Florida in 1985 and her Juris Doctorate from Duke University School of Law in 1988.

## Senate Health Policy Committee Presentation-Physician Supervision of CRNAs March 22, 2017

PRESENTED BY: Lori Killinger, Legislative Counsel, FL Assn of Nurse Anesthetists



# CONCLUSION

The Florida Legislature should remove barriers (i.e., physician "supervision") from the law that keep CRNAs from practicing to the full extent of their education and training.



# FANA

Founded in 1936, the Florida Association of Nurse Anesthetists (FANA) represents the almost 5,400 Certified Registered Nurse Anesthetists (CRNAs) licensed in Florida.



# What is a CRNA?

Certified Registered Nurse Anesthetists (CRNAs) provide comprehensive anesthesia care to patients before, during, and after surgical and obstetrical procedures.

- <u>Primary anesthesia providers</u> in rural and underserved areas.
- Practice in <u>every setting</u> in which anesthesia is administered (e.g., hospitals, critical access hospitals, and ambulatory surgical centers).
- Practice in the offices of dentists and physicians, such as ophthalmologists, plastic surgeons, dermatologists, orthopedists, etc.
- VA and military hospitals.



## **"SUPERVISION" OF CRNAs IN FLORIDA**



## "Supervision" of CRNAs is Illusory

Florida law requires CRNAs to be "supervised," not by anesthesiologists, but by <u>ANY</u> physician, MD, DO, or dentist regardless of that person's training and experience with sedation.

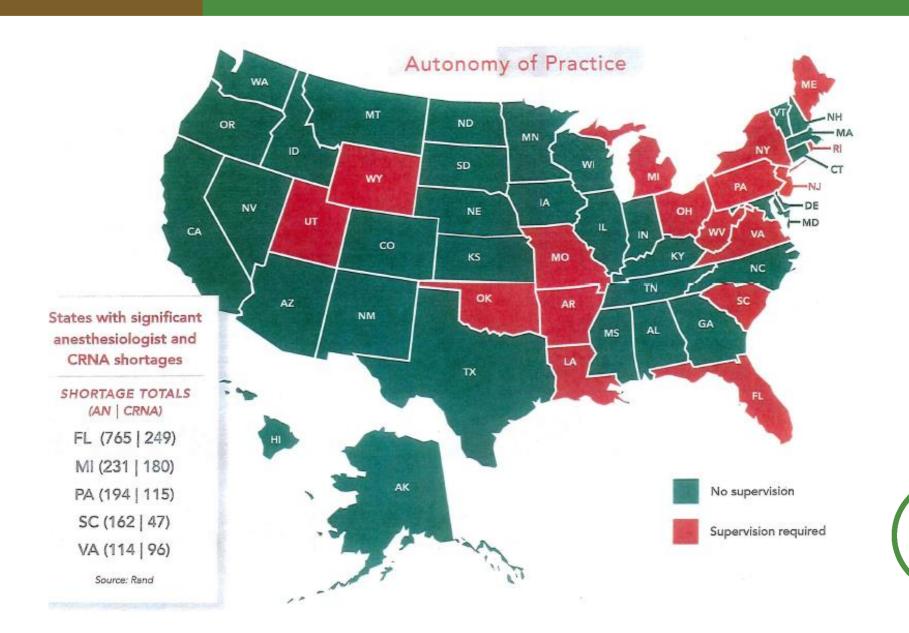
This paradigm has existed since the beginning; thus, Florida CRNAs have always practiced without a requirement for anesthesiologist supervision.

CRNAs are often the only anesthesia provider in rural settings, including hospitals, in Florida.

CRNAs are the primary anesthesia providers in the military, working without anesthesiologist supervision.



## **33 STATES ALLOW PRACTICE** WITHOUT SUPERVISION



## **SAFE CARE**



## **CRNAs Provide Safe Care**

Independent, third-party, peer-reviewed studies show that unsupervised CRNAs deliver anesthesia care as safely as anesthesiologists or CRNAs supervised by a physician.

Additionally, advances in anesthetics and technology have made the delivery of anesthesia safer than ever before.



# STUDIES SHOWING SAFETY



### "Scope of Practice Laws and Anesthesia Complications" by Brighita Negrusa, PhD and others (Medical Care, October 2016)

- Examined more than <u>5.7 million</u> anesthesia cases.
- Cases had a wide range of complexity.
- <u>Covered 38 states</u> with and without CRNA supervision.
- Conclusion: <u>Scope of practice restriction and physician</u> <u>supervision requirements for nurse anesthetists have no</u> <u>impact on anesthesia safety.</u>



### "No Harm Found When Nurse Anesthetists Work Without Supervision by Physicians" by Dulisse and Cromwell (Health Affairs, August 2010)

- Analyzed 481,440 anesthesia cases States where physician supervision is required compared with 14 states with no physician supervision requirement.
- Mortality rate <u>decreased</u> for CRNAs providing solo anesthesia in both groups of states after 2001, when states were first allowed to "opt out" of physician supervision.
- <u>Removal of the physician supervision requirement for nurse anesthetists did not</u> <u>result in increased risk to patients.</u>
- Patient safety was not compromised by allowing nurse anesthetists to practice without physician supervision.
- Conclusion: <u>No increase in adverse outcomes</u>.



### "Anesthesia Provider Model, Hospital Resources, and Maternal Outcomes" by Needleman and Minnick (Health Services Research, November 2008)

- Analyzed 1.141 million obstetrical patients from 369 hospitals in 7 states, including Florida.
- Compared nurse anesthetists, and a combination of nurse anesthetists and physician anesthesiologists.
- Study results confirmed a 2007 study (by Simonson) using Washington state data that showed <u>no difference in OB anesthesia complication or</u> <u>mortality rates</u> between hospitals using nurse anesthetists compared with hospitals that use only anesthesiologists.
- Conclusion: OB anesthesia is equally safe in hospitals using either model.



### OB Anesthesia Study by Simonson, Ahern and Hendryx (Nursing Research, 2007)

- Analyzed 134,806 obstetrical patient records from Washington state hospitals between 1993 and 2004.
- Conclusion: <u>No difference in complication or</u> <u>mortality rates between hospitals using only CRNAs</u> <u>compared with hospitals using only</u> <u>anesthesiologists</u>.



## "Surgical Mortality and Type of Anesthesia Provider" by Pine, Holt and Lou (AANA Journal, 2003)

- Analyzed 404,194 Medicare cases in 22 states between 1995 and 1997.
- Conclusion: <u>No difference in mortality rates</u> <u>between nurse anesthetists and anesthesiologists</u> <u>working independently, or nurse anesthetists and</u> <u>anesthesiologists working together</u>.



## **NO CONTRARY STUDIES**

To date, there are no peer reviewed studies that contradict the findings in these studies that anesthesia delivered by unsupervised CRNAs is less safe than when it is delivered by a supervised CRNA or by an anesthesiologist.



## **COST-EFFECTIVE**



## **CRNAs Provide Cost-Effective Care**

Studies show that CRNAs practicing independently are 30-34% less expensive than anesthesiologists or supervised CRNAs. This is largely due to anesthesia subsidies that hospitals pay to anesthesiology groups for supervision of CRNAs.

In 2012, the average anesthesia subsidy was over <u>\$160,000</u> per operating room or other anesthesia location in the hospital. Anesthesia subsidies ARE often a hospital's single largest provider-related cost.



## **INCREASED ACCESS**



## **Increased Access to Anesthesia Care**

Recent surveys found that Florida faces the largest shortage of anesthesiologists of any state and the third-largest shortage of CRNAs.



# EDUCATION AND TRAINING



## CRNAs ARE HIGHLY TRAINED IN ANESTHESIA DELIVERY AND ACUTE CARE

- Anesthesia educational programs for CRNAs average 29 months in length, (approximately 2,500 clinical hours).
- CRNAs must complete college with a nursing degree, obtain licensure as an RN, and work for at least one year in an acute care setting (hospital intensive care or critical care unit) <u>before</u> beginning an anesthesia educational program.
- On average, CRNAs have 3.5 years of experience as an acute care nurse before entering an anesthesia educational program.
- Thus, CRNAs have an average of 9,500 clinical hours in anesthesia and acute care nursing by the time they complete their anesthesia training.



# COMPARISON

### Certified Registered Nurse Anesthetists (CRNAs) and Anesthesiologists (MDs or DOs) A Comparison of Education and Training - October 2013

Provider Type	Required Pre-Anesthesia Education and Licensure	Clinical Requirement prior to Clinical Anesthesia Training	Training in Clinical Anesthesia	National Board Certification	% Board Certified
Certified Registered Nurse Anesthetist (CRNA)	Bachelor's Degree Licensure as a Registered Nurse (RN)	Minimum 1 yr Acute Care Nursing (3.5 years average experience as an acute care nurse in 2012)	Average 29 months with range 24 – 40 months in an accredited nurse anesthesia educational program Masters or Doctoral Degree	National certification exam administered by the National Board of Certification and Recertification for Nurse Anesthetists (NBCRNA).	100% (must pass certification exam to become CRNA)
Anesthesiologist (MD or DO)	Bachelor's Degree Medical School – Doctoral Degree	1 yr Clinical Base Year	36 month academic or hospital residency	National certification exam administered by the American Board of Anesthesiology (ABA).	74.8%



## REMINDER



## **33 Other States Allow CRNAs to Practice** Without Physician Supervision

No state has reversed independent practice for CRNAs once granted.



# CONCLUSION

Florida's antiquated regulatory scheme prohibits CRNAs from practicing independently and to the full scope of their education and training.

This scheme unnecessarily limits patients' access and adds significant cost to the health care system.



### Brence Alan Sell, M.D.

### **Curriculum Vitae**

### 2017

### ADDRESS

4770 Buckhead Court Tallahassee, Florida 32309

#### PLACE OF BIRTH

Albany, Georgia 17 July 1955

### EDUCATION AND TRAINING

Bachelor of Science (Chemistry) Granted June 1977 Emory University (August 1973 – June 1977) Atlanta, Georgia

Doctor of Medicine Granted June 1981 Emory University (August 1977 – June 1981) Atlanta, Georgia

Internship July 1981 – June 1982 Walter Reed Army Medical Center Washington, D.C.

Residency – Anesthesiology July 1982 – June 1984 Walter Reed Army Medical Center Washington, D.C.

### Brence A. Sell, M.D.

Fellowship in Neurosurgical Anesthesia July 1984 – June 1985 Johns Hopkins Hospital and Walter Reed Army Medical Center Baltimore, Maryland and Washington, D.C.

#### PROFESSIONAL EXPERIENCE AND APPOINTMENTS

Staff Anesthesiologist Walter Reed Army Medical Center Washington, D.C. 1985 – 1989

Chief, Neuro-Anesthesia Section Walter Reed Army Medical Center 1987 – 1989

Assistant Professor of Anesthesiology Uniformed Services University of Health Sciences Bethesda, Maryland 1985 – 1989

Staff Anesthesiologist Tallahassee Memorial Hospital 1988 – Present

Staff Anesthesiologist Capital Regional Medical Center (Formerly Tallahassee Community Hospital) Tallahassee, Florida 1988 – Present

Chairman, Department of Anesthesiology Tallahassee Memorial Hospital Tallahassee, Florida 1994 – 1996

### Brence A. Sell, M.D.

Chairman, Department of Anesthesiology Capital Regional Medical Center Tallahassee, Florida 1996 – 1997

Secretary, Medical Staff Capital Regional Medical Center Tallahassee, Florida 1997 – 1998

Clinical Assistant Professor Florida State University School of Medicine Tallahassee, Florida 2004 - Present

Chairman, Department of Anesthesiology Capital Regional Medical Center Tallahassee, Florida 2005 – 2008

Chairman, Pharmacy and Therapeutics Committee Tallahassee Memorial Hospital Tallahassee, Florida 2005 – Present

Member, Medical Executive Committee Tallahassee Memorial Hospital Tallahassee, Florida 2005 – 2008

Member of the Board of Directors Florida Society of Anesthesiologists 2011 – Present

Chairman, Pharmacy and Therapeutics Committee Capital Regional Medical Center 2012 - Present

### Brence A. Sell, M.D.

### SPECIALTY CERTIFICATIONS

- Diplomate of the American Board of Anesthesiology (Lifetime Certificate – Voluntarily renewed 2010)
- Diplomate of the National Board of Echocardiography (Renewed 2010 – Expires 2020)

Diplomate of the American Board of Neurophysiologic Monitoring (Renewed 2016 - Expires 2027)

#### **OTHER CERTIFICATIONS**

- Provider Advanced Cardiac Life Support (Renewed 8/2016 – Expires 8/2018)
- Provider Pediatric Advanced Life Support (Renewed 5/2015 – Expires 5/2017)
- Provider Advanced Trauma Life Support (Renewed 2014 – Expires 2018)

#### PROFESSIONAL SOCIETY MEMBERSHIPS

American Society of Anesthesiologists International Anesthesia Research Society Society for Neurosurgical Anesthesia and Critical Care Society of Cardiovascular Anesthesiologists American Society of Echocardiography Society for Pediatric Anesthesia American Clinical Neurophysiology Society American Society of Neurophysiological Monitoring American Medical Association Capital Medical Society American Society for Regional Anesthesia

#### PERSONAL INTERESTS

Flying – Licensed Private Pilot, Instrument Rated, Aerobatics Skydiving – Class A License Travel Reading

www.drsell.org



## FLORIDA'S TRAUMA SYSTEM

### FLORIDA DEPARTMENT OF HEALTH MARCH 22, 2017



### **HISTORY AND BACKGROUND**

2

### History: 1990 - 2004

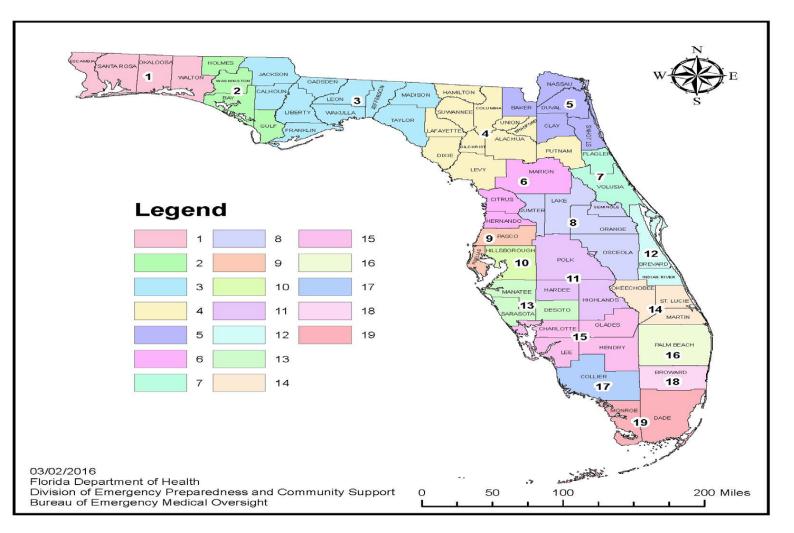


- Legislative report establishes state-sponsored trauma system to ensure access to high quality trauma services:
  - 19 Trauma Service Areas (TSA)
  - At least one Level I or Level II Trauma Center per TSA
  - No more than 44 trauma centers statewide
  - State agency responsibility to develop and implement state trauma system

### History: 1990 - 2004 (cont'd)



- Allocation Rule developed to allocate trauma centers
- 19 trauma centers in 11 TSAs by 1999
- Department of Health's 1999 Trauma System Report
- Creation of Trauma Response Fees to offset costs
- Development of Annual Assessment to assess provision of trauma care within the TSAs





Trauma Service Areas

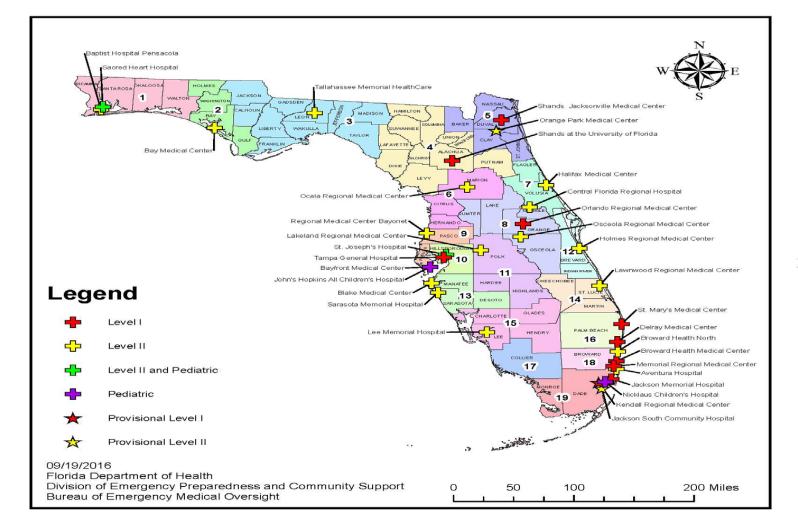
Disclaimer: This thematic map is for reference purposes. Any reliance on the information contained herein is at the user's own risk. The Florida Department of Health and its agents assume no responsibility for any use of the information contained herein or any loss resulting there from.

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# **Current Status**



- Trauma System treats more than 44,000 trauma patients annually
- Thirty-three (33) verified and provisional trauma centers in eighteen (18) TSAs
- 100% data submission to the Next Generation Trauma Registry





## Trauma Centers & Trauma Service Areas (2016)

Disclaimer: This thematic map is for reference purposes. Any reliance on the information contained herein is at the user's own risk. The Florida Department of Health and its agents assume no responsibility for any use of the information contained herein or any loss resulting there from.



# **TRAUMA CENTER VERIFICATION**

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## **Trauma Center Verification Process**

- Letters of Intent received
- Application and "Critical Element" Review
- Provisional Status granted
- "In-depth" application review
- On site assessment
- Verification
- 15 months from application receipt to verification





# **BARRIERS AND CHALLENGES**

10

# Litigation: Allocation of Trauma Centers in the TSAs



- ➢ 2014 Rule Challenge
  - Trauma Allocation Methodology upheld
- > 2015 Rule Challenges
  - Trauma Center Allocations to TSAs and Trauma Service Area Assessment
  - Regional Trauma Agency development
- 2016 Rule Challenges
  - Agency determination of need in each TSA

# **Litigation: Trauma Center Designation**

Florida HEALTH

- > 2015 Trauma Center Application Challenge
  - Trauma center application review and provisional approval process
- > 2016 Trauma Center Provisional Designation Challenges
  - Provisional designation to trauma centers in TSAs 5 and 19

# **Implementation Barriers and Challenges**

Florida HEALTH

- Litigation
- Rule Promulgation
- Trauma Center verification and designation

### CURRICULUM VITAE ROBERT J. WINCHELL, MD, FACS

## **PROFESSIONAL APPOINTMENTS:**

July 2015 – Present	Chief of the Division of Trauma, Burns, Acute and Critical Care Department of Surgery Weill Cornell Medical College New York, New York
July 2015 – Preseent	Director of the Trauma Center New York – Presbyterian Weill Cornell Medical Center New York, New York
July 2015 – Present	Professor of Surgery Weill Cornell Medicine New York, New York
July 2014 – July 2015	Visiting Professor of Surgery University of Texas Health Science Center at Houston Houston, Texas
July 2014 – July 2015	Chief of Trauma Memorial Hermann – Texas Medical Center Houston, Texas
October 2004 – July 2014	Chief, Division of Trauma and Burn Surgery Maine Medical Center Portland, Maine
July 2010 – July 2014	Associate Professor of Surgery Tufts University School of Medicine Boston, Massachusetts
July 2002 – June 2010	Clinical Associate Professor of Surgery Department of Surgery University of Vermont College of Medicine Burlington, Vermont
August 2001 – September 2004	Trauma and Critical Care Surgeon Maine Medical Center Portland, Maine
January 2000 – August 2001	Associate Clinical Professor of Surgery, voluntary Division of Trauma, Department of Surgery U.C. San Diego School of Medicine San Diego, California

January 2000 – August 2001	Head of Adult Tr The Tacoma Tra St. Joseph Medic Tacoma General Tacoma, Washin	uma Center cal Center Hospital
July 1997 –December 1999	Division of Trau	sor of Clinical Surgery ma, Department of Surgery School of Medicine ornia
July 1991 – June 1997	Division of Trau	or of Surgery, IR ma, Department of Surgery School of Medicine ornia
BOARD CERTIFICATION:		
	American Board Recertified, Recertified, Certificate Numb	November 1999 December 2010
	Certificate of Ad Recertified, Recertified, Certificate Numb	ded Competency,Surgical Critical Care October 1992 October 2001 September 2012 Der 1072
MEDICAL LICENSURE:		
	New York Texas California: Maine: Washington:	281064, July 2015 Q1058, July 2014 G56513, June 1985 015765, August 2001 (inactive) MD00038374, March 2000 (inactive)
EDUCATION:		
1980 - 1984	New Haven, CT	School of Medicine gnetic Contrast Agents in NMR Imaging."
1979 - 1980	University of Art Tucson, AZ	Chemical Engineering izona ocirculatory Transport Phenomena"
1976 - 1979	B.S. with Honors California Institu Pasadena, CA	s ite of Technology

1974 - 1976	Undergraduate Study St. Mary's College Moraga, CA
POSTGRADUATE APPOINTMENTS:	
1990 - 1991	Fellowship in Trauma and Critical Care Division of Trauma, Department of Surgery UCSD School of Medicine
1985 - 1990	Surgical Residency Department of Surgery UCSD School of Medicine
1984 - 1985	Surgical Internship Department of Surgery UCSD School of Medicine
HONORS AND AWARDS:	
2015	ACS/AAST Trauma Health Policy Scholarship
1992	Outstanding Teaching Staff Emergency Medicine Residency Program U.S. Naval Hospital, San Diego
1990	Resident's Teaching Award Department of Surgery UCSD School of Medicine
1984	Louis G. Welt Prize, (Outstanding Thesis) Yale University
MEMBERSHIPS/CERTIFICATIONS:	
	<ul> <li>Fellow, American College of Surgeons</li> <li>Fellow, American Association for the Surgery of Trauma</li> <li>Fellow, Southwest Surgical Congress</li> <li>Member, Pan American Trauma Society</li> <li>Member, International Surgical Society</li> <li>Member, International Association for Trauma Surgery &amp; Intensive Care</li> <li>Member, American Burn Association</li> <li>Member, New England Surgical Society</li> <li>Member, Association for Academic Surgery</li> <li>Member, Society of Critical Care Medicine</li> <li>Member, American Medical Association</li> <li>Advanced Trauma Life Support (ATLS) Instructor, National Faculty</li> <li>Advanced Surgical Skills for Exposure in Trauma (ASSET) Instructor</li> <li>Advanced Burn Life Support (ABLS) Provider</li> <li>Basic Life Support Provider</li> <li>Fluoroscopy Supervisor and Operator</li> </ul>

#### **EXTRAMURAL ACTIVITIES:**

2015 – present	Member, Regional Emergency Medical Services Council of New York City
2010 – present	Chairman Trauma Systems Evaluation and Performance Sub-Committee, American College of Surgeons Committee on Trauma
	Team Leader, Santa Clara County Trauma System Consultation 2016 Team Leader, California State Trauma System Consultation 2016 Team Leader, New Hampshire State Trauma System Consultation 2015 Team Leader, Virginia State Trauma System Consultation 2015 Team Member, Iowa State Trauma System Consultation 2015 Team Leader, South Carolina State Trauma System Consultation 2014 Team Leader, Solano County Trauma System Consultation 2013 Team Member, Ohio State Trauma System Consultation 2013 Team Member, Ohio State Trauma System Consultation 2013 Team Leader, Florida State Trauma System Consultation 2013 Team Leader, Arizona State Trauma System Consultation 2012 Team Leader, Massachusetts State Trauma System Consultation 2012 Team Leader, Solano County Focused System Consultation 2012 Team Leader, District of Columbia Trauma System Consultation 2011 Team Leader, Arkansas State Trauma System Consultation 2011 Team Leader, Navaho Nation Trauma System Consultation 2010
2010 – present	Member Executive Committee American College of Surgeons Committee on Trauma
2010 - present	Member, American College of Surgeons Committee on Trauma
2007 – present	Trauma Systems Consultation Site Visit Team Team Leader since 2008 Trauma Systems Evaluation and Performance Sub-Committee, American College of Surgeons Committee on Trauma Team Leader, Louisiana StateTrauma System Consultation 2009 Team Leader, Georgia State Trauma System Consultation 2009
	Team Leader, North Dakota Trauma System Consultation 2008 Team Member, Tennessee Trauma System Consultation 2008 Team Member, Minnesota Trauma System Consultation 2007
2006 – present	Member ATLS Sub-Committee, American College of Surgeons Committee on Trauma
2006 - present	Trauma Center Site Reviewer, Lead Reviewer since 2008 Verfication Review Sub-Committee,

American College of Surgeons Committee on Trauma

Senior Reviewer:

Concord Hospital, Concord, New Hampshire, 2016 Providence Hospital & Medical Center, Southfield, Michigan, 2015 University of California Davis Medical Center, Sacramento, Calif. 2015 Denver Health Medical Center, Denver, Colorado, 2015 St. Anthony Hospital, Lakewood, Colorado, 2015 University of Michang Health Systems, Ann Arbor, Michigan, 2014 Providence Hospital & Medical Center, Southfield, Michigan, 2014 Harlem Hospital, New York, New York, 2014 Strong Memorial Hospital, Rochester, New York, 2014 South Nassau Commities Hospital, Oceanside, New York, 2013 Bellevue Hospital Center, New York, New York, 2013 Oakwood Southshore Medical Center, Trenton, Michigan, 2013 Santa Clara Valley Medical Center, San Jose, California 2013 Stanford Hospital and Clinics, Palo Alto, California 2013 St Joseph Hospital, Houston Texas 2012 St. Joseph Mercy Oakland Hospital, Pontiac, Michigan 2012 Strong Memorial Hospital, Rochester, New York 2012 Waterbury Hospital, Waterbury, Connecticut 2012 Parkland Hospital, Dallas, Texas 2011 University Medical Center of El Paso, El Paso Texas 2011 Flagstaff Medical Center, Flagstaff, Arizona 2011 Beaumont Hospital, Royal Oak, Michigan 2011 Carolinas Medical Center, Charlotte, North Carolina 2010 San Jose Region Medical Center, San Jose, California 2010 Stanford University Medical Center, Stanford California 2010 Santa Clara Valley Hosptial, San Jose, California 2010 Capital Health, Trenton, New Jersey 2010 Duke University Hospital, Raleigh, North Carolina 2009 Wake Forest University, Winston-Salem, North Carolina 2009 Beverly Hospital, Beverly, Massachusetts 2009 Hospital of St. Raphael, New Haven Connecticut 2009 Inova Fairfax Hospital, Falls Church, Virginia 2008 **Reviewer:** Yale New Haven Hospital, New Haven, Connecticut 2007 Yale New Haven Hospital, New Haven, Connecticut 2007 Sunrise Hospital and Medical Center, Las Vegas, Nevada 2007 Hennepin County Medical Center, Minneapolis, Minnesota 2007 Member, Trauma Systems Committee Governors's EMS and Trauma Advisory Council State of Texas

2004 - 2014	Member
	Trauma Advisory Council
	State of Maine

2014 - 2015

2006 - 2010	Chairman American College of Surgeons Regional Committee on Trauma, State of Maine
2008 - 2010	Vice Chair Trauma Systems Evaluation and Performance Sub-Committee, American College of Surgeons Committee on Trauma
2006 - 2010	Member Trauma Systems Evaluation and Performance Sub-Committee, American College of Surgeons Committee on Trauma
2004 - 2005	Vice-Chair American College of Surgeons Regional Committee on Trauma, State of Maine
1996 - 2001	Chairman, American College of Surgeons Regional Committee on Trauma, San Diego and Imperial Counties
1996 – 2001	Member National Trauma Data Bank Sub-Committee, American College of Surgeons Committee on Trauma
2000 - 2001	Member, Data Technical Advisory Committee Steering Committee on Emergency Medical Services and Trauma State of Washington
2000 - 2001	Member, Cost Technical Advisory Committee Steering Committee on Emergency Medical Services and Trauma State of Washington
2000 - 2001	Co-Chair, West Region Quality Improvement Forum West Region Council for Emergency Medical Services and Trauma State of Washington
INTERNATIONAL ACTIVITIES:	
2016	Invited Speaker ATLS Region IX Meeting Mexico City, Mexico
2015	HL7 International Conference Paris, France
2015	Visiting Professorship Centre Hospitalier Universitaire Vaudois Lausanne, Switzerland
2015	American College of Surgeons Representative World Health Organization Global Alliance for the Care of the Injured Geneva, Switzerland

2013	Official Launch of the Global Alliance for the Care of the Injured World Health Organization World Health Assembly Geneva, Switzerland
2012	Trauma Center and Trauma Systems Consultation Rigshospitalet University Hospital, Copenhagen, Denmark
2012	American College of Surgeons Representative World Health Organization Global Alliance for the Care of the Injured Geneva, Switzerland
2012	American College of Surgeons Representative World Health Organization Consultation on Trauma Systems Geneva, Switzerland
2011	Cultural Exchange Xiuning County People's Hospital Xiuning, Anhue Province, China

### **EDITORIAL POSITIONS:**

2005 - present	Reviewer, Journal of Trauma and Acute Care Surgery
2005 - present	Reviewer, Archives of Surgery
2012 – present	Reviewer, World Journal of Surgery

### HOSPITAL COMMITTEES

2016 – present	Ethics Committee , New York – Presbyterian Weill Cornell Medical Center
2016 – present	Quality and Patient Safety Committee, Department of Surgery New York – Presbyterian Weill Cornell Medical Center
2014 - 2015	Medical Staff Quality Review Committee – Memorial Hermann – Texas Medical Center
2104 - 2015	Surgeon's Council, Memorial Hermann – Texas Medical Center
2007 - 2014	Patient Safety Committee, Maine Medical Center
2003 - 2014	Pharmacy and Therapeutics Committee, Maine Medical Center
2002 - 2014	Critical Care Services Committee, Maine Medical Center
2008 - 2012	Maine Medical Partners Board of Directors
2002 - 2010	Clinical Ethics Committee, Maine Medical Center
2003 - 2007	Information Services Committee, Maine Medical Center

2004 - 2007	Clinical Documentation Task Forece, Maine Medical Center
2002 - 2003	Institutional Animal Care and Use Committee, MMCRI
2000 - 2001	Chairman: St. Joseph's Medical Center Trauma Committee
2000 - 2001	Chairman: Tacoma General Hospital Trauma Committee
2000 - 2001	Tacoma Trauma Trust Executive Committee, Ex-Officio
2000 - 2001	Trauma Planning Group, Tacoma Trauma Center
2000 - 2001	Medical Executive Committee, Tacoma General Hospital, Ex-Officio
2000 - 2001	Surgery Committee, Tacoma General Hospital
1997 – 1999	Chairman: Medical Risk Management Committee UCSD
1997 – 1999	Patient Care Review Committee UCSD
1994 - 1999	Ethics Committee UCSD
1991 - 1999	General Surgery Quality Control Committee UCSD
1990 - 1999	SICU Users Group UCSD
1995 - 1997	Medical Risk Management Committee UCSD
1990 - 1997	Code Blue Committee UCSD
1994	Chairman: Surgical and Invasive Procedures Process Action Team UCSD
1994	Medical Practice Quality Improvement Team UCSD
1993	Medical Information Systems Planning Committee UCSD
1991 - 1993	Infection Control Committee UCSD
1992	Medical Group Operations Committee UCSD
1991	AIDS Ad Hoc Committee UCSD

### CONTRACTS/GRANTS

Fall 2000

Consultant: Heart Rate Variability Analysis NIOSH project: <u>SCBA Oximietry for Firefighter Physiologic</u> <u>Monitoring</u> Phase 1 SBIR to BioAssist, LLC

June 1992	UCSD Academic Senate
	Project Title: Development of a system for on-line data analysis in the
	<u>SICU.</u>
	Award: \$6000
July 1991	Trauma Research and Education Foundation
	Project Title: Development of a system for on-line data acquisition and
	numerical analysis in the SICU.
	Award: \$5000

### **RESEARCH INTERESTS AND EXPERIENCE:**

2000 – present	-Automated spectral analysis of heart rate variability -Digital data acquisition and signal processing in the ICU -Computerization of ICU management protocols -Computer assisted decision making.
1990 - 1999	Division of Trauma UCSD School of Medicine -Automated spectral analysis of heart rate variability -Digital data acquisition and signal processing in the SICU. -Computerization of ICU management protocols -Computer assisted decision making.
1987 - 1988	Research Assistant Department of Surgery UCSD School of Medicine -Basic research in organ preservation for transplantation.
1983 - 1984	Research Assistant Department of Radiology Yale University, New Haven, CT -Development of first NMR imaging system. Basic research and development of NMR contrast agents.
1979 - 1981	Staff Engineer Xytel Corporation Chicago, IL -System design and hardware implementation for computer controlled chemical process equipment.
1979	Staff Scientist Jet Propulsion Laboratory Pasadena, CA -Electron spectroscopy and molecular physics.
1978	Research Assistant California Institute of Technology, Pasadena, CA -Basic research in the atmospheric dispersion of pollutants.

#### **PUBLISHED WORKS:**

1.	Ajello JM, Chutjian A, <b>Winchell RJ</b> : <u>Threshold Photoelectron Spectrum of CO by</u> <u>Electron Attachment.</u> Journal of Electron Spectroscopy and Related Phenomena <b>19</b> :197-201 1979	RESEARCH ARTICLE
2.	Caride VJ, Sostman HD, <b>Winchell RJ</b> , Gore JC: <u>Relaxation Enhancement Using</u> <u>Liposomes Carrying Paramagnetic Species</u> . Magnetic Resonance Imaging <b>2</b> :107- 112 1984	RESEARCH ARTICLE
3.	Winchell RJ, Halasz N: <u>The Effects of Cooling Rates and Storage Temperature on</u> <u>the Function of 24-Hour Cold-Preserved Rabbit Kidneys.</u> Transplantation <b>46</b> :918- 919 1988	LETTER
4.	Winchell RJ, Halasz N: <u>Lack of Effect of Oxygen-Radical Scavenging Systems in</u> <u>the Preserved Reperfused Rabbit Kidney.</u> Transplantation <b>48</b> :393-396 1990	RESEARCH ARTICLE
5.	<b>Winchell RJ</b> : <u>Definitive Care Phase: Orthopedic and Spinal Injuries</u> . In: Surgery: Scientific Principles and Practice. Greenfield L, Mulholland M, Oldham K, Zelenock G (Editors) J. B. Lippincott Company 331-334 1992	BOOK CHAPTER
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8.	Winchell RJ, Hoyt DB, Walsh J, Simons RK, Eastman AB: <u>Pattern of Use of the</u> <u>Vena Caval Filter for Prophylaxis Against Pulmonary Embolism in the Trauma</u> <u>Patient.</u> J Trauma <b>35</b> :173 1993	ABSTRACT
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12.	Hoyt DB, Bulger EM, Knudson MM, et.al.: <u>Death in the Operating Room: An</u> <u>Analysis of a Multi-Center Experience</u> . J Trauma <b>37</b> :426-432, 1994 <b>Winchell RJ (9th Author)</b>	RESEARCH ARTICLE
13.	Winchell RJ, Hoyt DB, Simons RK: <u>Risk Factors Associated with Pulmonary</u> <u>Embolism Despite Routine Prophylaxis: Implications for Improved Protection.</u> J Trauma <b>37</b> :600-606, 1994	RESEARCH ARTICLE

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15.	Hoyt DB, <b>Winchell RJ</b> : <u>Endocrine and Metabolic Complications</u> in Complications in Trauma and Critical Care. Maull KI, Rodriguez A, Wiles CE (Editors.) W.B. Saunders Company 1994 (In Press)	BOOK CHAPTER
16.	Winchell RJ, Hoyt DB, Simons RK: <u>Use of Computed Tomography of the Head in</u> <u>the Hypotensive Blunt Trauma Patient.</u> Ann Emerg Med <b>25</b> :737-742, 1995	RESEARCH ARTICLE
17.	Simons RK, <b>Winchell RJ</b> , Hoyt DB: <u>Continuous Quality Improvement in the</u> <u>Intensive Care Unit.</u> In Advances in Trauma and Critical Care, Volume 10. Maull KI (Editor) Mosby-Year Book Incorporated, Chicago, Illinois 1995	REVIEW ARTICLE
18.	Simons RK, Hoyt DB, <b>Winchell RJ</b> , Holbrook T, Eastman AB: <u>A Risk Analysis</u> of Stress Ulceration after Trauma. J Trauma <b>39</b> :289-294 1995	RESEARCH ARTICLE
19.	Winchell RJ, Hoyt DB: <u>Real Time Spectral Analysis of Heart Rate Variability in</u> <u>the Intensive Care Unit.</u> J Surg Res 63:11-16 1996	RESEARCH ARTICLE
20.	Healey MA, Simons RK, <b>Winchell RJ</b> , et. al.: <u>Prospective Evaluation of</u> <u>Abdominal Ultrasound in Blunt Trauma: Is It Useful?</u> J Trauma <b>40</b> :875-885 1996	RESEARCH ARTICLE
21.	Winchell RJ, Simons RK,, Hoyt DB: <u>Transient Systolic Hypotension</u> : <u>A Serious</u> <u>Problem In The Management Of Head Injury.</u> Arch Surg <b>131</b> :533-539 1996.	RESEARCH ARTICLE
22.	Simons RK, Hoyt DB, <b>Winchell RJ</b> , Rose RM: <u>Elevated P Selectin Following</u> <u>Severe Trauma - A Potential Target for Immunomodulatory Therapy.</u> J Trauma <b>41</b> :653-662 1996	RESEARCH ARTICLE
23.	Coimbra R, Hoyt DB, <b>Winchell RJ</b> , Simons RK, Fortlage DA: <u>The Ongoing</u> <u>Challenge of Retroperitoneal Vascular Injuries.</u> Am J Surg <b>172</b> :541-544 1996	RESEARCH ARTICLE
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25.	Winchell RJ, Hoyt DB, Simons RK. <u>Endotracheal Intubation in the Field</u> <u>Improves Survival in Patients with Severe Head Injury</u> . Annual Meeting of the Western Surgical Association, Portland, Oregon, November 1996	ABSTRACT
26.	Winchell RJ: <u>Chest Injury</u> . In: Surgery: Scientific Principles and Practice. (2nd Edition) Greenfield L, Mulholland M, Oldham K, Zelenock G, Lillemoe K. (Editors) ) Lippincott-Raven Publishers, New York, New York 1997	BOOK CHAPTER
27.	Winchell RJ, Healey MA: <u>Definitive Care Phase: Orthopedic and Spinal Injuries</u> . In: Surgery: Scientific Principles and Practice. (2nd Edition) Greenfield L, Mulholland M, Oldham K, Zelenock G, Lillemoe K. (Editors) Lippincott-Raven Publishers, New York, New York 1997	BOOK CHAPTER

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29.	Winchell RJ and Hoyt DB: Endotracheal Intubation in the Field Improves Survival in Patients with Severe Head Injury, Arch Surg 132:592-597 1997	RESEARCH ARTICLE
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32.	Shah KH, Simons RK, Holbrook T, Fortlage D, <b>Winchell RJ</b> , and Hoyt DB. <u>Trauma in Pregnancy: Maternal and Fetal Outcomes</u> . J Trauma, <b>45</b> :83-6 1998	RESEARCH ARTICLE
33.	Acosta JA, Yang JC, <b>Winchell RJ</b> , Simons RK, Fortlage DA, Hollingsworth- Fridlund P, and Hoyt DB. <u>Lethal Injuries and Time to Death in a Level I Trauma</u> <u>Center</u> . Journal of the American College of Surgeons, <b>186</b> :528-33 1998.	RESEARCH ARTICLE
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36.	Winchell RJ and Hoyt DB. <u>Hemostasis and Transfusion</u> . In Surgery, Corson JD, Williamson RCN (Eds), Mosby Wolf, 2000	BOOK CHAPTER
37.	Winchell RJ: <u>Chest Injury</u> . In: Surgery: Scientific Principles and Practice. (3rd Edition) Greenfield L, Mulholland M, Oldham K, Zelenock G, Lillemoe K. (Editors) ) Lippincott-Williams & Wilkins, Philadelphia, Pennsylvania 2001	BOOK CHAPTER
38.	Engelhardt S, <b>Winchell RJ:</b> <u>Definitive Care Phase: Orthopedic and Spinal</u> <u>Injuries</u> . In: Surgery: Scientific Principles and Practice. (3rd Edition) Greenfield L, Mulholland M, Oldham K, Zelenock G, Lillemoe K. (Editors) Lippincott- Williams & Wilkins, Philadelphia, Pennsylvania 2001	BOOK CHAPTER
39.	Hoyt DB, Coimbra R, <b>Winchell RJ</b> . <u>Management of Acute Trauma</u> . In: Sabiston Textbook of Surgery, The Biological Basis of Modern Surgical Practice (16th Edition), Townsend CM, Beauchamp RD, Evers MB, and Mattox KL (Editors), W.B. Saunders, 2001	BOOK CHAPTER
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43.	Clark DE and Winchell RJ. <u>Risk Adjustment for Injured Patients Using</u> <u>Administrative Data.</u> J Trauma <b>57:</b> 130-40. 2004	RESEARCH ARTICLE
44.	Kortbeek JB, Al Turki SA, Ali J, et. al. (Winchell RJ 57th author). <u>Advanced</u> <u>trauma life support, 8<sup>th</sup> edition, the evidence for change</u> . J Trauma <b>64</b> (6) 1638-50 2008	REVIEW
45.	Winchell RJ, Ball, JW, Cooper, GF, Sanddal ND, Rotondo MF. <u>An assessment of the impact of trauma systems consultation on the level of trauma system</u> <u>development.</u> JACS <b>207</b> (5). 623-9 2008	RESEARCH ARTICLE
46.	Velmahos GC, Tabbara M, Gross R, et. al. (Winchell RJ 9 <sup>th</sup> author). <u>Blunt</u> pancreaticoduodenal injury: a multicenter study of the Research Consortium of New England Centers for Trauma (ReCONECT). Arch Surg 144(5) 413-9. 2009	RESEARCH ARTICLE
47.	Velmahos GC, Zacharias N, Emhoff TA, et al ( <b>Winchell RJ</b> 13 <sup>th</sup> author) <u>Management of the most severely injured spleen: a multicenter study of the</u> <u>Research Consortium of New England Centers for Trauma (ReCONECT)</u> Arch Surg <b>145</b> (5) 456-60 2010	RESEARCH ARTICLE
48.	Winchell RJ. <u>Teaching a new dog old tricks</u> Arch Surg <b>146</b> (5) 624 2011	INVITED COMMENT
49.	Michetti CP, Fakhry SM, Ferguson PL, et al ( <b>Winchell RJ</b> 46 <sup>th</sup> author) <u>Ventilator-associated pneumonia rates at major trauma centeres compared with a national benchmark: a multi-institutional study of the AAST</u> . J Trauma Acute Care Surg <b>72</b> (5) 1165-1173 2012	RESEARCH ARTICLE
50.	Clark DE, Qian J, <b>Winchell RJ</b> , Betensky RA. <u>Hazard Regression Models of Early</u> <u>Mortality in Trauma Centers</u> . J Am Coll Surg <b>215</b> (6) 841-9 2012	RESEARCH ARTICLE
51.	van der Vilden GM, et al ( <b>Winchell RJ</b> 13 <sup>th</sup> author) <u>Successful Nonoperative</u> <u>Management of the Most Severe Blunt Liver Injuries: A Multicenter Study of the</u> <u>Research Consortium of New England Centers for Trauma.</u> Arch Surg <b>147</b> (5) 423-8 2012	RESEARCH ARTICLE
52.	Clark DE, <b>Winchell RJ</b> , Betensky RA. Estimating the effect of emergency care on early survival after traffic crashes. Accid Anal Prev <b>60</b> :141-144 2013	RESEARCH ARTICLE
53.	Clark DE, Doolittle PC, <b>Winchell RJ,</b> Betensky RA. <u>The effect of hospital care on</u> <u>early survival after penetrating trauma.</u> Inj Epidemiol. <b>1(1):</b> 24 2014	RESEARCH ARTICLE

54.	<b>Winchell RJ</b> , Sanddal N, Ball J, Michaels H, Kaufmann CR, Gupta R, Esposito TJ, and Subacius H <u>A Reassessment of the Impact of Trauma Systems Consultation on Regional Trauma System Development</u> Presented at the 73 <sup>rd</sup> Annual Meeting of the American Association for the Surgery of Trauma, Philadelphia, Pennsylvania. September 12, 2014	ABSTRACT
55.	Winchell RJ, Sanddal N, Ball J, Michaels H, Kaufmann CR, Gupta R, Esposito TJ, and Subacius H <u>A Reassessment of the Impact of Trauma Systems Consultation on Regional Trauma System Development</u> J Trauma Acute Care Surg <b>78</b> :6 1102-1110 2015	RESEARCH ARTICLE
56.	DuBose JJ, Perlick A, Fortuna GR, Leake SS, Miller CC, <b>Winchell RJ</b> , Safi HJ, Azizzadeh A <u>Predictors of Aortic-Related Mortality in Blunt Thoracic Aortic</u> <u>Injury.</u> J Vasc Surg <b>61</b> :65 165S 2015	ABSTRACT
57.	Jenkins DH, <b>Winchell RJ,</b> Coimbra R, Rotondo MF, Weireter LJ, Bulger EM, Kozar RA, Nathens AB, Reilly PM, Henry SM, et al. <u>Position statement of the</u> <u>American College of Surgeons Committee on Trauma on the National</u> <u>Academies of Sciences, Engineering and Medicine Report, A National Trauma</u> <u>Care System: Integrating Military and Civilian Trauma Systems to Achieve Zero</u> <u>Preventable Deaths After Injury.</u> J Trauma Acute Care Surg <b>Nov;81(5):</b> 819-23 2016	ARTICLE
58.	Maung AA, Johnson DC, Barre K, Peponis T, Mesar T, Velmahos GC, McGrail D, Kasotakis G, Gross RI, Rosenblatt MS, et al. ( <b>Winchell RJ</b> 12 <sup>th</sup> author) <u>Cervical</u> <u>spine MRI in patients with negative CT: A prospective, multicenter study of the</u> <u>Research Consortium of New England Centers for Trauma (ReCONECT).</u> J Trauma Acute Care Surg. 2016 Nov 23. [Epub ahead of print]	RESEARCH ARTICLE

#### UNPUBLISHED MATERIAL

 1.
 Winchell RJ: Paramagnetic Contrast Agents in NMR Imaging, M.D. Thesis: Yale
 DOCTORAL

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 THESIS

### WORK IN PROGRESS

#### PRESENTATIONS

1.	Penetrating Abdominal Trauma, 14th Annual Postgraduate Assembly in Surgery, San Diego, California January 1991	LECTURE
2.	AIDS, The Surgeon's Dilemma, Surgical Grand Rounds, UCSD Medical Center, San Diego, California July 1991	LECTURE
3.	<u>A Critical Analysis of Errors in the Care of the Trauma Patient</u> , 7th Argentine Congress on Critical Care, Buenos Aires, Argentina August 1992	LECTURE
4.	<u>The San Diego County Trauma System</u> , 7th Argentine Congress on Critical Care, Buenos Aires, Argentina August 1992	LECTURE
5.	Computers in the ICU, Present and Future, 7th Argentine Congress on Critical Care, Buenos Aires, Argentina August 1992	LECTURE
6.	<u>Computed Tomography of the Head in the Hypotensive Trauma Patient</u> , 5th Pan American Congress on Trauma, Guadalajara, Mexico September 1992	ABSTRACT
7.	Mechanical Ventilation, Past and Present, Surgical Grand Rounds, UCSD Medical Center, San Diego, California December 1992	LECTURE
8.	<u>The Truth About the AIDS Risk</u> , California Trauma Conference, San Diego, California January 1993	LECTURE
9.	Liver Trauma, 16th Annual Postgraduate Assembly in Surgery, San Diego, California January 1993	LECTURE
10.	Chest Trauma, Emergency Medicine Symposium, San Diego, California. March 1993	LECTURE
11.	Pattern of Use of the Vena Caval Filter for Prophylaxis Against Pulmonary Embolism in the Trauma Patient. 53rd Annual Meeting of the American Association for the Surgery of Trauma, New Orleans, Louisiana. September 1993	ABSTRACT
12.	<u>Chest Trauma</u> , Emergency Medicine Symposium, San Diego, California. December 1993	LECTURE
13.	<u>Blood Transfusion in Jehovah's Witnesses</u> , Surgical Grand Rounds, UCSD Medical Center, San Diego, California. March 1994	LECTURE
14.	Shock, Emergency Medicine Symposium, San Diego, California March 1994	LECTURE
15.	<u>Abdominal Trauma</u> , Emergency Medicine Symposium, San Diego, California. March 1994	LECTURE

16.	<u>Pelvic and Genitourinary System Trauma,</u> Emergency Medicine Symposium, San Diego, California. March 1994	LECTURE
17.	<u>Blood Transfusion in Jehovah's Witnesses</u> , Sixth Annual Trauma Nurses' Conference, San Diego, California June 1994	LECTURE
18.	Shock, Emergency Medicine Symposium, San Diego, California August 1994	LECTURE
19.	Abdominal Trauma, Emergency Medicine Symposium, San Diego, California. August 1994	LECTURE
20.	Pelvic and Genitourinary System Trauma, Emergency Medicine Symposium, San Diego, California. August 1994	LECTURE
21.	Chest Trauma, Emergency Medicine Symposium, San Diego, California. August 1994	LECTURE
22.	Chest Trauma, Emergency Medicine Symposium, San Diego, California. December 1994	LECTURE
23.	<u>Ventilating the Unventilatable: Ventilatory Strategy in ARDS</u> , California Trauma Conference, San Diego, California, January 1995	LECTURE
24.	Penetrating Abdominal Trauma, 18th Annual Postgraduate Assembly in Surgery, San Diego, California, February 1995	LECTURE
25.	Shock, Emergency Medicine Symposium, San Diego, California March 1995	LECTURE
26.	<u>Abdominal Trauma</u> , Emergency Medicine Symposium, San Diego, California. March 1995	LECTURE
27.	Pelvic and Genitourinary System Trauma, Emergency Medicine Symposium, San Diego, California. March 1995	LECTURE
28.	Chest Trauma, Emergency Medicine Symposium, San Diego, California. March 1995	LECTURE
29.	<u>Ventilation in Severe ARDS</u> , Surgical Grand Rounds, Naval Medical Center, San Diego, California. March 1995	LECTURE
30.	<u>Triage of the Multiply Injured Patient</u> , 81st Annual Clinical Congress, American College of Surgeons, New Orleans, Louisiana. October 1995	LECTURE
31.	Real Time Spectral Analysis of Heart Rate Variability in the Intensive Care Unit. The Twenty-Ninth Annual Meeting of the Association for Academic Surgery, Ann Arbor, Michigan, November 1995	POSTER
32.	<u>Transient Systolic Hypotension: A Serious Problem In The Management Of Severe Head</u> <u>Injury.</u> Annual Meeting of the Western Surgical Association, Chicago, Illinois, November 1995	ABSTRACT
33.	Shock, Emergency Medicine Symposium, San Diego, California December 1995	LECTURE
34.	<u>Chest Trauma</u> , Emergency Medicine Symposium, San Diego, California. December 1995	LECTURE

35.	<u>Trauma Surgeons and Computer Network Communications</u> , California Trauma Conference, Sacramento, California, January 1996	LECTURE
36.	Surgery in Jehovah's Witnesses, 19th Annual Postgraduate Assembly in Surgery, San Diego, California, February 1996	LECTURE
37.	Shock, Emergency Medicine Symposium, San Diego, California March 1996	LECTURE
38.	Chest Trauma, Emergency Medicine Symposium, San Diego, California. March 1996	LECTURE
39.	<u>Diagnostic Modalities in Blunt Abdominal Trauma</u> . 12 <sup>th</sup> International Congress in Medicine, Instituto Tecnologico y de Estudios Superiores de Monterrey, Monterrey, Nuevo Leon, Mexico. April 1996	LECTURE
40.	<u>Trauma of the Spleen, Pancreas, and Duodenum</u> . 12 <sup>th</sup> International Congress in Medicine, Instituto Tecnologico y de Estudios Superiores de Monterrey, Monterrey, Nuevo Leon, Mexico. April 1996	LECTURE
41.	Surgeons in Cyberspace. Surgical Grand Rounds, UCSD Medical Center, San Diego, California. August 1996	LECTURE
42.	Winchell RJ, Hoyt DB. <u>Analysis of Heart Rate Variability: A Non-Invasive Predictor of Death and Poor Outcome in Severe Head Injury</u> . 56th Annual Meeting of the American Association for the Surgery of Trauma, Houston, Texas, September 1996	POSTER
43.	Winchell RJ, Hoyt DB, Simons RK. <u>Endotracheal Intubation in the Field Improves</u> <u>Survival in Patients with Severe Head Injury</u> . Annual Meeting of the Western Surgical Association, Portland, Oregon, November 1996	ABSTRACT
44.	Priorities in Management, Head vs Abdomen, 82nd Annual Clinical Congress, American College of Surgeons, San Francisco, California. October 1996	LECTURE
45.	Shock, Emergency Medicine Symposium, San Diego, California December 1996	LECTURE
46.	<u>Abdominal Trauma,</u> Emergency Medicine Symposium, San Diego, California December 1996	LECTURE
47.	Pelvic and Gentio-Urinary Injury. Emergency Medicine Symposium, San Diego, California. December 1996	LECTURE
48.	<u>Chest Trauma</u> , Emergency Medicine Symposium, San Diego, California. December 1996	LECTURE
49.	Shock, Emergency Medicine Symposium, San Diego, California. March 1997	LECTURE
50.	<u>Abdominal Trauma,</u> Emergency Medicine Symposium, San Diego, California. March 1997	LECTURE
51.	Pelvic and Gentio-Urinary Injury. Emergency Medicine Symposium, San Diego, California. March 1997	LECTURE
52.	Chest Trauma, Emergency Medicine Symposium, San Diego, California. March 1997	LECTURE

53.	Discussion of abstract titled <u>Impact of a Clinical Pathway for Severe Closed Head Injury</u> on Resource Utilization at 57 <sup>th</sup> Annual Meeting of the American Association for the Surgery of Trauma, Hilton Waikoloa Villiage, Waikoloa, Hawaii, September 1997	INVITED DISCUSSION
54.	Shock, Emergency Medicine Symposium, San Diego, California. December 1997	LECTURE
55.	<u>Abdominal Trauma, Emergency Medicine Symposium, San Diego, California.</u> December 1997	LECTURE
56.	Pelvic and Gentio-Urinary Injury, Emergency Medicine Symposium, San Diego, California., December 1997	LECTURE
57.	<u>Chest Trauma</u> , Emergency Medicine Symposium, San Diego, California. December 1997	LECTURE
58.	Spectral Analysis of Heart Rate Variability in the Intensive Care Unit. Annual Symposium, Society for Critical Care Medicine, San Antonio, Texas, February 1998	LECTURE
59.	Shock, Emergency Medicine Symposium, San Diego, California. March 1998	LECTURE
60.	<u>Abdominal Trauma,</u> Emergency Medicine Symposium, San Diego, California. March 1998	LECTURE
61.	Pelvic and Gentio-Urinary Injury, Emergency Medicine Symposium, San Diego, California. March 1998	LECTURE
62.	Chest Trauma, Emergency Medicine Symposium, San Diego, California. March 1998	LECTURE
63.	Winchell RJ and Hoyt DB. <u>Alterations in Heart Rate Variability are Predictive of</u> <u>Episodes of Altered Cerebral Perfusion in Head Injury</u> . 58th Annual Meeting of the American Association for the Surgery of Trauma, Baltimore, Maryland, September 1998	POSTER
64.	Injuries to the Colon and Rectum. 22nd Annual San Diego Postgraduate Assembly in Surgery, San Diego, California. February 1999	LECTURE
65.	Shock, Emergency Medicine Symposium, San Diego, California. March 1999	LECTURE
66.	<u>Abdominal Trauma,</u> Emergency Medicine Symposium, San Diego, California. March 1999	LECTURE
67.	Pelvic and Gentio-Urinary Injury, Emergency Medicine Symposium, San Diego, California. March 1999	LECTURE
68.	Chest Trauma, Emergency Medicine Symposium, San Diego, California. March 1999	LECTURE
69.	<u>Complex Ventilatory Modalities.</u> Critical Care Summer Session 1999, San Diego, California. August 1999	LECTURE
70.	Winchell RJ, Hoyt DB, Wilson WC, Ying C. <u>Ventilator Management in the Intensive</u> <u>Care Unit: Computerization Can Lead to Improved Care.</u> 59 <sup>th</sup> Annual Meeting of the American Association for the Surgery of Trauma, Boston, Massachusetts September 1999	POSTER

71.	Non-operative Management of Solid Organ Injury: Have We Gone Too Far?, 5nd Annual Meeting of the Southwest Surgical Congress, Colorado Springs, Colorado. April 2000	LECTURE
72.	The History of Trauma Surgery, Tacoma Surgical Society Annual Symposium, Tacoma, Washington. May 2000	LECTURE
73.	Management of Solid Organ Injury, West Region Quality Assurance Forum, Ocean Shores, Washington. September 2000	LECTURE
74.	Blood Transfusion in Jehovah's Witnesses, Surgical Grand Rounds, Maine Medical Center, Portland, Maine, August 2001	LECTURE
75.	New Strategies for Mechanical Ventilation, xxth Annual Spring Symposium, Maine Medical Center, Portland, Maine. April 2002	LECTURE
76.	Management of Solid Organ Injury, Annual Meeting, Maine Chapter, American College of Surgeons, Eastport, Maine. May 2002	LECTURE
77.	<u>Use of Computed Tomography in the Evaluation of Abdominal Trauma</u> , 50 <sup>th</sup> Annual Spring Meeting, Maine Society of Radiologic Technologists, Rockport, Maine, May 2002	LECTURE
78.	Management of Blunt Splenic Injury in Maine: A 20 Year Persepctive, Hartnett K, Winchell RJ, Clark DE, 2002 Annual Meeting of the New England Surgical Society, Dixville Notch, New Hampshire. September 2002	RESIDENT PAPER
79.	<u>Triage of the Mulitply Injured Patient</u> , Annual Meeting, Maine Committee on Trauma, Augusta, Maine, October 2002	LECTURE
80.	Strategies for Mechanical Ventilation of the Surgical Patient: Annual Respiratory Therapy "Mud Season" Conference, Portland, Maine, April 2003	LECTURE
81.	Evolving Strategies in Mechanical Ventilation: Annual Meeting of the Illinois Surgical Society, BoothBay Harbor, Maine September 2003	LECTURE
82.	<u>Difficult Airway Cases.</u> 2004 Emergency Medicine Winter Symposium - Sugarloaf XXII, Sugarloaf, Maine. March 2004	PANEL DISCUSSION
83.	CT in the Evaluation of the Trauma Patient. Surgical Grand Rounds, Maine Medical Center, Portland, Maine, September 2004	LECTURE
84.	Difficult Trauma Cases. 9 <sup>th</sup> Annual New England Regional Trauma Conference, Burlington, Massachusetts, November 2004	SESSION MODERATOR
85.	Discussion of abstract titled <u>Physiologic Exhaustion is Signaled by Reduced Heart Rate</u> Variability & Failure of the Autonomic Nervous System: A Study of 1000 Trauma <u>Patients</u> at 64 <sup>th</sup> Annual Meeting of the American Association for the Surgery of Trauma, Atlanta, Georgia, September 2005	INVITED DISCUSSION
86.	<u>The Mangled Extremity.</u> Trauma Across the Spectrum, Maine Medical Center, Portland, Maine, December 2005	LECTURE

87.	<u>Abdominal Pain.</u> Medical Grand Rounds, Maine Medical Center, Portland, Maine, November 2006	LECTURE
88.	Penetrating Abdominal Trauma. 11 <sup>th</sup> Annual New England Regional Trauma Conference, Burlington, Masschusetts, November 2006	LECTURE
89.	<u>Ventilation in Burn Patients</u> , Session moderator: 30 <sup>th</sup> Northeast Region Burn Conference, Philadelphia, Pennsylvania, October 2007	SESSION MODERATOR
90.	<u>Retroperitoneal Hematomas: When to Explore:</u> Harvard/MGH Critical Care and Trauma Symposium, Boston, Massachusetts November 2007	LECTURE
91.	<u>Trauma Systems:</u> Trauma Across the Spectrum, Maine Medical Center, Portland Maine. November 2007	LECTURE
92.	Trauma Systems. Mid-Coast Regional EMS Conference, Rockland, Maine. November 2008	LECTURE
93.	Pancreatic Injuries. Harvard/MGH Critical Care and Trauma Symposium, Boston, Massachusetts November 2008	LECTURE
94.	Trauma for the Rural Surgeon. American College of Surgeons, 95th Annual Clinical Congress, Chicago, Illinois. October 2009	SESSION MODERATOR
95.	Activated Protein C in Sepsis. Harvard/MGH Critical Care and Trauma Symposium, Boston, Massachusetts November 2009	LECTURE
96.	When to do Tracheostomy. Harvard/MGH Critical Care and Trauma Symposium, Boston, Massachusetts November 2009	LECTURE
97.	Open Pelvic Fracture. Harvard/MGH Critical Care and Trauma Symposium, Boston, Massachusetts November 2010	LECTURE
98.	Initial Evaluation of the Trauma Patient. Xiuning County People's Hospital, Xiuning, Anhui Province, China July 2011	LECTURE
99.	Improving Peri-Operative Care. Xiuning County People's Hospital, Xiuning, Anhui Province, China July 2011	LECTURE
100.	ARDS. Xiuning County People's Hospital, Xiuning, Anhui Province, China July 2011	LECTURE
101.	Evidence and Emminence Harvard/MGH Critical Care and Trauma Symposium, Boston, Massachusetts. November 2011	SESSION MODERATOR
102.	Status of US. Trauma System Development, World Health Organization Violence and Injury Prevention Programme, Geneva, Switzerland, June 2012	INVITED PRESENTATION
103.	Discussion of abstract titled <u>Which Central Venous Catheters Have The Highest Rate Of</u> <u>Catheter Associated Deep Venous Thrombosis: A Prospective Analysis Of 2128 Catheter</u> <u>Days In The Surgical Intensive Care Unit</u> at at 71st Annual Meeting of the American Association for the Surgery of Trauma, Kaui, Hawaii, September 2012	INVITED DISCUSSION

104.	When Not to Trust the Vital Signs. Harvard/MGH Critical Care and Trauma Symposium, Boston, Massachusetts November 2012	LECTURE
105.	Introduction to TQIP. 2012 Annual TQIP Scientific Meeting, Philadelphia, Pennsylvania February 2013	SESSION MODERATOR
106.	Discussion of abstract titled <u>Benchmarking Trauma Centers on Mortality Alone Does not</u> <u>reflect Quality of Care: Implications for P4P</u> at at 72nd Annual Meeting of the American Association for the Surgery of Trauma, San Francisco, California, September 2013	INVITED DISCUSSION
107.	Closing the Abdomen: Primary Closure, Meshes and Patches. Harvard/MGH Critical Care and Trauma Symposium, Boston, Massachusetts November 2013	LECTURE
108.	Tricks to Perform Colostomy in Obese Patients. Harvard/MGH Critical Care and Trauma Symposium, Boston, Massachusetts November 2013	LECTURE
109.	<u>Duodenal Injuries</u> , Visiting Professor, Department of Surgery, University of Texas Health Science Center at Houston, April 2014	LECTURE
110.	<u>Mechanical Ventilation</u> Anesthesiology Grand Rounds, University of Texas Health Science Center at Houston, September 2014	LECTURE
111.	<b>Winchell RJ</b> , Sanddal N, Ball J, Michaels H, Kaufmann CR, Gupta R, Esposito TJ, and Subacius H <u>A Reassessment of the Impact of Trauma Systems Consultation on Regional Trauma System Development</u> Presented at the 73 <sup>rd</sup> Annual Meeting of the American Association for the Surgery of Trauma, Philadelphia, Pennsylvania. September 12, 2014	ABSTRACT
112.	As Good As Dead: What the Heck is Brain Death Anyway? Surgical Grand Rounds, University of Texas Health Science Center at San Antonio, October 2014	LECTURE
113.	<u>Trauma Systems: Lessons Learned in the US</u> Visiting Professor Lecture, Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland, May 2015	LECTURE
114.	International Trauma Registries Invited Presentation, HL7 International Conference, Paris, France, May 2015	LECTURE
115.	Discussion of abstract titled <u>The Impact of a Standardized Prehospital Trauma Triage</u> <u>Protocol in a Rural State</u> at at the 74th Annual Meeting of the American Association for the Surgery of Trauma, Las Vegas, Nevada, September 2015	INVITED DISCUSSION
116.	Discussion of abstract titled <u>Despite Trauma Center Closures, Trauma System</u> <u>Regionalization Reduces Mortality and Time to Definitive Care in Severely Injured Patients</u> at at Scientific Forum, American College of Surgeons Clinical Congress, Chicago, Illinois, September 2015	INVITED DISCUSSION
117.	The History of the Trauma Center Verification Program, Guest Lecture, New York Presbyterian Queens, Queens, New York. October 2015	LECTURE
118.	<u>Trauma System Development: A Historical Perperspective</u> , Grand Rounds, Department of Surgery, Weill Cornell Medicine, New York, New York. November 2015	LECTURE
119.	<u>Trauma Center Verification</u> , Grand Rounds, Department of Surgery, New York Methodist Hospital, Brooklyn, New York. December 2015	LECTURE

120.	Damage Control Resuscitation, Grand Rounds, Department of Anesthesiology, Weill Cornell Medicine, New York, New York. January 2016	LECTURE
121.	Damage Control Resuscitation, Critical Care Grand Rounds, Weill Cornell Medicine, New York, New York. February 2016	LECTURE
122.	<u>Trauma Center Verification and Consultation in Middle and Low Income Countries</u> , Advanced Trauma Life Support (ATLS) Global Symposium, San Diego, California. March 2016	LECTURE/ PANEL
123.	<u>Creating Unity from Diversity</u> , California Trauma Conference, San Francisco, California. June 2016	LECTURE
124.	<u>The Trauma Quality Improvement Process (TQIP)</u> , HCA Trauma Summit, Nashville, Tennessee. August 2016	LECTURE
125.	Performance Improvement, HCA Trauma Summit, Nashville, Tennessee. August 2016	LECTURE
126.	International Trauma Registries, ATLS Region IX Meeting, Mexico City, Mexico, September 2016	LECTURE
127.	Discussion of abstract titled <u>The Trauma Ecosystem: The Economics And Impact Of New</u> <u>Trauma Centers On Existing Centers</u> at at the 75th Annual Meeting of the American Association for the Surgery of Trauma, Waikoloa, Hawaii, September 2016	INVITED DISCUSSION
128.	Achieving Zero Preventable Deaths after Injury, Town hall session, American College of Surgeons Clinical Congress, Washington, DC October 2016	PANEL MODERATOR
129.	<u>Trauma Center Designation in the 20<sup>th</sup> Century</u> , Visiting professor lecture, University of South Florida, Tampa General Hospital, Tampa, Florida October 2016	LECTURE
130.	<u>Trauma Center Designation in the 20<sup>th</sup> Century</u> , Visiting professor lecture, University of Florida Shands Trauma Center, Gainesville, Florida October 2016	LECTURE
131.	<u>Trauma Center Designation in the 20<sup>th</sup> Century</u> , Visiting professor lecture, University of Florida, , Jacksonville, Florida October 2016	LECTURE
132.	<u>As Good As Dead</u> , Visiting professor lecture, University of Miami, Ryder Trauma Center, Miami, Florida October 2016	LECTURE
133.	<u>Trauma Center Designation in the 20<sup>th</sup> Century</u> , Visiting professor lecture, Florida Committee on Trauma Annual Meeting, Orlando, Florida October 2016	LECTURE

- 134. <u>Enlightened Management of Duodenal Injury</u>, Harvard/MGH Critical Care and Trauma LECTURE Symposium, Boston, Massachusetts. November 2016
- 135. <u>Trauma System Development</u>, ATLS Region II Annual Resident Paper Competition, New LECTURE York, New York, December 2016

### OTHER CONTRIBUTIONS:

1.	Winchell RJ: <u>Management of Hepatic Trauma.</u> Audio Digest-General Surgery Volume 40, Number 7, 1993	AUDIO TAPE
2.	Winchell RJ: <u>Risks of HIV Transmission.</u> Audio Digest-General Surgery Volume 40, Number 24, 1993	AUDIO TAPE
3.	Winchell RJ: <u>Ventilating the Unventilatable</u> . Audio Digest-General Surgery Volume 42, Number 6, 1995	AUDIO TAPE
4.	Winchell RJ. <u>Blunt and Penetrating Chest Trauma</u> . Audio Digest-General Surgery Volume 45, Number 16, 1998	AUDIO TAPE
5.	Winchell RJ. <u>Chest Trauma</u> . Audio Digest-Emergency Medicine Volume 15, Number 23, 1998	AUDIO TAPE
6.	Winchell RJ. <u>Lower Trunk Trauma</u> . Audio Digest-Emergency Medicine Volume 16, Number 2, 1999	AUDIO TAPE
7.	Statement on trauma center designation based on system need, (Winchell RJ, primary contributor) Bulletin of the American College of Surgeons 100:1 51-52 2015	ARTICLE
8.	Winchell RJ, Stewart RM, Price M. <u>Committee on Trauma introduces needs</u> <u>assessment tool aimed at resolving trauma center debate</u> . Bulletin of the American College of Surgeons <b>101:9</b> 11-16 2016	ARTCILE
9.	Stewart RM, Jenkins DH, <b>Winchell RJ</b> , and Rotondo, MF. <u>ACS Committee on</u> <u>Trauma pledges to make zero preventable deaths a reality</u> . Bulletin of the American College of Surgeons <b>101:10</b> 23-28 2016	ARTICLE

## David Joseph Ciesla MD, FACS

Professor of Surgery Director, Division Acute Care Surgery Program Director, Surgical Critical Care Residency University of South Florida, College of Medicine Medical Director Regional Trauma Program Tampa General Hospital

1 Tampa General Cir G417 Tampa Florida 33606 dciesla@health.usf.edu Phone: 813-844-7968

#### **Education**

University of Colorado, Boulder, Colorado Bachelor of Arts, Chemistry August 1985-May 1989 Magna cum Laude, Dean's List

University of Colorado, Boulder, Colorado Master of Sciences, Chemistry July 1992-December 1993

University of Colorado Health Sciences Center, Denver Colorado Doctor of Medicine, July 1990-June 1995

University of Colorado Health Sciences Center, Denver Colorado Surgical Internship July 1995-June 1996

National Institutes of Health Sponsored Trauma Research Fellowship Denver Health Medical Center, University of Colorado Health Sciences Center, July 1998-June 2000 Research Advisor: Ernest E. Moore, MD

University of Colorado Health Sciences Center, Denver Colorado General Surgery Residency, July 1996 to June 2002 Chairman: Alden H. Harken, MD

University of Colorado Health Sciences Center, Denver Colorado General Chief Surgery Resident, July 2001 to June 2002 Chairman: Frederick L Grover, MD

University of Colorado Health Sciences Center/Denver Health Medical Center Surgical Critical Care Residency Jan 2003 to Dec 2003 Program Director: Jon M Burch MD

#### **Board Certification**

American Board of Surgery #059255, General Surgery, 02-05-03 Exp: 7-1-23 American Board of Surgery #2098, Surgical Critical Care, 10-18-04 Exp: 7-1-25

#### Medical Licensure

Florida Exp 01-31-16

#### **Additional Training/Courses**

Leadership Development Program, Academic Physician Harvard School of Public Health November 2010 Advanced Trauma Life Support (ATLS ID#278205) Instructor Course: Dec 6, 2005 Boston MA Instructor: Feb 2, 2006 Washington DC Course Director: July 10-11, 2006 Washington DC Course Director: April 19-20, 2007 Washington DC Instructor: Sept 14, 2007 Fairfax VA Course Director: March 15th 2008 Tampa FL Course Director: November 9th 2008 Tampa FL Instructor: February 24, 2011 Tampa FL Instructor: June 21, 2014 Tampa FL Advanced Trauma Operative Management (ATOM) Instructor Course: Dec 1 2006, Baltimore MD Instructor: March 22 2007, Hartford CT Instructor: April 30 2007, Baltimore MD Instructor: August 14 2007, Baltimore MD Instructor: September 20 2007, Hartford CT Instructor: October 16 2007, Baltimore MD Instructor: November 30 2007, Baltimore MD Instructor: May 11-12 2010, Gainesville FL Instructor: Feb 12 2011, Gainesville FL Instructor: Apr 17 2013, Gainesville FL Instructor: May 14 1014, Gainesville FL Instructor: Apr 2015, Tampa FL Instructor: Apr 2016, Tampa FL Advanced Surgical Skills for Exposure in Trauma (ASSET) Instructor: Mar 2011 Tampa FL Hospital Disaster Life Support (HDLS) Provider Course, April 2006 **Disaster Management and Emergency Planning (DMEP)** Course: January 1 2008, Jacksonville FL Instructor: April 29 2008, Daytona FL Instructor: November 21 2008, Tallahassee FL Co-Director: March 21 2008, Tampa FL Instructor: June 5 2009, Okinawa Japan Instructor: February 3, 2011, Tampa, FL Instructor: June 13, 2011, Tampa, FL **Rural Trauma Team Development Course** Instructor: April 17, 2012 Wauchula Fl. Course Director June 4 2014, Sebring FL Course Director July 8 2015, Wauchula FL **Emergency War Surgery** Instructor: Uniformed Services University for the Health Sciences, April 16-18, 2007 Bethesda MD

#### **Hospital Affiliations**

Tampa General Hospital 2 Columbia Dr, Suite G417 Tampa Florida 33606 Active Medical Staff, January 2008 to Present

Washington Hospital Center 110 Irving St NW Washington DC 20010 Active Medical Staff January 2006 to December 2007

Denver Health Medical Center 777 Bannock St Denver CO 80204 Active Medical Staff, July 2002 to January 2006

Vail Valley Medical Center 181 W Meadow Dr # 100 Vail CO 81657 Active Medical Staff, July 2002 to January 2006

#### **Professional Societies**

Present

Fellow, American College of Surgeons 03033131 American Association for the Surgery of Trauma Western Trauma Association Eastern Association for the Surgery of Trauma Tampa Bay Trauma Society (Charter Member) Association for Academic Surgery Surgical Critical Care Program Directors Society Southern Surgical Association Southwestern Surgical Congress Shock Society Society of Critical Care Medicine American Medical Association Florida Medical Association Past Colorado Medical Society Denver Medical Society Denver Academy of Surgery

#### **Present Position**

- " Professor of Surgery, University of South Florida, Tampa Florida, 2013 to present
- <sup>"</sup> Vice Chair for Administration and Finance, Dept of Surgery, University of South Florida College of Medicine, 2013 to present
- Director Division of Acute Care Surgery University of South Florida, College of Medicine, 2008 to present
- Director, Surgical Critical Care Training Program, University of South Florida, College of Medicine, 2009 to Present
- " Medical Director, Tampa General Hospital Regional Trauma Program 2008 to Present

<sup>"</sup> Medical Director Inpatient Med/Surg ward, Tampa General Hospital, 2008 to Present

## Past Positions

- Associate Professor of Surgery, University of South Florida College of Medicine, Tampa Fl, 2008-13
- " Medical Director, Trauma/Surgical Intensive Care Unit, Tampa General Hospital 2009-11
- Director, Trauma Services, Washington Hospital Center, Washington DC, 2006-07
- Program Director, Surgical Critical Care Residency, Washington Hospital Center Washington DC, 2006-07
- Medical Director, 4H surgical Critical Care Unit 4H Washington Hospital Center Washington Hospital Center, Washington DC, 2006-07
- " Associate Professor of Surgery, Georgetown School of Medicine, Washington DC, 2006-07
- Assistant Professor of Surgery, University of Colorado School of Medicine, 2002-05
- Trauma Surgeon, Rocky Mountain Regional Trauma Center at Denver Health Medical Center, 2002-05
- " Chief, Pediatric Trauma, Denver Health Medical Center, 2002-05
- Program Director, Surgical Critical Care Residency, Denver Health Medical Center and University of Colorado School of Medicine, 2005
- Associate Program Director, Surgical Critical Care Residency, Denver Health Medical Center and University of Colorado School of Medicine, 2004-05

## **Certification**

- " Surgical Critical Care Fellowship, University of Colorado Health Sciences Center, Denver, Colorado 2003
- " General Surgery Residency, University of Colorado Health Sciences Center, Denver, Colorado 2002
- " Surgical Internship, University of Colorado Health Sciences Center, Denver, Colorado1996
- " United States Medical Licensing Exam: Steps I, II, and III
- " American Chemical Society Certification, 1989

## **Medical Service**

## Present

University

- <sup>"</sup> Claims Committee, University of South Florida Physicians Practice Group, 2008 to Present *Department*
- Associate Chair for Finance and Administration, University of South Florida Department of Surgery 2014 to present
- " Education Committee, University of South Florida Department of Surgery, 2008 to Present *Professional*
- <sup>"</sup> Vice Chair, American College of Surgeons Florida Committee on Trauma, 2016 to Present
- " American College of Surgeons Florida Committee on Trauma, 2008 to Present
- <sup>"</sup> American Association for the Surgery of Trauma Disease Severity Assessment Committee, 2012 to present
- " Ad Hoc Reviewer, Journal of Trauma, 2007 to Present
- " Ad Hoc Reviewer, Journal of the American College of Surgeons, 2008 to Present
- " Ad Hoc Reviewer, Journal of Orthopedic Trauma, 2008 to Present

## Hospital

Chair, Trauma Program Operational Performance Improvement Committee Tampa General Hospital, 2008 to Present

- " Peer Review Committee, Tampa General Hospital, 2009 to Present
- " Credentials Committee, Tampa General Hospital, 2011 to Present
- " Surgical Suites Committee, Tampa General Hospital 2010-2012, 2014-2016
- " Disaster Planning Committee Tampa General Hospital 2008 to Present Community
- " Honorary Deputy, Hillsborough County Sheriff, 2011 to Present
- " Hillsborough County Trauma Advisory Committee 2008 to Present
- " Hillsborough County Emergency Medical Planning Council, 2008 to Present

### Past

### University

- <sup>w</sup> Financial Oversight Committee, University of South Florida College of Medicine 2013-16
- " Faculty Council, University of South Florida College of Medicine, 2008-10

### Department

- " Search Committee for Director of Division of General Surgery, University of South Florida Department of Surgery, College of Medicine 2008
- " Research Committee, University of South Florida Department of Surgery, 2008-13
- " Steering Committee, University of South Florida Department of Surgery, 2008-14 Professional
- " Section Editor General Surgery, Journal of Orthopedic Trauma, 2008 to 2016
- " American Board of Surgery General Surgery Associate Certifying Examiner, New Orleans LA, 2014
- American Association for the Surgery of Trauma Acute Care Surgery Research Agenda Committee, 2012 to 2014
- American Association for the Surgery of Trauma Disease and Injury Severity Assessment Committee 2012-16
- " Western Trauma Association Program Committee 2013-2015
- " Western Trauma Association Publications Committee, 2007-09, 2011-13
- " Medical Consultant, Florida State Trauma System, 2008-10
- " Editorial Advisory Board, Journal of Hospital Ethics, 2007-10
- Institute of Medicine: Moving Forward in Increasing Organ Donation Opportunities and Barriers to Uncontrolled DCDD in Major Metropolitan Cities. Washington DC, December 20, 2006
- " American College of Surgeons Committee on Trauma, District of Columbia, 2006-08
- <sup>"</sup> Mile-Hi Regional Emergency Medical and Trauma Advisory Council, Denver County 2004-05

Hospital

- " Medical Executive Committee, At large Representative Tampa General Hospital 2012-14
- " Critical Care Steering Committee, Tampa General Hospital, 2008-14
- " Pharmacy and Therapeutics Committee, Tampa General Hospital, 2009-11
- " Electronic Medical Record Steering Committee, Tampa General Hospital 2008-11
- Emergency Preparedness Initiative, Washington Hospital Center, 2006-08
- " Surgical Suites Committee, Tampa General Hospital 2008-13

### Community

- " District of Columbia Continuum of Care Task Force, 2006-08
- " Washington Hospital Center Surgical Improvement Committee 2006-08
- " Denver Health Medical Center Ethics Committee 2003-05

## Honors and Awards

- <sup>"</sup> Merck Index Award for Chemistry, 1989
- Western Medical Student Research Forum, Meritorious Research Award, 1992
- " Student Honor and Research Committee Award UCHSC, 1992
- " Denver Academy of Surgery, Outstanding Promise in the Field of Surgery, 1995
- " Earl C. Young Award, Western Trauma Association Annual Meeting, 2000
- American College of Surgeons Committee on Trauma Resident Competition Region VIII Winner, Basic Science
- " Resident Research Award, Surgical Infection Society Annual Meeting, 2000
- " Young Investigator Travel Award, Shock Society Annual Meeting, 2004

## **Research Funding**

- <sup>\*\*</sup> Undergraduate Research Opportunities Program Grant: The Synthesis of Soluble Bimetallic Compounds for the Study of Carbon-Carbon Bond Forming Reactions Across Metal-Metal Bonds, University of Colorado, Boulder, Colorado, 1988
- <sup>...</sup> NIH Medical Student Research Grant: *Magnetic Resonance Spectroscopy of the Isolated Perfused Kidney*, University of Colorado Health Sciences Center, Denver, Colorado, 1991
- N.I.H. 3 P50GM49222 Trauma Research Center (Co-Investigator, Human Subjects Core, "Trauma Primes Cells") 2001-2005
- " N.I.H. Loan Repayment Program grant: Postinjury Multiple Organ Failure. Denver Health Medical Center and the University of Colorado School of Medicine, Sponsor Ernest E Moore MD, 2003-2005.
- " N.I.H. H133N060028 Department of Education/National Institute on Disability and Rehabilitation Research, National Capital Spinal Cord Injury Model System. Role: Clinical System of Care Division/Acute Care Workgroup
- Takeda TAK-242 A Pivotal, Multicenter, Multinational, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of TAK-242 in Adults with Severe Sepsis (Principal Investigator for Washington Hospital Center, 2006)
- " NovoNordisk Study to Evaluate the Safety and Efficacy of NovoSeven<sup>®</sup> in Adults with Intraparenchymal Hemorrhage from Traumatic Brain Injury (Principal Investigator for Washington Hospital Center, 2006)

### **Invited Reviews and Book Chapters**

- 1. Splenic Trauma, <u>Ciesla DJ</u> and Moore EE, Chapter in Abernathy's Surgical Secrets Ed: Harken AH and Moore EE, Haley and Belfus Inc. Philadelphia, 4<sup>th</sup> Ed. 2000, 5<sup>th</sup> Ed. 2003
- Blunt Abdominal Trauma. <u>Ciesla DJ</u> and Moore EE, Chapter in Abernathy's Surgical Secrets. Ed: Harken AH and Moore EE, Haley and Belfus Inc. Philadelphia, 4<sup>th</sup> Ed. 2000, 5<sup>th</sup> Ed. 2003, 6<sup>th</sup> Ed. 2008.
- 3. Pancreatic and Duodenal Injuries. <u>Ciesla DJ</u>, Burch JM, Chapter in Current Surgical Therapy 8<sup>th</sup> Ed. Ed John L Cameron, Mosby Philadelphia, 2003.
- 4. Postoperative Fever. <u>DJ Ciesla</u> and R Franciose, Chapter in Surgical Decision Making 5<sup>th</sup> Ed. Ed Robert C McIntyre, Saunders Philadelphia, 2003.
- 5. Multiple Organ Failure, <u>Ciesla DJ</u>, Moore FA, Moore EE, Chapter in Trauma 6<sup>th</sup> Ed. Ed Moore, Feliciano, Mattox, McGraw Hill, New York, 2008.
- 6. Fundamental operative approaches in acute care surgery. <u>Ciesla DJ</u>, Moore EE, Chapter in Acute Care Surgery, 1<sup>st</sup> Ed. Ed Britt LD, Springer-Verlag Inc, New York 2008.
- Colon and Rectal Injuries. <u>Ciesla DJ</u>, Burch JM, Chapter in Current Therapy of Trauma and Surgical Critical Care, 1<sup>st</sup> Ed. Ed Asensio JA and Trunkey DD, Mosby-Elsevier, Philadelphia 2008.
- 8. The Management of Rectal Injuries. <u>Ciesla DJ</u>, Cha JY, Chapter in Current Surgical Therapy 11<sup>th</sup> Ed. Ed John L Cameron, Andrew M Cameron, Mosby Philadelphia, 2014.
- Colon and Rectal Injuries. <u>Ciesla DJ</u>, Burch JM, Chapter in Current Therapy of Trauma and Surgical Critical Care, 2<sup>nd</sup> Ed. Ed Asensio JA and Trunkey DD, Mosby-Elsevier, Philadelphia 2015.

## **Invited Presentations**

- 1. The Illinois Surgical Society Fall Meeting Scientific Program, September 2000: Surveillance for Metastatic Colorectal Cancer Following Resection of the Primary Tumor.
- 2. Northern Plains Vascular Surgical Society, January 2002: Blunt Carotid Artery Injuries: Invasive Intervention vs. Observation.
- 3. Surgical Grand Rounds, University of Colorado School of Medicine, November 2002: Post-Injury Multiple Organ Failure.
- 4. Multi-Disciplinary SICU Conference, Denver Health Medical Center, July 2003: Postinjury MOF: How are we Doing?
- 5. Surgical Grand Rounds, University of Colorado School of Medicine, November 2003: Post-Injury Multiple Organ Failure: 10 Years of Study.
- 6. Horizons in Surgery, University of Colorado School of Medicine Breckenridge, Colorado February 29, 2004: What's New in Postinjury Multiple Organ Failure?
- 7. Colorado Plains Medical Center Multidisciplinary Trauma Conference, April 2004: Blunt Abdominal Trauma Management.
- 8. 31<sup>st</sup> Annual Rocky Mountain Trauma and Emergency Medicine Conference Copper Mountain Colorado, July 2004: Multiple Organ Failure in the Critically Injured Patient.
- 9. Surgical Grand Rounds, University of Colorado School of Medicine, August 2004: Initial Evaluation and Management of Thoracic and Abdominal Injuries.

- 10. Oral Surgery Grand Rounds, Denver Health Medical Center, August 2004: Initial Evaluation and Stabilization of the Trauma Patient: Life threatening Problems.
- 11. Surgical Grand Rounds, University of Colorado School of Medicine, September 2004: Training the Future: Trauma and Acute Care Surgery.
- 12. Surgical Grand Rounds, St Joseph's Hospital, January 2005: Trauma and Acute Care Surgery, The Model for Training the Emergency Surgeon.
- 13. Orthopedic Surgery Grand Rounds, University of Colorado School of Medicine, March 2005: Resuscitation of the Multiply Injured Patient.
- 14. Summer Trauma Lecture Series, Memorial Hospital Douglas Wyoming, June 2005: High Risk Injury Patterns.
- 15. Trauma Lecture Series, Valley View Hospital, Glenwood Springs Colorado August 2005: High Risk Injury Patterns.
- 16. Surgical Grand Rounds, University of Colorado School of Medicine, August 2005: Chest and Abdominal Injuries: Initial Evaluation and Management.
- 17. Surgical Grand Rounds, Washington Hospital Center, March 2006: Postinjury Inflammation, the Pathophysiology Underlying Multiple Organ Failure.
- 18. Anesthesia Grand Rounds, Washington Hospital Center, May 2006: Anesthesia Considerations in the Severe Trauma Patient; Resuscitation and Damage Control.
- 19. Surgical Grand Rounds, Washington Hospital Center, August 2006: Trauma Systems and Access to Emergency Medical Care.
- 20. Trauma Institute of San Antonio (TRISAT) San Antonio Texas, September 2006: Trauma Systems and Access to Emergency Medical Care.
- 21. Surgical Grand Rounds, University of South Florida, April 2007: Postinjury MOF, 12 Years of Prospective Study.
- 22. Crossing the Line: Defining the Business of Surgery, Washington DC May 2007: Trauma Centers as Profit Centers.
- 23. 22<sup>nd</sup> Annual Conference for Nursing Professionals, 2007 Spotlight on Critical Care, Springfield VA November 2007: A Practical Approach to Trauma Resuscitation
- 24. Surgical Grand Rounds, University of South Florida, April 2008: The Impact of Triage on Trauma System Resources
- 25. Virginia Commonwealth University Annual Trauma Symposium 2008 Richmond Virginia, April 2008; Special Populations, Special Challenges: Field Triage: As Good as it Gets?
- 26. Florida Society of Critical Care Medicine Annual Symposium August 2008 Marco Island Florida: Triage and its impact on Trauma Systems.
- 27. Radiology Grand Rounds, University of South Florida, November 2008: The primary survey, secondary survey, and imaging in chest and abdominal injury evaluation.
- 28. General Surgery Forum, Copper Mountain Colorado Jan 19-23 2009: Trauma care for the practicing general surgeon, Critical care for the practicing general surgeon
- 29. Tampa Police Department June 1 2010, Trauma Systems and effects of penetrating trauma on human tissue.

- 30. Distance Learning CBBW Sao Paulo Brazil Oct 19 2010, Introduction to trauma: Global burden of disease, early traumatic deaths, and hemorrhage control.
- 31. American Society of Abdominal Surgeons Annual Meeting, Nov 7, 2010 Tampa Florida: Trauma to the liver, biliary tree, pancreas and spleen.
- 32. American Society of Abdominal Surgeons Annual Meeting, Nov 7, 2010 Tampa Florida: Mass casualty care.
- 33. American Association for the Surgery of Trauma Annual Meeting September 14, 2011 Chicago IL: Blunt Abdominal Catastrophes. Ciesla DJ, Croce MA
- 34. American College of Surgeons Clinical Congress October 6-10, 2013 Washington DC: Panel Session: Help I Can't Close the Abdomen.
- Austin Trauma and Critical Care Conference 2<sup>nd</sup> annual meeting, May 29-30, 2014 Austin Texas: What Scans Should I Order? Practical CT Algorithms in Trauma: CT Angiogram of the Neck.
- Austin Trauma and Critical Care Conference 2<sup>nd</sup> annual meeting, May 29-30, 2014 Austin Texas: CSF Leaks in Head Trauma.
- 37. Surgical Grand Rounds, University of South Florida, November 2014: Operative treatment of Rib Fractures
- 38. Surgical Grand Rounds, University of South Florida, October 2015: Endovascular control of hemorrhage and measuring hemorrhage induced coagulopathy
- 39. 10<sup>th</sup> Annual Tampa General Hospital Trauma Symposium, November 2015: Evolution of the Florida Trauma System.

#### **Scientific Abstracts and Presentations**

- <u>DJ Ciesla</u>, JJA Huntley RB Hutchinson JI Shapiro. <sup>23</sup>Na Nuclear Magnetic Resonance Studies of Red Blood Cell from Chronic Hemodialysis Patients: Implication for Systemic Sodium Metabolism. (Presented at the *Western Medical Research Conference Annual Meeting*, Carmel, California, February 1992)
- <u>DJ Ciesla</u>, N Ku, RC. McIntyre Jr, SW Subber, N Pearlman, DA Kumpe. Provocative Angiography Seldom Adds to the Management of Occult GI Bleeding (Presented at the *Southwestern Surgical Congress Annual Meeting*, San Antonio, Texas, April 1998)
- 3. <u>DJ Ciesla</u>, EE Moore, G Zallen, CC Silliman. Hypertonic Saline Reversibly Attenuates Human PMN O<sub>2</sub>- Production via a Tyrosine Kinase Pathway (Presented at the *Society of University Surgeons Annual Meeting; Residents Section*, New Orleans, Louisiana, February 1999)
- 4. CH Selzman, <u>DJ Ciesla</u>, RC McIntyre, N Pearlman. The Postman Always Rings Twice: Lessons learned from Pelvic Exenteration (Presented at the *Western Trauma Association Annual Meeting*, Crested Butte, Colorado, March 1999)
- <u>DJ Ciesla</u>, EE Moore, G Zallen, WL Biffl, CC Silliman. Lipid Priming for PMN Elastase Release Requires p38 MAPK (Presented at *Shock Society Annual Meeting*, Philadelphia, Pennsylvania, June 1999)
- <u>DJ Ciesla</u>, EE Moore, G Zallen, WL Biffl, DJ Elzi, CC Silliman. Hypertonic Saline Attenuation of PMN Cytotoxic Function is Reversed Upon Return to Normotonicity (Presented at the 85<sup>th</sup> Annual Clinical Congress of the American College of Surgeons, San Francisco, California, October, 1999)

- 7. <u>DJ Ciesla</u>, EE Moore, G Zallen, CC Silliman. Hypertonic Saline Attenuation of PMN Cytotoxicity: Timing is Everything. (Presented at the *American Association for the Surgery of Trauma Annual Meeting*, Boston, Massachusetts, September 1999)
- 8. <u>DJ Ciesla</u>, EE Moore, WL Biffl, RJ Gonzalez, HB Moore, CC Silliman. Hypertonic Saline Activation of p38 MAPK Primes the PMN Respiratory Burst, (Presented at the *Association for Academic Surgery Annual Meeting*, Philadelphia Pennsylvania, November 1999)
- <u>DJ Ciesla</u>, PJ Offner, EE Moore, WL Biffl, JB Haenel, G Zallen, Steroid Rescue of Late ARDS Patients Decreases PMN Cytotoxicity and Cytokine Production. (Presented at the *Western Trauma Association Annual Meeting,* Earl C. Young Award for Resident Research Paper, Squaw Valley, California, March 2000)
- <u>DJ Ciesla</u>, EE Moore, RJ Musters, RJ Gonzalez, J Aiboshi, WL Biffl, CC Silliman Hypertonic Saline Inhibits Neutrophil Cytotoxic Function by Attenuating Intracellular Signal Transduction: Role of the Actin Cytoskeleton and p38 MAPK. (Presented at the *American College of Surgeons Committee on Trauma Annual Meeting* Resident Research Competition, Reno, Nevada, March 2000)
- <u>DJ Ciesla</u>, EE Moore, RJ Gonzalez, Walter L Biffl, CC Silliman, Hypertonic Saline Inhibits Neutrophil (PMN) Priming via Attenuation of p38 MAPK Signaling. (Presented at *the Surgical Infection Society Annual Meeting*, Providence, Rhode Island, April 2000)
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AMERICAN COLLEGE OF SURGEONS COMMITTEE ON TRAUMA Trauma Systems Evaluation and Planning Committee

# Trauma System Consultation Report

**State of Florida** 

Tallahassee, FL February 2-5, 2013



AMERICAN COLLEGE OF SURGEONS Inspiring Quality: Highest Standards, Better Outcomes A multidisciplinary working group prepared this document based on the consultation visit that took place February 2-5, 2013 in the State of Florida and included the following members:

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# **Executive Summary**

# **Overview**

Florida has been a leader in the development of trauma systems since the early 1980's. Through the cooperative efforts of a broad group of stakeholders and an engaged state government, Florida has enacted some of the most comprehensive legislation, provided for substantial ongoing funding, and established a network of trauma centers that provide coverage for the majority of the population, while delivering good outcomes as measured against national benchmarks. Over the past two years the Department of Health (DOH) and trauma system stakeholders have been embroiled in a contentious legal battle regarding the rules that govern the designation of new trauma centers. As a result, the policy development and planning necessary for ongoing trauma system development have come to a halt. At present, relationships between hospitals and stakeholders are strained to the breaking point. The controversy around trauma center distribution has resulted in the neglect of nearly all other important trauma system elements.

Although the conflict may be particularly intense in Florida, its nature and potential to consume the attention of trauma system stakeholders is far from unique. Several other states and urban areas struggle with similar challenges regarding trauma center distribution. All of these challenges share a common theme - while a clear and undisputed need for additional trauma centers exists in much of the country, oversupply is common in metropolitan areas. In areas with a potential oversupply of trauma centers, the determination of need for a new trauma center is frequently contentious and is further compounded by a lack of objective standards that would enable a clear data-driven decision. As in Florida, trauma centers in metropolitan areas compete for patient volume. Established trauma centers often resist the addition of new centers, arguing that dilution of patient volumes will be detrimental. Trauma centers seeking to enter the trauma system counter with benefits such as improving access to potentially underserved areas, shortening transport times, and easing overcrowding in existing trauma centers. All ultimately agree that trauma centers should be designated primarily to serve the needs of the population, but each group interprets need in a way that supports their position.

A long standing tenet of trauma system design is that the system's lead agency must have the ability to limit the number and level of trauma centers, and that decisions regarding trauma center distribution should be based upon the needs of the population served. Unfortunately, no consensus exists regarding what metrics should be used to determine need, and population-based data rarely exist for an objective analysis to set appropriate benchmarks. However, a set of choices for determining the nature of the trauma system and the trade-offs inherent in these choices can be outlined.

The optimal balance between these choices and trade-offs will not yield a single universal solution, but will depend upon uniquely local factors, including geography, resource availability, and regional social elements. In the end, the decision is inherently political rather than purely scientific. For that reason, it is a decision that few regions have been able to execute successfully. Appendix D outlines a set of parameters that have been used to measure need and the benchmarks used in different regions to guide trauma center designation.

It is noteworthy that the concept of designation based upon need is clearly embodied within the Florida statute. This statute establishes criteria for the needs assessment, places an absolute ceiling on the number of trauma centers in the state, and lays out a general regional plan for the placement those centers based upon need (as assessed circa 1990). The difficulty associated with the ongoing political process of needs assessment is equally well exemplified by the DOH's inability to complete the periodic needs assessments mandated in statute, a failure that ultimately underlies the current legal challenges.

The competition between existing trauma centers for patient volume is further amplified by the manner in which the state funds for trauma care, derived from traffic fines, are distributed. The current rule allocates funds between existing trauma centers with a formula based upon patient volume and injury severity. Unfortunately, the threshold value for severity represents relatively minor injury. This distribution scheme creates an environment in which the addition of a new trauma center decreases the share received by every other trauma center (e.g., the funds are divided among more trauma centers and patient volume is redistributed). Existing trauma centers have a clear financial incentive to keep new hospitals out of the pool for trauma funding, and an incentive to compete with one another for patients. Both factors may run counter to the true needs of the patients served.

It is the opinion of the trauma system consultation (TSC) team that the solution to the current conflict around trauma center designation must be solved by a collaborative process, involving all stakeholders and the DOH. The collaborative effort should focus on the universally accepted concept of trauma center designation based upon system need and optimal patient care. The stakeholder group, along with the DOH and perhaps the people of Florida speaking through the legislature, must arrive at a process for the needs assessment that is transparent and acceptable to all. Next, a definitive and transparent process of governance must be established to make decisions about the designation of new trauma centers and re-designation of existing trauma centers based upon that assessment. Given the lack of both current data and an accepted process for decision making, the TSC team also recommends a moratorium on new trauma center designations, either provisional or verified, until the new process is in place.

Despite the tendency to focus on trauma centers, especially in times of controversy, a trauma system is much more than a collection of trauma centers. The trauma center distribution issue is not the biggest challenge to the optimal provision of trauma care in Florida. While the distribution of trauma centers is important, it must not be allowed to paralyze all other aspects of trauma system function and development.

Though the current statute correctly defines and seeks to establish an inclusive trauma system, on an operational basis the trauma system functions much more along the older exclusive model rather than embracing an inclusive approach. For example, most of the state's acute care facilities do not participate in the trauma system, and the statutory mandate for all hospitals to submit a minimum data set on injury patients is not enforced. No standards exist for inter-facility transfer and its evaluation, and patient flow at the EMS level is not adequately controlled. The principle of including all hospitals in the trauma system has been misinterpreted as a directive to create more high-level trauma centers, or to allow individual hospitals to participate at a level of their choice. The tenets of the inclusive system model require that all hospitals participate in a defined way. This does not mean that the hospital is free to choose its own level of participation, independent of need within the trauma system. The appropriate number and location of higher-level trauma centers is independent of the existence of an inclusive system. Most facilities within the trauma system will be focused on the appropriate triage and transfer of severely injury patients to the higher-level trauma centers while providing definitive care for the less severely injured locally, depending upon facility resources. The TSC team recommends that the vision of an inclusive trauma system be revived, renewed, and implemented. This broad recommendation has been embodied through the many recommendations that target the various functional and institutional elements of the Florida state trauma system.

# **Advantages and Assets**

The long history of dedicated participation in Florida's trauma system development is a significant advantage and asset. This is noted on various levels, including hospitals, stakeholder leadership in the trauma community, and the many dedicated providers involved in the trauma system in all capacities. This effort has been in synergy with long-standing public support expressed through legislative action by state government. This synergy has produced strong enabling legislation, substantial funding, and the establishment of the current trauma system. The success of the system can be measured by the provision of trauma care within a Level I or II trauma center within 60 minutes to 97% of Florida's population and 80% of its land area. The national average is 82% of population and 29% of land area. The state faces no major geographical challenges and has few isolated rural areas.

Florida is fortunate to have a wealth of expertise and experience within its wellestablished trauma centers. These academic trauma centers have a long history of research in trauma care and trauma systems, a history of national leadership, and a demonstrated commitment to data-driven solutions. These academic trauma centers have a legacy of training trauma care providers and providing many of the human resources and much of the social capital that drive the current trauma system. In addition to these academic trauma centers, the state is fortunate to have a significant number of well-organized health care facilities with the commitment, resources, and willingness to seek new trauma center designation. The willingness of new trauma centers to join the ranks of existing centers to create a more comprehensive regional trauma system is an important asset that can ultimately result in a stronger system of injury care for the state's population and visitors.

The commitment of the DOH leadership to the ongoing development and improvement of the current trauma system is another important asset. The DOH has undergone major structural reorganization, which will strengthen the efforts toward improved integration of the various trauma system components. Florida has a strong and welltested disaster response system, a system that is well positioned to form the regional infrastructure for a more comprehensive trauma system. The well-established programs for the collection and analysis of injury data are available to inform trauma system planning and to support the several strong injury prevention programs. Florida has a trauma plan, one that has been updated and distributed on a regular basis, most recently in 2011. Unfortunately, the plan does not address the most pressing issues facing the Florida trauma system

Florida also has a very organized and well established network for rehabilitation services that has historically targeted traumatic brain injury and spinal cord injury. This infrastructure can provide the basis for a more extensive rehabilitation network to serve other injury populations, as well.

# **Challenges and Opportunities**

The most striking challenge to the progress and ultimate success of the Florida trauma system is the adversarial relationship that has developed between factions in the previously cooperative stakeholder community. The conflict over trauma center distribution has resulted in deep divisions within the community of trauma advocates and providers and has stalled all aspects of system development. The conflict and the almost exclusive focus on issues surrounding trauma center designation have the potential to endanger the larger collective mission.

The vision for Florida's state trauma system growth and development is outdated, having been carried forward almost unchanged since the early 1990's. Although this vision was ahead of its time when created, the structure of Florida's trauma system has failed to adapt to changing times and improved models of trauma system design. An incomplete understanding and application of the principles underlying an inclusive trauma care system exists. This outdated vision has perpetuated an outdated advisory board structure that no longer represents the current stakeholder community. Truly inclusive stakeholder involvement is lacking, especially for those stakeholders not associated with the existing Level I and II trauma centers. Further, the regional structure described in the original statute and subsequent plan was never fully implemented, potentially due to a lack of resources to support the planned regional trauma agencies. As a result, much of the state has inadequate regional integration.

Although the Florida state trauma plan is well thought out, and regularly updated, it does not adequately address the most complex and difficult issues that arise within the course of trauma system planning. The planning process has been unable to establish a

broadly accepted vision for the future development of Florida's trauma system, especially in regard to balancing system needs, financial incentives, and free-market principles that are related to trauma center designation. The inability of the planning process to address these issues has contributed to the ongoing reliance on the outdated trauma system vision that is at the heart of the litigation dominating the attention of the stakeholders. The trauma system plan has not adequately addressed the metrics and the process for necessary periodic trauma system needs assessment, and it has no systematic process for the designation of trauma centers based upon those needs. Inadequate central coordination of patient flow exists, either from the field to the trauma center or between hospitals within the state trauma system. Even though current statute mandates that all acute care facilities submit data on injured patients, no rules for this mandate have been written. The state trauma program has access to hospital discharge data and the expertise to analyze that data to provide a populationbased assessment of injury; however, these resources have been underutilized. As a result, the trauma system does not optimize the use of available data and has not established the infrastructure and processes necessary to monitor system performance.

Florida's trauma system is fortunate to have significant public funding, but these funds are not utilized in a way that optimizes their impact. The current distribution model divides the available funds among the designated trauma centers and apportions the funds by a formula based on volume and the estimated severity of injury. This distribution model creates adverse incentives that place the interests of an individual trauma center in competition with the needs of the trauma system, and thus it does not support balanced system development. Existing trauma centers have clear financial incentives to compete for patient volume and to keep new centers out of the funding pool. These incentives may run counter to the best interests of the state trauma system and of the population that it serves.

# **General Themes**

Find a negotiated solution to the current conflict and re-unify the stakeholder community. The stakeholders have a clear collective commitment to the goal of providing the best care possible to Florida's injured patients. Use this shared commitment to provide the common ground upon which to build a collaborative solution that will benefit injured patients and the allow Florida to build upon the existing successes of its trauma system.

A clear vision and plan accepted by all stakeholders is the necessary foundation for Florida's future trauma system development. This plan should encompass all aspects of system function, specifically including needs assessment, trauma center distribution, EMS operations, system-wide performance improvement, rehabilitation, injury epidemiology, and injury prevention.

The DOH must have unambiguous support from the broad stakeholder community to assume an active role as the lead agency, supported by consistent and uncontested statutory and regulatory authority.

The advisory committee structure must be reconfigured to reflect broader multidisciplinary stakeholder participation and to be representative of the current trauma system composition. The advisory committee structure must be established and accepted as the balanced policy development body responsible for overall system policy and planning.

The current system vision and structure are out of date and should be updated to reflect the principles of an inclusive and comprehensive trauma system design. It is essential to recognize that a trauma system be more than a collection of individual trauma centers, and that an inclusive system is not an unregulated system.

Trauma center designation should be based upon system need, and consistent and objective data should be used in a transparent process to determine that need.

A strong regional infrastructure is needed to adapt statewide policy and procedures to reflect unique local circumstances and to meet local needs.

Florida's trauma system provides good care to its injured citizens, and its development is ahead of many comparable states, yet many aspects of the trauma system can be improved and must be updated. The great wealth and breadth of experience, talent, and resources that exist among the stakeholders can be used to improve Florida's trauma system and drive it to a higher level of function.

Much work is needed. Change is often painful, but stagnation and an inability to adapt are unnecessarily costly on all levels.

# **Priority Recommendations**

# Statutory Authority

- Convene a small <u>multidisciplinary</u> work group to analyze all existing statutes and regulations pertaining to the trauma system, including, methodology for needs assessment, process for trauma center designation based on system needs, and control of patient flow (field triage criteria/destination protocols).
  - Review legislation from other states
  - Achieve consensus on the necessary statutory or administrative code changes

# System Leadership

- Appoint a new Florida Trauma System Advisory Council (FTSAC) to provide input to policy development for the trauma system.
  - Include both trauma center and non-participating hospitals.

# Lead Agency and Human Resources within the Lead Agency

- Establish and fund a statewide performance improvement coordinator position to lead the development of a statewide performance improvement process.
- Contract for the state trauma medical director position and provide compensation for his/her time.

# Trauma System Plan

• Revise immediately the Florida trauma system plan to address key issues necessary for the further development of the regional and statewide trauma system.

## System Integration

- Use the Regional Domestic Security Task Force Regions (RDSTFR) as the TSA regions.
  - Develop a strong regional structure based on the 7 RDSTFR that enables the integration of trauma centers with EMS, disaster preparedness, and other regional activities.

# Financing

- Revise the distribution method of the trauma center fund.
  - Change the statutes and rules governing the fund to ensure that designated trauma centers receive level-appropriate support for the "cost of readiness".
  - Develop a formula for distribution of funds that focuses on specific deliverables by trauma center level rather than volume and acuity.
  - Include a mechanism to support trauma rehabilitation services (e.g., establish in rule and/or direct trauma centers to use some of their funds to "buy" beds in rehabilitation centers).
  - Revisit the allocation method/ formula on a regular basis (every 3-5 years)

## **Emergency Medical Services**

• Collaborate with the Florida Department of Transportation Governor's Highway Safety Program to initiate and conduct a National Highway Traffic Safety Administration EMS System Reassessment.

# **Definitive Care**

- Conduct an assessment of the current system, including the parameters outlined in Florida statute 395.402, to inform decisions regarding the location and level of new trauma center designations.
- Establish a transparent, broadly accepted process for future provisional trauma center designation based upon both capacity and trauma system need.
  - Work with stakeholder advisory groups to establish criteria for need
  - o Utilize findings from newly conducted needs assessment.
- Establish a transparent, broadly accepted process for initial full designation and ongoing re-designation based upon system participation, center performance, and participation in quality improvement programs.
  - Work with Florida Trauma System Advisory Committee (FTSAC) to establish criteria for initial and ongoing designation
- Impose a moratorium on any new provisional or verified trauma center designation until these new processes are in place.
- Require that all acute care facilities participate in the inclusive and integrated trauma system as a condition of licensure.
  - Designate each acute care facility at an appropriate level, either as a trauma center or a participating facility
  - Require all facilities to submit at least a minimal set of data on every injured patient to the state registry.

# System Coordination and Patient Flow

- Evaluate the content, implementation, and method of enforcement of trauma transport protocols (TTPs) to assure uniformity and efficiency of patient flow both within trauma regions as well as statewide.
- Task the Trauma Program with annual reporting on trauma center and non-trauma center destination and patient outcomes (initial destination and transfer).
  - Correct identified deficiencies in trauma system coordination and patient flow using structured processes identified by the Trauma Program.

# Disaster Preparedness

- Develop the healthcare coalitions and align with the seven Regional Domestic Security Task Force Regions.
  - Ensure that the disaster medical response plans are integrated through regional planning between members of the healthcare coalition (hospitals, EMS, fire, public health, dispatch, emergency management and law enforcement).

# System-wide Evaluation and Quality Assurance

- Reactivate the state Performance Improvement Committee as a subcommittee of the Florida Trauma System Advisory Council (FTSAC) to develop a statewide performance improvement (PI) plan.
  - Ensure that the PI plan outlines the PI process at the provider, regional, and state levels and includes process, structure and outcome measures.
  - Review PI plan templates from other states to guide development of the Florida PI plan.
  - Ensure that the PI plan includes all aspects of trauma care and trauma system performance.
  - Use data from all continuum-of-care participants including trauma centers, nontrauma hospitals, rehabilitation centers, EMS providers and dispatch for system evaluation.
  - Include population-based data.

# Trauma Management Information System

- Complete the implementation of the Next Generation trauma registry.
  - Ensure participation by all hospitals.

# **Purpose and Rationale**

Injury epidemiology is concerned with the evaluation of the frequency, rates, and pattern of injury events in a population. Injury pattern refers to the occurrence of injury-related events by time, place, and personal characteristics (for example, demographic factors such as age, race, and sex) and behavior and environmental exposures, and, thus, it provides a relatively simple form of risk- factor assessment.

The descriptive epidemiology of injury among the whole jurisdictional population (geographic area served) within a trauma system should be studied and reported. Injury epidemiology provides the data for public health action and becomes an important link between injury prevention and control and trauma system design and development. Within the trauma system, injury epidemiology has an integral role in describing the root causes of injury and identifying patterns of injury so that public health policy and programs can be implemented. Knowledge of a region's injury epidemiology enables the identification of priorities for directing better allocation of resources, the nature and distribution of injury prevention activities, financing of the system, and health policy initiatives.

The epidemiology of injury is obtained by analyzing data from multiple sources. These sources might include vital statistics, hospital administrative discharge databases, and data from emergency medical services (EMS), emergency departments (EDs), and trauma registries. Motor-vehicle crash data might also prove useful, as would data from the criminal justice system focusing on interpersonal conflict. It is important to assess the burden of injury across specific population groups (for example, children, elderly people and ethnic groups) to ensure that specific needs or risk factors are identified. It is critical to assess rates of injury appropriately and, thus, to identify the appropriate denominator (for example, admissions per 100,000 population). Without such a measure, it becomes difficult to provide valid comparisons across geographic regions and over time.

To establish injury policy and develop an injury prevention and control plan, the trauma system, in conjunction with the state or regional epidemiologist, should complete a risk assessment and gap analysis using all available data. These data allow for an assessment of the "injury health" of the population (community, state, or region) and will allow for the assessment of whether injury prevention programs are available, accessible, effective, and efficient.

An ongoing part of injury epidemiology is public health surveillance. In the case of injury surveillance, the trauma system provides routine and systematic data collection and, along with its partners in public health, uses the data to complete injury analysis, interpretation, and dissemination of the injury information. Public health officials and trauma leaders should use injury surveillance data to describe and monitor injury events

and emerging injury trends in their jurisdictions; to identify emerging threats that will call for a reassessment of priorities and/or reallocation of resources; and to assist in the planning, implementation, and evaluation of public health interventions and programs.

# **Optimal Elements**

I. There is a thorough description of the epidemiology of injury in the system jurisdiction using population-based data and clinical databases. **(B-101)** 

- a. There is a through description of the epidemiology of injury mortality in the system jurisdiction using population-based data. **(I-101.1)**
- b. There is a description of injuries within the trauma system jurisdiction, including the distribution by geographic area, high-risk populations (pediatric, elderly, distinct cultural/ethnic, rural, and others), incidence, prevalence, mechanism, manner, intent, mortality, contributing factors, determinants, morbidity, injury severity (including death), and patient distribution using any or all the following: vital statistics, ED data, EMS data, hospital discharge data, state police data (data from law enforcement agencies), medical examiner data, trauma registry, and other data sources. The description is updated at regular intervals. (I-101.2) *Note:* Injury severity should be determined through the consistent and system-wide application of one of the existing injury scoring methods, for example, Injury Severity Score (ISS).
- c. There is comparison of injury mortality using local, regional, statewide, and national data. **(I-101.3)**
- d. Collaboration exists among EMS, public health officials, and trauma system leaders to complete injury risk assessments. **(I-101.4)**
- e. The trauma system works with EMS and public health agencies to identify special at-risk populations. **(I-101.7)**

II. Collected data are used to evaluate system performance and to develop public policy. **(B-205)** 

a. Injury prevention programs use trauma management information system data to develop intervention strategies. **(I-205.4)** 

III. The trauma, public health, and emergency preparedness systems are closely linked. **(B-208)** 

a. The trauma system and the public health system have established linkages, including programs with an emphasis on population based public health surveillance and evaluation for acute and chronic traumatic injury and injury prevention. **(I-208.1)** 

IV. The jurisdictional lead agency, in cooperation with the other agencies and organizations, uses analytic tools to monitor the performance of population based prevention and trauma care services. **(B-304)** 

- a. The lead agency, along with partner organizations, prepares annual reports on the status on injury prevention and trauma care in the state, regional, or local areas. (I-304.1)
- b. The trauma system management information system database is available for routine public health surveillance. There is concurrent access to the databases (ED, trauma, prehospital, medical examiner, and public health epidemiology) for the purpose of routine surveillance and monitoring of health status that occurs regularly and is a shared responsibility. (I-304.2)

# **Current Status**

The description of injuries for Florida using population-based data resources was published in the 2009 – 2013 Injury Prevention Strategic Plan. Vital statistics, emergency department, and hospital discharge datasets were used. A description of injuries by age group, mechanism, fatality, and intent has been updated and published on the Injury Prevention Program website. Clinical data from the trauma registry were not used to enhance the description of injury in this plan. The trauma program has access to other datasets, such as motor vehicle crash records, the child death review program, emergency medical services reports, and law enforcement reports, however, no reports using these data were provided for review. The trauma program annual report describes the injuries treated in the trauma centers, but it does not integrate data from the other population datasets.

The Injury Prevention Program has published on its website fact sheets that address specific mechanisms of injury and related economic information. These fact sheets were last updated using 2009 data, but it was stated that plans exist to update these fact sheets soon. Tables describing injuries in Florida using 2011 data were provided to the trauma system consultation (TSC) team. The website has multiple reports that describe specific mechanisms of injuries from the emergency department and hospital discharge databases. A more detailed analysis of injury using resources from data linkage with other data sets, e.g., motor vehicle crash data, Geographic Information System (GIS) mapping, and International Classification of Disease-9 Injury Severity Score (ICISS) mapping to describe injuries by injury severity are not available.

The Bureau of Emergency Medical Oversight (BEMO) recently formed the Health Information and Policy Analysis Program. Within that program, a dedicated epidemiologist is available for injury epidemiology, EMS, and the trauma program. A statistician is to be hired to support the effort. The epidemiologist responds to special requests for injury data from EMS agencies, hospitals, and injury prevention advocates.

The epidemiologist has identified additional education needed to specialize in injury data and to perform data linkage, such as ICISS, GIS mapping, and probabilistic data linkage. Such training will enhance the quality and depth of injury data analysis to support trauma system program needs assessment, planning, and evaluation. Once the "next generation" trauma registry is functional, the epidemiologist should participate with the performance improvement (PI) committee to learn about the specific PI indicators of

interest and to assist with the selection of variables that will be helpful for tracking regional and statewide trauma system performance. The new Health Information and Policy Analysis Program should be an excellent resource for the trauma program, as well as the Injury Prevention Program, Emergency Medical Services (EMS), and the Traumatic Brain and Spinal Cord Injury Program.

The state has several strategic plans that focus on injury issues: the 2009-2013 Injury *Prevention Strategic Plan*, the *Suicide Prevention Strategy*, and *Enhancing the Traumatic Brain Injury System of Care Action Plan*. Opportunities exist to more fully describe the impact of injury from all mechanisms in Florida to elected officials, health professionals, and advocates within the state.

# Recommendations

- Ensure that the epidemiologist has access to advanced training in probabilistic data linkage, International Classification of Disease-9 Injury severity score (ICISS), and Geographic Information System (GIS) mapping to enhance skills in injury epidemiology.
- Update the injury fact sheets on an annual basis to inform the public about the injury problem in Florida.
- Develop a template for an annual or biennial report describing injuries in Florida using both population-based and clinical databases that can be used for the trauma system needs assessment.
  - Produce the report at regular intervals and disseminate it to the public, elected officials, the Florida Trauma System Advisory Council, and all trauma system stakeholders.
- Integrate the injury prevention strategic planning and annual reports between the state injury, trauma, and EMS programs.

# **Purpose and Rationale**

In the absence of validated national benchmarks, or norms, the benchmarks, indicators and scoring (BIS) process included in the Health Resources and Services Administration's *Model Trauma System Planning and Evaluation* document provides a tool for each trauma system to define its system-specific health status benchmarks and performance indicators and to use a variety of community health and public health interventions to improve the community's health status. The tool also addresses reducing the burden of injury as a community-wide public health problem, not strictly as a trauma patient care issue.

This BIS tool provides the instrument and process for a relatively objective state and substate (regional) trauma system self-assessment. The BIS process allows for the use of state, regional, and local data and assets to drive consensus responses to the BIS. It is essential that the BIS process be completed by a multidisciplinary stakeholder group, most often the equivalent of a state trauma advisory committee. The BIS process can help focus the discussion on various system strengths and weaknesses, can be used to set goals or benchmarks, and provides the opportunity to target often limited resources and energies to the areas identified as most critical during the consensus process. The BIS process is useful to develop a snapshot of any given system at a moment in time. However, its true usefulness is in repeated assessments that reveal progress toward achieving various benchmarks identified in the previous application of the BIS. This process further permits the trauma system to refine goals to be attained before future reassessments using the tool.

# **Optimal Element**

I. Assurance to constituents that services necessary to achieve agreed-on goals are provided by encouraging actions of others (public or private), requiring action through regulation, or providing services directly. **(B-300)** 

# **Current Status**

A Benchmarks, Indicators and Scoring (BIS) assessment from the 2006 Health Resources and Services Administration (HRSA) *Model Trauma System Evaluation and Planning* document was conducted in 2005. Indicator scores were included in the January 25, 2006 meeting summary of the State Trauma System Plan Implementation Committee Meeting minutes. None of the participants recalled participating in the process, so no information about how the assessment was conducted was available. Trauma system deficiencies identified using this assessment as reported in the Pre-Review Questionnaire (PRQ) included data integration, injury prevention, and the continuum of care. The BIS assessment can be a valuable process when stakeholders representing all aspects or pillars of the trauma system are engaged. It may be educational in raising awareness and understanding about aspects of the trauma system that are less well understood by some stakeholders. Optimally the assessment is completed separately by each individual, and then data are summarized, rather than reviewing each indicator as a group. The process enables the trauma system leadership (e.g. the proposed Florida Trauma System Advisory Council [FTSAC]) to become informed about the current status of the trauma system and aspects of the trauma system that need attention for development. When summary scores are reviewed with all stakeholders in a facilitated process, consensus building regarding priorities for trauma system development can be achieved. Such a process engages multiple stakeholders and provides direction for strategic planning. Repeating the BIS assessment process with stakeholders at regular intervals provides a quantifiable measure of progress in trauma system development.

When the process for development of the next trauma system plan is initiated, the Florida trauma program should consider using the HRSA BIS assessment to collect data about the trauma system status and to establish priorities for trauma system development in the plan. The use of the BIS assessment every 5 years when a new plan is developed is one method to quantify progress in trauma system development.

## Recommendations

- Assemble a multidisciplinary group of stakeholders to conduct a trauma system assessment using the national Health Resources and Services Administration (HRSA) trauma system assessment process in preparation for planning the next Five Year Strategic Plan for the trauma program.
- Perform repeat HRSA trauma system assessments at regular intervals to document progress in addressing priorities for trauma system development.

Reducing morbidity and mortality due to injury is the measure of success of a trauma system. A key element to this success is having the legal authority necessary to improve and enhance care of injured people through comprehensive legislation and through implementing regulations and administrative code, including the ability to regularly update laws, policies, procedures, and protocols. In the context of the trauma system, comprehensive legislation means the statutes, regulations, or administrative codes necessary to meet or exceed a pre-described set of standards of care. It also refers to the operating procedures necessary to continually improve the care of injured patients from injury prevention and control programs through post injury rehabilitation. The ability to enforce laws and rules guides the care and treatment of injured patients throughout the continuum of care.

There must be sufficient legal authority to establish a lead trauma agency and to plan, develop, maintain, and evaluate the trauma system during all phases of care. In addition, it is essential that as the development of the trauma system progresses, included in the legislative mandate are provisions for collaboration, coordination, and integration with other entities also engaged in providing care, treatment, or surveillance activities related to injured people. A broad approach to policy development should include the building of system infrastructure that can ensure system oversight and future development, enforcement, and routine monitoring of system performance; the updating of laws, regulations or rules, and policies and procedures; and the establishment of best practices across all phases of intervention. The success of the system in reducing morbidity and mortality due to traumatic injury improves when all service providers and system participants consistently comply with the rules, have the ability to evaluate performance in a confidential manner, and work together to improve and enhance the trauma system through defined policies.

## **Optimal Elements**

I. Comprehensive state statutory authority and administrative rules support trauma system leaders and maintain trauma system infrastructure, planning, oversight, and future development. **(B-201)** 

- a. The legislative authority states that all the trauma system components, emergency medical services (EMS), injury control, incident management, and planning documents work together for the effective implementation of the trauma system (infrastructure is in place). **(I-201.2)**
- b. Administrative rules and regulations direct the development of operational policies and procedures at the state, regional, and local levels. **(I-201.3)**

II. The lead agency acts to protect the public welfare by enforcing various laws, rules, and regulations as they pertain to the trauma system. **(B-311)** 

a. Laws, rules, and regulations are routinely reviewed and revised to continually strengthen and improve the trauma system. **(I-311.4)** 

### **Current Status**

Florida's trauma system has been under development since the passage of landmark trauma legislation in the early 1990s. Key components of this system include trauma centers, trauma agencies, and trauma service areas, as well as trauma transport protocols, trauma triage criteria for emergency medical service providers, and state-designated brain and spinal cord injury rehabilitation centers.

In 1998, the Florida Legislature directed the Department of Health (DOH) to conduct a study focusing on the state's trauma system and how best to ensure timely access to trauma care. During the 1999 Florida Legislative Session, the DOH Bureau of Emergency Medical Services Oversight (BEMO) was authorized to issue a five-year state trauma plan. This report, published in December 2000, systematically reviewed strategies required to accomplish the state plan objective of meeting the needs of all trauma patients in an inclusive trauma system.

In 2004, the Florida Legislature provided funding for a comprehensive assessment of the Florida trauma system. Based on the findings from this report, the *2005-2010 Trauma System Plan* was developed to improve the existing trauma system.

The authority for the Florida trauma system development is located in Chapter 395, Part II of the Florida Statutes. The Florida trauma system has strong support from the senior leadership in the DOH. The statutes are well written, but very prescriptive. It is obvious the Florida Legislature supports the state trauma system.

The Trauma System Plan Advisory Council (TSPAC) member's terms expired in June 2011. As a result of recent litigation no new appointments were made and the activities associated with TSPAC were suspended. Although Florida has comprehensive and very prescriptive statutes regarding the apportionment of trauma centers, the litigation resulted from an allegation that the state did not revise Rule 64J-2.010, "Apportionment of Trauma Centers within a Trauma Service Area (TSA)" to ensure alignment with the most recent statute and to be consistent with the State Trauma System Plan. Florida Administrative Code Chapter 64J-2 contains the rules promulgated and is based on the authority in Chapter 395, Part II of the Florida Statutes. These rules govern the processes used in the operation of the Florida state trauma system.

The DOH desires that planning and decision making regarding the trauma system remain open and transparent as it carries out its mission. For that purpose, it is essential that a system policy advisory group composed of the trauma system stakeholders be established and remain involved.

Florida has an excellent reputation of collaboration among those interested in reducing the state's mortality and morbidity. Collaboration among the stakeholders must remain a priority to continue improving the care of trauma patients. A small group of stakeholders should be appointed and charged with assisting the state to analyze all existing statutes and regulations pertaining to the trauma system, and include the following:

- methodology for needs assessment,
- process for trauma center designation based on system needs, and
- control of the patient flow.

This group is encouraged to review trauma statutes from other states and to achieve consensus on the necessary statutory or administrative code changes.

Section 395.404(1), Florida statutes, states that "Each trauma center shall furnish, and, upon request of the Department, all acute care hospitals shall furnish for the department review trauma registry data as prescribed by rule of the department for the purpose of monitoring patient outcome and ensuring compliance with the standards of approval." Currently, no rule exists to ensure compliance with this statute. In order to obtain an accurate picture of the effectiveness of the trauma system, data must be available from all licensed hospitals in the state.

BEMO is to be commended for implementing the Emergency Medical Services Tracking and Reporting System (EMSTARS) data system. Unfortunately participation is voluntary with only approximately 50% of the EMS agencies contributing data at the time of the TSC visit. The DOH should adopt rules to require that all EMS agencies and providers participate in EMSTARS and to enter data for each patient encounter. Prehospital data are essential for planning the trauma system and a valuable tool for improving outcomes among the state's residents and visitors who require emergent care.

The state supports EMS protocols, but they are driven by the local EMS agencies. While this has some benefit, the challenge is that no statewide baseline has been established to standardize the prehospital care being provided. The DOH should adopt rules to require a statewide set of EMS protocols that set the minimum standard of care for all licensed EMS agencies. Rules could allow flexibility at the local level to exceed the minimum standard when appropriate. One benefit could be a potential reduction in error rates by EMS personnel because of changing employment between EMS agencies and not being totally familiar with the local system-specific protocols.

In addition to trauma, patients with other time-sensitive disease events such as stroke and ST-Elevation Myocardial Infarction (STEMI) need to arrive at the appropriate facility that can provide optimal care in the most expeditious and efficient manner. Destination protocols need to be established statewide for EMS personnel to accomplish this. Again, this will require rule development to establish destination protocols for trauma and other specific time-sensitive conditions on a regional basis.

- Convene a small <u>multidisciplinary</u> work group to analyze all existing statutes and regulations pertaining to the trauma system, including, methodology for needs assessment, process for trauma center designation based on system needs, and control of patient flow (field triage criteria/destination protocols).
  - Review legislation from other states
  - Achieve consensus on the necessary statutory or administrative code changes
- Develop a rule for statute 395.404 requiring all licensed hospitals to submit a minimum set of data elements to the state trauma registry. Implement and enforce the rule.
- Establish a rule requiring all licensed EMS agencies and providers to submit data to the Emergency Medical Services Tracking and Reporting System on each patient encounter.
- Establish a rule requiring the development and use of minimum statewide clinical protocols for each licensed EMS agency.
  - Allow for regional rather than local EMS agency variability.
- Develop a rule to require model statewide time-sensitive disease destination protocol templates to establish a minimum standard of care for licensed EMS agencies.
  - Require participation of local EMS, trauma centers, non-trauma center hospitals, and county governments in the local response area in the development of regional protocols consistent with the statewide templates.
- Enact and enforce rules consistent with statutory authority.

In addition to lead agency staff and consultants (for example, trauma system medical director), there are other significant leadership roles essential to developing mature trauma systems. A broad constituency of trauma leaders includes trauma center medical directors and nurse coordinators, prehospital personnel, injury prevention advocates, and others. This broad group of trauma leaders works with the lead agency to inform and educate others about the trauma system, implements trauma prevention programs, and assists in trauma system evaluation and research to ensure that the right patient, right hospital, and right time goals are met. There is a strong role for the trauma system leadership in conveying trauma system messages, building communication pathways, building coalitions, and collaborating with relevant individuals and groups. The marketing communication component of trauma system development and maintenance begins with a consensus-built public information and education plan. The plan should emphasize the need for close collaboration between coalitions and constituency groups and increased public awareness of trauma as a disease. The plan should be part of the ongoing and regular assessment of the trauma system and be updated as frequently as necessary to meet the changing environment of the trauma system.

When there are challenges to providing the optimal care to trauma patients within the system, the leadership needs to effect change to produce the desired results. Broad system improvements require the ability to identify challenges and the resources and authority to make changes to improve system performance. However, system evaluation is a shared responsibility. Although the leadership will have a key role in the acquisition and analysis of system performance data, the multidisciplinary trauma oversight committee will share the responsibility of interpreting those data from a broad systems perspective to help determine the efficiency and effectiveness of the system in meeting its stated performance goals and benchmarks. All stakeholders have the responsibility of identifying opportunities for system improvement and bringing them to the attention of the multidisciplinary committee or the lead agency. Often, subtle changes in system performance are noticed by clinical care providers long before they become apparent through more formal evaluation processes.

Perhaps the biggest challenge facing the lead agency is to synergize the diversity, complexity, and uniqueness of individuals and organizations into a finely tuned system for prevention of injury and for the provision of quality care for injured patients. To meet this challenge, leaders in all phases of trauma care must demonstrate a strong desire to work together to improve care provided to injured victims.

## **Optimal Elements**

I. Trauma system leaders (lead agency, trauma center personnel, and other stakeholders) use a process to establish, maintain, and constantly evaluate

and improve a comprehensive trauma system in cooperation with medical, professional, governmental, and other citizen organizations. **(B-202)** 

- II. Collected data are used to evaluate system performance and to develop public policy. **(B-205)**
- III. Trauma system leaders, including a trauma-specific statewide multidisciplinary, multiagency advisory committee, regularly review system performance reports. **(B-206)**
- IV. The lead agency informs and educates state, regional, and local, constituencies and policy makers to foster collaboration and cooperation for system enhancement and injury control. (B-207)

### **Current Status**

The DOH is the lead agency for the trauma system in Florida, and responsibility for the trauma program is assigned to the BEMO in the Division of Emergency Preparedness and Community Support. Prior to a recent reorganization within the DOH, the Trauma Program was referred to as the Trauma Office. The Injury Prevention Program was also placed within the BEMO during the reorganization. At the time of the site visit, the Trauma Program was managed by an interim director.

The Trauma Program is supported by:

- A Trauma System Leadership Team consisting of the BEMO/Trauma Program leadership team, Trauma System support staff, BEMO and DOH internal leadership partners.
- A State Trauma Medical Director who is the current chairperson of the Florida chapter Committee on Trauma (COT). This unpaid consultant position (some travel expenses are reimbursed) is traditionally filled by the Florida COT Chair. This position provides trauma surgeons with a prominent voice in the state's trauma program and trauma system.
- The Trauma System Plan Advisory Council (TSPAC) formerly consisted of a large group of stakeholders. The TSPAC is currently suspended pending the resolution of the legal challenges regarding the trauma system. The majority of stakeholder input appears to occur through TSPAC, and suspension of its meetings limits the participation of stakeholders.
- The Florida Committee on Trauma is the state chapter of the American College of Surgeons Committee on Trauma (ACS-COT). This group continues to provide consultation to the DOH and Trauma Program during the suspension of the TSPAC, usually through the State Trauma Medical Director.
- Several planning teams involving stakeholders are in place. These provide opportunity to coordinate with other state and local agencies, the health care community, and professional organizations.

The system leadership currently faces several challenges in addition to the litigation. The suspension of the broadly-based advisory council deprives the majority of stakeholders with an opportunity to provide input to the trauma system leadership in an orderly manner. The Florida COT has assumed the role of advisory council. However, it is not able to truly function as a balanced policy advisory group due to the limitations in voting membership, the preponderance of representation from historical trauma centers and their staff, and the size of the overall body. The Florida COT has an important ongoing mission in the planning and operation of the trauma system.

Given the complex and contentious issues facing the trauma system, a permanent advisory council that is accepted as both balanced and representative of all stakeholders is essential to permit various groups to voice concerns, provide input, and foster renewed collaboration. A vital function of this advisory council would be to create a unifying vision that all stakeholders can support and provide the guiding principles for trauma system operations and future trauma system development. This advisory council could also serve as a mechanism by which to unify the parties regarding systemwide goals, create buy-in, and drive policy and rule-making. An early charge to this group would be to develop broadly accepted, data-driven guidelines for the allocation of trauma centers in the state. Representation from non-trauma center hospitals on the advisory council is essential since many trauma patients are managed in these facilities. To avoid making this advisory group's membership too large and unwieldy, voting membership should be limited to 25 or fewer. Subcommittees or work groups should be formed involving additional stakeholders to address specific tasks (e.g., performance improvement, data management, statewide protocols).

- Appoint a new Florida Trauma System Advisory Council (FTSAC) to provide input to policy development for the trauma system.
  - Include both trauma center and non-participating hospitals.
- Assign critical roles to the FTSAC to include the following:
  - Develop a vision for the trauma system that is supported by a large majority of stakeholders.
  - Develop criteria for determining the location and level of additional trauma centers.
  - Provide ongoing oversight of the trauma system.
  - Advise the Department of Health, Surgeon General, and director of the trauma program regarding important policies regarding trauma system development and operations.

- Establish appropriate committees of the FTSAC to support key development and policy activities, such as data, performance improvement, and statewide trauma destination protocols.
- Hire a Trauma Program director with clinical expertise in trauma.

Coalition building is a continuous process of cultivating and maintaining relationships with constituents (interested citizens) in a state or region who agree to collaborate on injury control and trauma system development. Key constituents include health professionals, trauma center administrators, prehospital care providers, health insurers and payers, data experts, consumers and advocates, policy makers, and media representatives. The coalition of key constituents comprises the trauma system's stakeholders. The involvement of these key constituents is important for the following:

- Trauma system plan development
- Regionalization: promoting collaboration rather than competition between trauma centers
- System integration
- State policy development: authorizing legislation and regulations
- Financing initiatives
- Disaster preparedness

The coalition should be effectively organized through the formation of multidisciplinary state and regional advisory groups to coordinate trauma system planning and implementation efforts. Constituents also communicate with elected officials and policy leaders regarding the development and sustainability of the trauma system. Information and education are needed by constituents to be effective partners in policy development for trauma system planning. Regular communication about the status of the trauma system helps these key partners to recognize needs and progress made with trauma system implementation.

One of the most effective ways to educate elected officials and the public is through an organized public information and education effort that may involve a media campaign about the burden of injury in the state and the need for trauma system development. Information and education are important to reduce the incidence of injury in all age groups and to demonstrate the value of an effective trauma system when a serious injury occurs.

## **Optimal Element**

I. The lead agency informs and educates state, regional, and local constituencies and policy makers to foster collaboration and cooperation for system enhancement and injury control. **(B-207)** 

## **Current Status**

Florida has a long history of engaging individuals and organizations in the development of its trauma system. Numerous organizations and groups were listed as participants in

the most recently published *Trauma System Strategic Plan.* Stakeholders are multidisciplinary, representing trauma surgeons, trauma centers, trauma program managers, emergency nurses; prehospital providers, educators, medical directors, and EMS agencies; air medical personnel; and brain injury and spinal injury rehabilitation professionals. One identified weakness with regard to stakeholder representation is the lack of participants from non-trauma hospitals that do care for injured patients in their communities. However, the state hospital association was represented and presumably advocated for the non-trauma hospitals. While stakeholders are multidisciplinary, the perception of the TSC team is that trauma surgeons are the dominant influential group of stakeholders, potentially to the detriment of overall trauma system planning.

Prior advisory councils convened for the development of the trauma system have had numerous members, and these members have often participated on work groups to address specific trauma system issues. A similar process and evidence of extensive stakeholder involvement exists for the injury prevention program.

Many trauma surgeon stakeholder participants for the TSC visit were those with long term experience in their trauma centers. When asked how they were preparing the future leaders of the trauma system, these stakeholders described efforts they were making to engage more recently trained trauma surgeons in trauma system planning. However, none of the more recently trained trauma surgeons were present during the visit to describe their opportunities for involvement in trauma system planning. The state trauma program should work to identify opportunities or specify certain membership requirements so that more recently trained trauma surgeons gain experience needed for future trauma system leadership roles.

Stakeholders are informed about trauma system developments through an electronic list and updates to the website. The legislature is informed about the trauma system through annual reports prepared by the DOH and stakeholder efforts (Florida COT) to educate elected officials. When asked, the participants did not identify any specific state legislative champions for the trauma program.

- Re-engage the broad multidisciplinary group of stakeholders in development of the trauma system planning and evaluation.
- Identify opportunities for more recently trained trauma surgeons to participate in trauma system planning and evaluation.
- Disseminate annual reports about the trauma system that can help inform the stakeholders, state population, and elected officials about the trauma system.
  - Develop fact sheets that can be shared with the public and elected officials based on information in the annual report.

# Lead Agency and Human Resources Within the Lead Agency

# **Purpose and Rationale**

Each trauma system (state, regional, local, as defined in state statute) should have a lead agency with a strong program manager who is responsible for leading the trauma system. The lead agency, usually a government agency, should have the authority, responsibility, and resources to lead the planning, development, operations, and evaluation of the trauma system throughout the continuum of care. The lead agency, empowered through legislation, ensures system integrity and provides for program integration with other health care and community-based entities, namely, public health, EMS, disaster preparedness, emergency management, law enforcement, social services, and other community-based organizations.

The lead agency works through a variety of groups to accomplish the goals of trauma system planning, implementation, and evaluation. The ability to bring multidisciplinary, multiagency advisory groups together to accomplish trauma system goals is essential in developing and maintaining the trauma system and is part of providing leadership to evolving and mature systems.

The lead agency's trauma system program manager coordinates trauma system design, the adoption of minimum standards (prehospital and in-hospital), and provides for overall system evaluation through performance indicator assessment and assurance. In addition to a trauma program manager, the lead agency must be sufficiently staffed to actively participate in each phase of development and in maintaining the system through a clearly defined structure for decision making (policies and procedures) and through proactive surveillance and evaluation. *Minimum* staffing usually consists of a trauma system program manager, data entry and analysis personnel, and monitoring and compliance personnel. Additional staff resources include administrative support and a part-time commitment from the public health epidemiology service to provide system evaluation and research support.

Within the leadership and governance structure of the trauma system, there is a role for strong physician leadership. This role is usually fulfilled by a full- or part-time trauma medical director within the lead agency.

## **Optimal Elements**

I. Comprehensive state statutory authority and administrative rules support trauma system leaders and maintain trauma system infrastructure, planning, oversight, and future development. **(B-201)** 

a. The legislative authority (statutes and regulations) plans, develops, implements, manages, and evaluates the trauma system and its component parts, including the identification of the lead agency and the designation of trauma facilities. (I-201.1)

b. The lead agency has adopted clearly defined trauma system standards (for example, facility standards, triage and transfer guidelines, and data collection standards) and has sufficient legal authority to ensure and enforce compliance. (I-201.4).

II. Sufficient resources, including financial and infrastructure-related, support system planning, implementation, and maintenance. **(B-204)** 

### **Current Status**

The Florida DOH has the legislative authority to establish a strong infrastructure for overall planning and design of a comprehensive and inclusive statewide trauma system. The DOH role in the trauma system development is clear in state statutes, but authority to enforce the statutes does not exist. The process by which the agency integrates trauma care and quality improvement into all the hospitals and the EMS program should be better defined. For example, statewide standardized transport protocols are not required, and limited coordination of the trauma assets occurs.

The Trauma Program is currently led (in an interim capacity) by the manager of the Injury Prevention Program. The Division of Emergency Preparedness and Community Support (DEPCS) was recently reorganized, and recruitment has been initiated to fill vacancies, including the BEMO and trauma program director positions. Given the complexity of the tasks involved and the interface with a large cross-section of trauma providers, hiring a trauma program director with clinical experience would be optimal.

In addition to one full-time equivalent (FTE) trauma program director, an additional 6.0 FTEs support the trauma center verification, site survey, strategic planning, and statute and rule implementation activities for the trauma program. No information was provided about the ability of the trauma program to support the trauma service areas with the existing personnel. The data unit has an additional 2.66 FTEs dedicated to the trauma registry data collection analysis and reporting.

No individual was identified with expertise to support the performance improvement effort once the next generation trauma registry is operational. Such an individual will be important to support assessment of the trauma system and to help the regions identify specific issues for performance improvement. Similarly, no personnel were identified who could coordinate the trauma service areas and support their focus on issues such as transport protocols or performance improvement.

The trauma system currently has a designated physician who voluntarily provides medical oversight of the trauma system, the chairperson of the Florida COT. To ensure that sufficient time is allocated for system medical direction, the medical director position requires a commitment of .25 FTE through a funded contractual arrangement. Having a contract for this position invests the person with accountability to the DOH rather than the uncertain accountability associated with a voluntary position. Since it is unclear how the trauma system medical director's role interacts with the state EMS medical director, a job description should be established with clearly defined

deliverables for the trauma medical director position. This will prevent potential confusion and overlap in responsibilities.

- Establish and fund a statewide performance improvement coordinator position to lead the development of a statewide performance improvement process.
- Contract for the state trauma medical director position and provide compensation for his/her time.

Each trauma system, as defined in statute, should have a clearly articulated trauma system planning process resulting in a written trauma system plan. The plan should be built on a completed inventory of trauma system resources identifying gaps in services or resources and the location of assets. It should also include an assessment of population demographics, topography, or other access enhancements (location of hospital and prehospital resources) or barriers to access. It is important that the plan identify special populations (for example, pediatric, elderly, in need of burn care, ethnic groups, rural) within the geographic area served and address the needs of those populations within the planning process. A needs assessment (or other method of identifying injury patterns, patient care review/preventable death study) should also be completed for initial trauma system planning and updated periodically as needed to assess system changes over time.

The trauma system plan is developed by the lead trauma agency based on the results of a needs assessment and other data resources available for review. It describes the system design, integrated and inclusive, with adopted standards of care for prehospital and hospital personnel and a process to regularly review the plan over time. The plan is built on input from trauma advisory committees (or stakeholder groups) that assist in analyzing data, identifying resources, and developing system standards of care, including system policies and procedures and overall system design. Ideally, although every stakeholder group may not be satisfied with the plan or system design, the plan, to the extent possible, should be based on consensus of the advisory committees and stakeholder groups. These advisory groups should be able to review the plan before final adoption and approve the plan before it is submitted to the lead agency with authority for plan approval.

The trauma system plan is used to guide system development, implementation, and management. Each component of the trauma system (for example, prehospital, hospital, communications, and transportation) is clearly defined and an established service level identified (baseline) with goals for enhancement (benchmark). Within the plan are incorporated other planning documents used to ensure integration of similar services and build collaboration and cooperation with those services. Service plans for emergency preparedness, EMS, injury prevention and control, public health, social services, and mental health are examples of services for which the trauma system plan should include an interface between agencies and services.

### **Optimal Element**

I. The state lead agency has a comprehensive written trauma system plan based on national guidelines. The plan integrates the trauma system with EMS, public health, emergency preparedness, and incident management. The written trauma system plan is developed in collaboration with community partners and stakeholders. **(B-203)** 

a. The trauma system plan clearly describes the system design (including the components necessary to have an integrated and inclusive trauma system) and is used to guide system implementation and management. For example, the plan includes references to regulatory standards and documents and includes methods of data collection and analysis. (I-203.4)

### **Current Status**

The *Florida Trauma System Strategic Plan* (January 2011-December 2015) has many good attributes, particularly around the nine goals, associated objectives and assigned responsibilities. Unfortunately, it does not address key issues currently facing the system. As an example, Goal 5 addresses the review and revision of trauma center standards but does not address a method for determining the location and level of any future trauma system expansion. An overarching plan to identify goals and objectives to address important trauma system development issues such as trauma center location and category, regional trauma system design, EMS field triage criteria and destination protocols, data needs, trauma fund distribution, and development and implementation of a performance improvement system is needed to guide and refocus the energy of the many dedicated trauma professionals across Florida.

One of the challenges facing the trauma system is the need for a truly representative body that can serve as an honest broker to complete such tasks as the revision of the trauma system plan. While the listing of more than 50 external, nine DOH, and nine national/federal partners in the current (2011-2015) plan is admirable, the responsibility for the revision of the plan needs to rest with the FTSAC as described in the leadership section. While the formal voting membership of the FTSAC will need input from a wide variety of stakeholders during the revision, the difficult decisions about key issues should be decided by the FTSAC and recommended to the DOH.

During the revision process, the *Model Trauma System Planning and Evaluation* document produced by HRSA's trauma program in 2006 should be carefully reviewed. The public health framework described in that resource should be applied to Florida's new trauma system plan. All aspects of the trauma system should be addressed. Within the three core functions of the public health model, objectives related to each of the following trauma system elements should be considered.

### Core Function: Assessment

Assessing the Injury Problem

Assessing the System Resources, Infrastructure, Processes, and Performance Benchmarks for the Assessment Phase

Core Function: Policy Development Designation of a Lead Agency Role of the Lead Agency in Policy Development Enabling Legislation State Trauma System Plan Preparation for the Plan Management Information System

Core Function: Assurance Enforcement and Regulation Patient Destination and Hospital Care EMS Systems and Assurance Training and Educating a Competent Workforce Trauma System Evaluation and Performance Improvement

Floridians may best be served by the development of an overarching, high level vision of an ideal trauma system. This high level document could then be organized by the goals, objectives and strategies necessary to attain the vision over time. This latter document could be similar in form and function to the *Florida Trauma System Strategic Plan* (2011-2015). As one set of goals and objectives are met, they could be replaced by others each of which would contribute to movement toward the overall vision.

Additional considerations should include: resources for trauma system disaster planning, importance of the trauma system and trauma centers to disaster response, the financial framework for the trauma system, financial planning, and reporting the trauma system financial status.

- Revise immediately the Florida trauma system plan to address key issues necessary for the further development of the regional and statewide trauma system.
- Adopt the plan formally through a broad trauma stakeholders group, the Florida Trauma System Advisory Council, and the Department of Health.
- Define the objectives, measurements, timeline, and assigned responsibilities for full implementation of the trauma plan.
  - Initiate any regulatory/statutory changes immediately to avoid the unnecessary proliferation and associated costly duplication of services of high level trauma centers.
  - Ensure integration of related strategic plans (e.g., injury prevention, disaster preparedness, highway safety, EMS, and rehabilitation)

- Establish a regular schedule and process for the trauma system plan revision.
- Consider the possible need for two trauma system plans, one at a visionary level and the other at a more strategic level.

Trauma system integration is essential for the daily care of injured people and includes such services as mental health, social services, child protective services, and public safety. The trauma system should use the public health approach to injury prevention to contribute to reducing the entire burden of injury in a state or region. This approach enables the trauma system to address primary, secondary, and tertiary injury prevention through closer integration with community health programs and mobilizing community partnerships. The partnerships also include mental health, social services, child protection, and public safety services. Collaboration with the public health community also provides access to health data that can be used for system assessment, development of public policy, and informing and educating the community.

Integration with EMS is essential because this system is linked with the emergency response and communication infrastructure and transports severely injured patients to trauma centers. Triage protocols should exist for treatment and patient delivery decisions. Regulations and procedures should exist for online and off -line medical direction. In the event of a disaster affecting local trauma centers, EMS would have a major role in evacuating patients from trauma centers to safety or to other facilities or to make beds available for patients in greater need.

The trauma system is a significant state and regional resource for the response to mass casualty incidents (MCIs). The trauma system and its trauma centers are essential for the rapid mobilization of resources during MCIs. Preplanning and integration of the trauma system with related systems (public health, EMS, and emergency preparedness) are critical for rapid mobilization when a disaster or MCI occurs. The extensive impact of disasters and MCIs on the functioning of trauma centers and the EMS and public health systems within the affected region or state must be considered, and joint planning for optimal use of all resources must occur to enable a coordinated response to an MCI. Trauma system leaders need to be actively involved in emergency management planning to ensure that trauma centers are integrated into the local, regional, and state disaster response plans.

## **Optimal Elements**

I. The state lead agency has a comprehensive written trauma system plan based on national guidelines. The plan integrates the trauma system with EMS, public health, emergency preparedness, and incident management. The written trauma system plan is developed in collaboration with community partners and stakeholders. **(B-203)** 

a. The trauma system plan has established clearly defined methods of integrating the trauma system plan with the EMS, emergency, and public health preparedness plans. **(I-203.7)** 

II. The trauma, public health, and emergency preparedness systems are closely linked. **(B-208)** 

### **Current Status**

The *Trauma System Strategic Plan* for 2011-2015 was completed with broad stakeholder input. Integration with EMS and emergency and public health preparedness plans is evident and ongoing with active communication between agencies and representation on each other's committees and working groups. The recent DOH reorganization has the Division of Emergency Preparedness and Community Support which facilitates the integration of emergency preparedness, EMS, and the Trauma Program. Plans are underway to integrate the Trauma Program and the Injury Prevention Program. With support from the newly formed Health Information and Policy Analysis Program, data acquisition and sharing between all these programs should be greatly facilitated.

Integration with EMS occurs at many levels including planning, operations, evaluation, and performance improvement. Established routines include feedback provided to EMS regarding any patient admitted to the intensive care unit when performance improvement issues related to prehospital care are applicable. EMS conducts a variety of injury prevention and outreach activities, and these are coordinated with the Injury Prevention Program. Information about these activities is shared with the Trauma Program.

Florida has 19 TSAs. In a few TSAs, a local multidisciplinary operational unit, called a trauma agency, is in place which provides an opportunity for local collaboration among agencies involved in trauma care. In the locales where the trauma agencies exist, they seem to be providing a useful function. Florida also has 7 Regional Domestic Security Task Force Regions.

Integration with disaster planning is evident. The State Emergency Response Team (SERT) is composed of agency-appointed Emergency Coordination Officers (ECOs) and staff from state agencies, and representatives from volunteer and non-governmental organizations that operate under the direction and control of the Governor and State Coordinating Officer (SCO). The SERT is grouped into 18 Emergency Support Functions (ESFs) that carry out coordination and completion of response and recovery activities in the State Emergency Operation Center (SEOC) during an emergency or disaster. These ESFs are grouped by function rather than agency, with each ESF headed by a primary state agency and supported by additional state agencies. The trauma system is integrated into the Florida Incident Command System through ESF-8, the Health and Medical function.

Standards exist for trauma centers to have written policies and protocols to provide mental health services, child protective services, and emotional support to trauma patients and their families. Trauma centers are also required to provide community injury prevention programs.

- Use the Regional Domestic Security Task Force Regions (RDSTFR) as the TSA regions.
  - Develop a strong regional structure based on the 7 RDSTFR that enables the integration of trauma centers with EMS, disaster preparedness, and other regional activities.
- Complete the integration of the Trauma Program and the Injury Prevention Program.

Trauma systems need sufficient funding to plan, implement, and evaluate a statewide or regional system of care. All components of the trauma system need funding, including prehospital, acute care facilities, rehabilitation, and prevention programs. Lead agency trauma system management requires adequate funding for daily operations and other important activities such as advisory committee meetings, development of regulations, data collection, performance improvement, and public awareness and education. Adequate funding to support the operation of trauma centers and their state of readiness to care for seriously injured patients within the state or region is essential. The financial health of the trauma system is essential for ensuring its integrity and its improvement over time.

The trauma system lead agency needs a process for assessing its own financial health, as well as that of the trauma system. A trauma system budget should be prepared, and costs should be reported by each component, if possible. Routine collection of financial data from all participating health care facilities is encouraged to fully identify the costs and revenues of the trauma system, including costs and revenues pertaining to patient care, administrative, and trauma center operations. When possible, the lead agency financial planning should integrate with the budgets and costs of the EMS system and disaster, rehabilitation, and prevention programs to enable development of a comprehensive financial health report.

Trauma system financial planning should be related to the trauma plan outcome measures (for example, patient outcome measures such as mortality rates, length of stay, and quality-of-life indicators). Such information may demonstrate the value added by having a trauma system in place.

## **Optimal Elements**

I. Sufficient resources, including financial and infrastructure-related, support system planning, implementation, and maintenance. **(B-204)** 

- a. Financial resources exist that support the planning, implementation, and ongoing management of the administrative and clinical care components of the trauma system. (I 204.2)
- b. Designated funding for trauma system infrastructure support (lead agency) is legislatively appropriated. **(I-204.3)**
- c. Operational budgets (system administration and operations, facilities administration and operations, and EMS administration and operations) are aligned with the trauma system plan and priorities. **(I-204.4)**

II. The financial aspects of the trauma systems are integrated into the overall performance improvement system to ensure ongoing fine tuning and cost-effectiveness. **(B-309)** 

 a. Collection and reimbursement data are submitted by each agency or institution on at least an annual basis. Common definitions exist for collection and reimbursement data and are submitted by each agency. (I-309.2)

### **Current Status**

Florida is fortunate to have several funding sources to support the trauma program. A fund of two million dollars is generated through a 10 cent vehicle registration tax and used for operation and management of the Trauma Program. Revenue generated through red light camera fines is distributed to all trauma centers in the state and in 2012 totaled \$12.6 million. Disbursement is based on a statutory formula that addresses patient volume and acuity.

Federal funding received through the Assistant Secretary of Preparedness and Response (ASPR) has provided \$46 million to support hospital preparedness efforts to 22 trauma centers and 19 non-trauma centers over the last 10 years. Additional revenue to support the trauma system is generated through school bus violation fines, speeding citations in certain counties on interstate I-95, and limited support through the Florida Office of Rural Health.

The federal funding sources may only provide short term assistance as they are primarily from federal grant programs, but they are beneficial until more sustainable state resources become available. The Trauma Program needs to continue to seek and maximize available resources that can be used to support and sustain the trauma system. The Trauma Program may also want to consider seeking available private foundation funding to support its goals and objectives.

The Trauma Program currently does not have a statewide performance improvement program. It is essential that funding be identified or redirected to support a statewide performance improvement program that includes the participation of all trauma centers and all EMS agencies. Likewise, data submission in the state trauma registry is essential for all trauma-designated and non-designated hospitals. All EMS agencies should submit data to the EMSTARS.

As the needs of the Trauma Program and trauma system change, the Trauma Program should consider revising the statutes and rules governing the trauma fund to ensure that designated trauma centers receive level-appropriate support for the "cost of readiness". In addition, distribution of funds should focus on the deliverables established by the Trauma Program rather than volume and acuity exclusively.

Trauma rehabilitation is an area the trauma system needs to assess to determine if the current system is meeting the needs of all trauma patients with severe injuries. It is important for the DOH to be creative in determining ways to support trauma

rehabilitation services. Consider promulgating rules to allow or require trauma centers to use funding to possibly buy beds in rehabilitation centers.

- Revise the distribution method of the trauma center fund.
  - Change the statutes and rules governing the fund to ensure that designated trauma centers receive level-appropriate support for the "cost of readiness".
  - Develop a formula for distribution of funds that focuses on specific deliverables by trauma center level rather than volume and acuity.
  - Include a mechanism to support trauma rehabilitation services (e.g., establish in rule and/or direct trauma centers to use some of their funds to "buy" beds in rehabilitation centers).
  - Revisit the allocation method/ formula on a regular basis (every 3-5 years)
- Assess the funding needs of the trauma system and determine if existing financial resources are sufficient to meet its needs (e.g. for regional support).
- Identify and provide sustainable funding to support a statewide performance improvement system.
- Identify and provide sustainable funding to enhance data sources to support clinical and business decisions of the trauma system.

Trauma systems must develop prevention strategies that help control injury as part of an integrated, coordinated, and inclusive trauma system. The lead agency and providers throughout the system should be working with business organizations, community groups, and the public to enact prevention programs and prevention strategies that are based on epidemiologic data gleaned from the system.

Efforts at prevention must be targeted for the intended audience, well defined, and structured, so that the impact of prevention efforts is system-wide. The implementation of injury control and prevention requires the same priority as other aspects of the trauma system, including adequate staffing, partnering with the community, and taking advantage of outreach opportunities. Many systems focus information, education, and prevention efforts directly to the general public (for example, restraint use, driving while intoxicated). However, a portion of these efforts should be directed toward emergency medical services (EMS) and trauma care personnel safety (for example, securing the scene, infection control). Collaboration with public service agencies, such as the department of health is essential to successful prevention program implementation. Such partnerships can serve to synergize and increase the efficiency of individual efforts. Alliances with multiple agencies within the system, hospitals, and professional associations, working toward the formation of an injury control network, are beneficial.

Activities that are essential to the development and implementation of injury control and prevention programs include the following:

• A needs assessment focusing on the public information needed for media relations, public officials, general public, and third-party payers, thus ensuring a better understanding of injury control and prevention

• Needs assessment for the general medical community, including physicians, nurses, prehospital care providers, and others concerning trauma system and injury control information

• Preparation of annual reports on the status of injury prevention and trauma care in the system

• Trauma system databases that are available and usable for routine public health surveillance

## **Optimal Elements**

I. The lead agency informs and educates state, regional, and local constituencies and policy makers to foster collaboration and cooperation for system enhancement and injury control. **(B-207)** 

a. The trauma system leaders (lead agency, advisory committees, and others) inform and educate constituencies and policy makers through community development activities, targeted media messaging, and active collaborations aimed at injury prevention and trauma system development. **(I-207.2)** 

II. The jurisdictional lead agency, in cooperation with other agencies and organizations, uses analytic tools to monitor the performance of population based prevention and trauma care services. **(B-304)** 

a. The lead agency, along with partner organizations, prepares annual reports on the status of injury prevention and trauma care in state, regional, or local areas. **(I-304.1)** 

III. The lead agency ensures that the trauma system demonstrates prevention and medical outreach activities within its defined service area. **(B-306)** 

- a. The trauma system is active within its jurisdiction in the evaluation of community based activities and injury prevention and response programs. **(I-306.2)**
- b. The effect or impact of outreach programs (medical and community training and support and prevention activities) is evaluated as part of a system performance improvement process. **(I-306.3)**

## **Current Status**

The Florida Trauma Program appears to be actively involved with injury prevention efforts in collaboration with the state's Injury Prevention Program. Although the Trauma Program does not have dedicated personnel to support injury prevention efforts by trauma centers, the Trauma Program compiles lists of injury prevention-related programs conducted by trauma centers and publishes the list on the program's website. The list serves as a great resource for the other hospitals, EMS agencies, and other organizations. Several of these injury prevention programs are evidence-based, such as the "WalkSafe", "Prom-Night" and "Shattered Dreams." Numerous other injury prevention resources are also available on the Injury Prevention Program's website. Some of the state injury prevention activities, conducted in collaboration with various organizational partners include: bike safety, drowning prevention, senior falls prevention, the Safe Kids program, and the special needs car seat program.

The state EMS program surveyed EMS providers to assess their involvement in injury prevention and outreach education activities. The survey results indicated that 25-35% of EMS providers were involved in injury prevention programs such as promoting "Prom-Night" and a motorcycle safety program. The state EMS program also administers the federally-funded EMS for Children program. Many injury prevention activities directed toward children are funded and administered through this program with resources available to hospitals and EMS providers. The state EMS Advisory Council is also active in injury prevention, provider safety, and pubic information efforts. It administers the Public Information and Education and Relations program, developed by the National Highway Traffic Safety Administration (NHTSA).

The recent integration of the Trauma Program and Injury Prevention Program will provide an opportunity for better coordination and integrated planning with injury prevention goals and strategies. Both programs have injury-related data that can be used to generate reports, focus injury prevention efforts, and educate the providers and the public. The new program integration may also provide opportunities for better collaboration at the state level with external partners like the Governor's Highway Safety Program and community organizations. EMS injury prevention goals and activities should also be included during efforts to collaborate with the Governor's Highway Safety Program strategic planning.

### <u>Outreach</u>

Trauma centers must offer educational opportunities to referring facilities and EMS agencies as a requirement of their designation. As an example, one facility provides disaster management education, training on chest tube insertion, EMS case reviews, and EMS continuing education. They also teach the Trauma Nurse Core Curriculum (TNCC), Emergency Nursing Pediatric Course (ENPC), and other trauma related courses. The telemedicine system is used to deliver outreach education to rural healthcare providers. Another facility offers 4 hour continuing medical education (CME) trauma modules to EMS providers. They also provide monthly feedback to EMS transport agencies and invite them to attend trauma grand rounds.

At the state level, examples of outreach education activities include a Trauma Awareness Day and Legislative Day where the public, media and policymakers are educated about the state trauma system. These outreach efforts have been very successful and can serve as a model for other states. Another successful outreach education effort includes the provision of the ACS's Rural Trauma Team Development Course (RTTDC) supported with funding from the Office of Rural Health. This course encourages a team approach to the treatment and stabilization of trauma patients by rural facilities.

- Ensure integration of the state's Injury Prevention Program with both the Trauma Program and EMS programs to facilitate the coordination of DOH injury prevention with other community injury prevention activities.
- Ensure the integration of EMS and Trauma Program injury prevention goals into the Governor's Highway Safety Program strategic plans.
- Expand the telemedicine network and include educational outreach activities for all acute care facilities (including critical access hospitals) and EMS providers.
- Seek opportunities to participate in targeted media efforts to educate the public on trauma system development and injury prevention.

The trauma system includes, and/or interacts with, many different agencies, institutions, and systems. The EMS system is one of the most important of these relationships. EMS is often the critical link between the injury-producing event and definitive care at a trauma center. Even though at its inception the EMS system was a very broad system concept, over time, EMS has come to be recognized as the prehospital care component of the larger emergency health care system. It is a complex system that not only transports patients, but also includes public access, communications, personnel, triage, data collection, and quality improvement activities.

The EMS system medical director must have statutory authority to develop protocols, oversee practice, and establish a means of ongoing quality assessment to ensure the optimal provision of prehospital care. If not the same individual, the EMS system medical director must work closely with the trauma system medical director to ensure that protocols and goals are mutually aligned. The EMS system medical director must also have ongoing interaction with EMS agency medical directors at local levels, as well as the state EMS for Children program, to ensure that there is understanding of and compliance with trauma triage and destination protocols.

Ideally, a system should have some means of ensuring whether resources meet the needs of the population. To achieve this end, a resource and needs assessment evaluating the availability and geographic distribution of EMS personnel and physical resources is important to ensure a rapid and appropriate response. This assessment includes a detailed description of the distribution of ground ambulance and aeromedical locations across the region. Resource allocations must be assessed on a periodic basis as needs dictate a redistribution of resources. In communities with full-time paid EMS agencies, ambulances should be positioned according to predictable geographic or temporal demands to optimize response efficiencies. Such positioning schemes require strong prehospital data collection systems that can track the location of occurrences over time. Periodic assessment of dispatch and transport times will also provide insight into whether resources are consistent with needs. Each region should have objective criteria dictating the level of response (advanced life support [ALS], basic life support [BLS]), the mode of transport, and the disposition of the patient based on the location of the incident and the severity of injury. A mechanism for case-based review of trauma patients that involves prehospital and hospital providers allows bidirectional information sharing and continuing education, ensuring that expectations are met at both ends. Ongoing review of triage and treatment decisions allows for continuing quality improvement of the triage and prehospital care protocols. A more detailed discussion of in-field (primary) triage criteria is provided in the section titled: System Coordination and Patient Flow (p 20) (White Book).

## Human Resources

Periodic workforce assessments of EMS should be conducted to ensure adequate numbers and distribution of personnel. EMS, not unlike other health care professions, experiences shortages and maldistribution of personnel. Some means of addressing recruitment, retention, and engagement of gualified personnel should be a priority. It is critical that trauma system leaders work to ensure that prehospital care providers at all levels attain and maintain competence in trauma care. Maintenance of competence should be ensured by requiring standards for credentialing and certification and specifying continuing educational requirements for all prehospital personnel involved in trauma care. The core curricula for Emergency Medical Responder, Emergency Medical Technician (EMT), Advanced EMT, and Paramedic, and other levels of prehospital personnel have an essential orientation to trauma care for all ages. However, trauma care knowledge and skills need to be continuously updated, refined, and expanded through targeted trauma care training such as Prehospital Trauma Life Support®, Basic Trauma Life Support<sup>®</sup>, and age-specific courses. Mechanisms for the periodic assessment of competence, educational needs, and education availability within the system should be incorporated into the trauma system plan.

Systems of excellence also encourage EMS providers to go beyond meeting state standards for agency licensure and to seek national accreditation. National accreditation standards exist for ground-based and air medical agencies, as well as for EMS educational programs. In some states, agency licensure requirements are waived or substantially simplified if the EMS agency maintains national accreditation.

EMS is the only component of the emergency health care and trauma system that depends on a large cadre of volunteers. In some states, substantially more than half of all EMS agencies are staffed by volunteers. These agencies typically serve rural areas and are essential to the provision of immediate care to trauma patients, in addition to provision of efficient transportation to the appropriate facility. In some smaller facilities, EMS personnel also become part of the emergency resuscitation team, augmenting hospital personnel. The trauma care system program should reach out to these volunteer agencies to help them achieve their vital role in the outcome of care of trauma patients. However, it must be noted that there is a delicate balance between expecting quality performance in these agencies and placing unrealistic demands on their response capacity. In many cases, it is better to ensure that there is an optimal BLS response available at all times rather than a sporadic or less timely response involving ALS personnel. Support to volunteer EMS systems may be in the form of quality improvement activities, training, clinical opportunities, and support to the system medical director.

Owing to the multidisciplinary nature of trauma system response to injury, conferences that include all levels of providers (for example, prehospital personnel, nurses, and physicians) need to occur regularly with each level of personnel respected for its role in the care and outcome of trauma patients. Communication with and respect for prehospital providers is particularly important, especially in rural areas where exposure to major trauma patients might be relatively rare.

#### Integration of EMS Within the Trauma System

In addition to its critical role in the prehospital treatment and transportation of injured patients, EMS must also be engaged in assessment and integration functions that include the trauma system and also public health and other public safety agencies. EMS agencies should have a critical role in ensuring that communication systems are available and have sufficient redundancy so that trauma system stakeholders will be able to assess and act to limit death and disability at the single patient level and at the population level in the case of mass casualty incidents (MCIs). Enhanced 911 services and a central communication system for the EMS/trauma system to ensure field-to-facility bidirectional communications, interfacility dialogue, and all-hazards response communications among all system participants are important for integrating a system's response. Wireless communications capabilities, including automatic crash notification, hold great promise for quickly identifying trauma-producing events, thereby reducing delays in discovery and decreasing prehospital response intervals.

Further integration might be accomplished through the use of EMS data to help define high-risk geographic and demographic characteristics of injuries within a response area. EMS should assist with the identification of injury prevention program needs and in the delivery of prevention messages. EMS also serves a critical role in the development of all-hazards response plans and in the implementation of those plans during a crisis. This integration should be provided by the state and regional trauma plan and overseen by the lead agency. EMS should participate through its leadership in all aspects of trauma system design, evaluation, and operation, including policy development, public education, and strategic planning.

### **Optimal Elements**

I. The trauma system is supported by an EMS system that includes communications, medical oversight, prehospital triage, and transportation; the trauma system, EMS system, and public health agency are well integrated. **(B-302)** 

- a. There is well-defined trauma system medical oversight integrating the specialty needs of the trauma system with the medical oversight for the overall EMS system. (I-302.1)
- b. There is a clearly defined, cooperative, and ongoing relationship between the trauma specialty physician leaders (for example, trauma medical director within each trauma center) and the EMS system medical director. **(I-302.2)**
- c. There is clear-cut legal authority and responsibility for the EMS system medical director, including the authority to adopt protocols, to implement a performance improvement system, to restrict the practice of prehospital care providers, and to generally ensure medical appropriateness of the EMS system. (I-302.3)
- d. The trauma system medical director is actively involved with the development, implementation, and ongoing evaluation of system dispatch protocols to ensure they are congruent with the trauma system design. These protocols include, but are not limited to, which resources to dispatch, for example, ALS versus BLS, air ground coordination, early notification of the trauma care facility, pre-arrival

instructions, and other procedures necessary to ensure that resources dispatched are consistent with the needs of injured patients. **(I-302.4)** 

- e. The retrospective medical oversight of the EMS system for trauma triage, communications, treatment, and transport is closely coordinated with the established performance improvement processes of the trauma system. (I-302.5)
- f. There is a universal access number for citizens to access the EMS/trauma system, with dispatch of appropriate medical resources. There is a central communication system for the EMS/trauma system to ensure field- to- facility bidirectional communications, interfacility dialogue, and all-hazards response communications among all system participants. **(I-302.7)**
- g. There are sufficient and well-coordinated transportation resources to ensure that EMS providers arrive at the scene promptly and expeditiously transport the patient to the correct hospital by the correct transportation mode. **(I-302.8)**
- II. The lead trauma authority ensures a competent workforce. (B-310)
  - a. In cooperation with the prehospital certification and licensure authority, set guidelines for prehospital personnel for initial and ongoing trauma training, including trauma-specific courses and courses that are readily available throughout the state. **(I-310.1)**
  - b. In cooperation with the prehospital certification and licensure authority, ensure that prehospital personnel who routinely provide care to trauma patients have a current trauma training certificate, for example, Prehospital Trauma Life Support or Basic Trauma Life Support and others, or that trauma training needs are driven by the performance improvement process. **(I-310.2)**
  - c. Conduct at least 1 multidisciplinary trauma conference annually that encourages system and team approaches to trauma care. **(I-310.9)**

III. The lead agency acts to protect the public welfare by enforcing various laws, rules, and regulations as they pertain to the trauma system. **(B-311)** 

 a. Incentives are provided to individual agencies and institutions to seek state or nationally recognized accreditation in areas that will contribute to overall improvement across the trauma system, for example, Commission on Accreditation of Ambulance Services for prehospital agencies, Council on Allied Health Education Accreditation for training programs, and American College of Surgeons (ACS) verification for trauma facilities. (I-311.6)

## **Current Status**

The state's EMS Program is located within the BEMO, under the DEPCS, within the DOH. The EMS Program has the authority to license ambulance agencies, ambulances, and prehospital care providers, to perform ambulance inspections, and to approve EMS education programs. An EMS Advisory Council, supported by statute, provides input to

the BEMO. The EMS Advisory Council membership has a broad array of stakeholders, including a trauma surgeon. The work of this Council is supported by 11 committees that address a comprehensive range of topics relevant to EMS. The Council meets quarterly. Committee meetings may occur in association with Council meetings or at other times that are appropriate.

Florida has a 0.5 FTE EMS Medical Director, contracted by the state. This position is not based on statute. The EMS Medical Director is not authorized to determine or enforce EMS state policies, but serves in an advisory capacity. One of the EMS Medical Director's major roles is to act as a liaison to EMS agencies and prehospital providers at a local level. The EMS Medical Director interacts regularly with various professional organizations in the state, including the Florida EMS Medical Directors and the Florida COT. The EMS Medical Director also serves as the chairperson of the Emergency Medical Review Committee for the BEMO. This Committee reviews any concerns regarding EMS agency or prehospital provider performance.

The *Florida Regional Common EMS Protocols* manual was developed by a large group of individuals involved in the emergency treatment of patients. The state funded the printing of this manual in 2004. These protocols include the Trauma Transport Protocol (1.10). However, except for certain components of the Trauma Transport Protocol, none of these protocols are mandated by the state.

In order to be licensed by the state, EMS agencies are required to get a certificate of public need (COPN) from the county in which their service area exists. Each EMS agency is required to have a medical director who is responsible for the agency's medical protocols as well as the medical care delivered by that agency's EMS personnel. No statewide EMS medical oversight or statewide system of regional EMS medical oversight occurs. Some counties and cities have formed agencies that provide oversight or direction of EMS activities.

Florida is served by air medical services in 55 locations. Each air medical service is required to have a medical director. Each ground ambulance service enters into a specific contractual agreement with an air service for support. As with ground ambulance services, air ambulance agencies, air ambulances, and air ambulance personnel must be licensed by the state. No specific state mandated protocols address air-transport of the trauma patient. The air ambulance service is required to follow the trauma transport protocols (TTP) of the ambulance service to which it is responding. No regular evaluation or continuous quality improvement (CQI) of air medical transport is conducted by the EMS Office.

Discussion with the EMS Medical Director indicated that time-critical systems of care for stroke and STEMI are being considered within the state. It is not clear what steps are being taken to ensure that these systems are developed in a harmonious manner. It is also not clear how the current statewide trauma system is being considered in the development of statewide systems to treat other time-sensitive conditions.

NHTSA conducted an evaluation of the state's EMS system in 1993. In general, the report was laudatory and praised the state for its dedication and leadership in the

provision of high quality EMS services. Today, Florida is still seen as leader in EMS, particularly in EMS education. An extraordinary population growth has occurred in Florida over the last decade, along with great population diversity, and a staggering number of visitors. However, since 1993, no external assessment of the EMS system or other statewide needs assessment has been conducted. Such an evaluation and/or assessment would be invaluable for ensuring that Florida continues to provide high quality and cost-efficient EMS services to its population and visitors.

- Collaborate with the Florida Department of Transportation Governor's Highway Safety Program to initiate and conduct a National Highway Traffic Safety Administration EMS System Reassessment.
- Review the membership of the EMS Advisory Council and its committees to ensure an appropriate representation of trauma surgeons and trauma program managers.
- Ensure that all state systems developed for response to time-critical diagnoses (currently trauma, stroke, STEMI) are integrated, efficient, and cost effective (not duplicative).
  - Implement, with consensus of the stakeholders, standardized statewide triage destination guidelines/protocols for time-critical diagnoses.
  - Develop a mechanism for the establishment and integration of additional timecritical diagnoses into the EMS system as they may emerge.

Inclusive trauma systems are the systems that include all acute health care facilities, to the extent that their resources and capabilities allow and in which the patient's needs are matched to hospital resources and capabilities. Thus, as the core of a regional trauma system, acute care facilities operating within an inclusive trauma system provide definitive care to the entire spectrum of patients with traumatic injuries. Acute care facilities must be well integrated into the continuum of care, including prevention and rehabilitation, and operate as part of a network of trauma-receiving hospitals within the public health framework. All acute care facilities should participate in the essential activities of a trauma system, including performance improvement, data submission to state or regional registries, representation on regional trauma advisory committees, and mutual operational agreements with other regional hospitals to address interfacility transfer, educational support, and outreach. The roles of all definitive care facilities, including specialty hospitals (for example, pediatric, burn, severe traumatic brain injury [TBI], spinal cord injury [SCI]) within the system should be clearly outlined in the regional trauma plan and monitored by the lead agency. Facilities providing the highest level of trauma care are expected to provide leadership in education, outreach, patient care, and research and to participate in the design, development, evaluation, and operation of the regional trauma system.

In an inclusive system, patients should be triaged to the appropriate facility based on their needs and facility resources. Patients with the least severe injuries might be cared for at appropriately designated facilities within their community, whereas the most severe should be triaged to a Level I or II trauma center. In rural and frontier systems, smaller facilities must be ready to resuscitate and initiate treatment of the major injuries and have a system in place that will allow for the fastest, safest transfer to a higher level of care.

Trauma receiving facilities providing definitive care to patients with other than minor injuries must be specifically designated by the state or regional lead agency and equipped and qualified to do so at a level commensurate with injury severity. To assess and ensure that injury type and severity are matched to the qualifications of the facilities and personnel providing definitive care, the lead agency should have a process in place that reviews and verifies the qualifications of a particular facility according to a specific set of resource and quality standards. This criteria-based process for review and verification should be consistent with national standards and be conducted on a periodic cycle as determined by the lead agency. When centers do not meet set standards, there should be a process for suspension, probation, revocation, or de-designation.

Designation by the lead agency should be restricted to facilities meeting criteria or statewide resource and quality standards and based on patient care needs of the regional trauma system. There should be a well-defined regulatory relationship between the lead agency and designated trauma facilities in the form of a contract, guidelines, or

memorandum of understanding. This legally binding document should define the relationships, roles, and responsibilities between the lead agency and the medical leadership from each designated trauma facility.

The number of trauma centers by level of designation and location of acute care facilities must be periodically assessed by the lead agency with respect to patient care needs and timely access to definitive trauma care. There should be a process in place for augmenting and restricting, if necessary, the number and/or level of acute care facilities based on these periodic assessments. The trauma system plan should address means for improving acute care facility participation in the trauma system, particularly in systems in which there has been difficulty addressing needs.

### Human Resources

The ability to deliver high-quality trauma care is highly dependent on the availability of skilled human resources. Therefore, it is critical to assess the availability and educational needs of providers on a periodic basis. Because availability, particularly of subspecialty resources, is often limited, some means of addressing recruitment, retention, and engagement of qualified personnel should be a priority. Periodic workforce assessments should be conducted. Maintenance of competence should be ensured by requiring standards for credentialing and certification and specifying continuing educational requirements for physicians and nurses providing care to trauma patients. Mechanisms for the periodic assessment of ancillary and subspecialty competence, educational needs, and availability within the system for all designated facilities should be incorporated into the trauma system plan. The lead trauma centers in rural areas will need to consider teleconferencing and telemedicine to assist smaller facilities in providing education on regionally identified needs. In addition, lead trauma centers within the region should assist in meeting educational needs while fostering a team approach to care through annual educational multidisciplinary trauma conferences. These activities will do much to foster a sense of teamwork and a functionally inclusive system.

## Integration of Designated Trauma Facilities Within the Trauma System

Designated trauma facilities must be well integrated into all other facets of an organized system of trauma care, including public health systems and injury surveillance, prevention, EMS and prehospital care, disaster preparedness, rehabilitation, and system performance improvement. This integration should be provided by the state and/or regional trauma plan and overseen by the lead agency.

Each designated acute care facility should participate, through its trauma program leadership, in all aspects of trauma system design, evaluation, and operation. This participation should include policy and legislative development, legislative and public education, and strategic planning. In addition, the trauma program and subspecialty leaders should provide direction and oversight to the development, implementation, and monitoring of integrated protocols for patient care used throughout the system (for example, TBI guidelines used by prehospital providers and non-designated transferring centers), including region specific primary (field) and secondary (early transfer) triage protocols. The highest level trauma facilities should provide leadership of the regional trauma committees through their trauma program medical leadership. These medical leaders, through their activities on these committees, can assist the lead agency and help ensure that deficiencies in the quality of care within the system, relative to national standards, are recognized and corrected. Educational outreach by these higher levels centers should be used when appropriate to help achieve this goal.

## **Optimal Elements**

I. Acute care facilities are integrated into a resource efficient, inclusive network that meets required standards and that provides optimal care for all injured patients. **(B-303)** 

a. The trauma system plan has clearly defined the roles and responsibilities of all acute care facilities treating trauma and of facilities that provide care to specialty populations (for example, burn, pediatric, SCI, and others). (I-303.1)

II. To maintain its state, regional, or local designation, each hospital will continually work to improve the trauma care as measured by patient outcomes. **(B-307)** 

a. The trauma system engages in regular evaluation of all licensed acute care facilities that provide trauma care to trauma patients and of designated trauma hospitals. Such evaluation involves independent external reviews. **(I-307.1)** 

#### III. The lead trauma authority ensures a competent workforce. (B-310)

- As part of the established standards, set appropriate levels of trauma training for nursing personnel who routinely care for trauma patients in acute care facilities. (I-310.3)
- b. Ensure that appropriate, approved trauma training courses are provided for nursing personnel on a regular basis. (I-310.4)
- c. In cooperation with the nursing licensure authority, ensure that all nursing personnel who routinely provide care to trauma patients have a trauma training certificate (for example, Advanced Trauma Care for Nurses, Trauma Nursing Core Course, or any national or state trauma nurse verification course). As an alternative after initial trauma course completion, training can be driven by the performance improvement process. **(I-310.5)**
- d. In cooperation with the physician licensure authority, ensure that physicians who routinely provide care to trauma patients have a current trauma training certificate of completion, for example, Advanced Trauma Life Support® (ATLS®) and others. As an alternative, physicians may maintain trauma competence through continuing medical education programs after initial ATLS completion. (I-310.8)
- e. Conduct at least 1 multidisciplinary trauma conference annually that encourages system and team approaches to trauma care. (I-310.9)

f. As new protocols and treatment approaches are instituted within the system, structured mechanisms are in place to inform all personnel about the changes in a timely manner. **(I-310-10)** 

## **Current Status**

Florida has been a leader in the development of trauma systems since the 1980's. A fairly comprehensive needs assessment was conducted, leading to the establishment of a regional infrastructure by the early 1990s. This plan, established in statute, included the definition of 19 TSAs and standards for the number and location of trauma centers. The TSAs are scaled to the level of individual counties or small groups of counties, and decisions were based on geography, traditional patient flow, and population. The plan called for at least one trauma center (Level I or Level II) in each TSA, plus a variable number of additional trauma centers apportioned largely on the basis of population. The apportionment plan established a ceiling of 44 trauma centers without clear justification for this number. The Florida statute was amended shortly after 2000 to require a comprehensive needs assessment, which was completed in 2005. The statute set specific parameters to be considered in the allocation of trauma centers and required a yearly needs assessment. No needs assessments have been conducted as required by statute, and no changes to the apportionment plan have occurred.

In the period between 2005 and 2010 the Trauma Program received a small number of requests for new trauma center designations. All were in areas of need, both as identified in the apportionment plan and in the perception of the trauma community. These requests were granted without opposition. In the 2011 application cycle, four new requests for provisional trauma center status were granted, all to hospitals operated by a single corporation. These requests were consistent with the existing 1990 apportionment plan, but existing trauma centers did not believe that all new trauma center designations were truly in areas of need. A group of existing trauma centers challenged the apportionment rule in court, and the rule was ruled invalid in late 2011 by an administrative law judge. This ruling was appealed by the DOH, but it was subsequently upheld by the district court of appeals in late 2012. During the course of the appeal, the DOH continued to follow existing statutory processes regarding provisional and permanent designation. As of December 2012, the DOH advised the trauma community that any new applications for provisional designation could not be approved. Two provisional trauma centers were granted verified status in early February of 2013.

A highly contentious atmosphere continues to generate legal challenges between hospital systems and animosity among providers related to the following:

- The sharp increase in interest in trauma center designation, especially among hospitals that are members of a single highly integrated hospital network,
- Differences in opinion about the need for these trauma centers and their impact on existing trauma centers, and
- The inconsistencies between Florida's statutes and rules

In the wake of this conflict, all stakeholder advisory committees have been suspended and all trauma-related strategic planning is on hold. Trauma system development and any efforts at a negotiated solution have come to a halt.

The Florida statute declares that the trauma system will be based upon an inclusive model, but operationally this is not the case. On a day-to-day basis, the trauma system functions as a loose aggregation of trauma centers, with little cooperation between trauma centers and almost no central coordination of EMS or trauma center activity. Trauma system operations, governance, and advisory leadership do not fully embrace the true essence of an inclusive system, and operate under the assumptions of an older exclusive model.

This trauma system has had substantial success, especially in urban areas with close proximity to large established trauma centers. In these urban areas, overall system mortality and system access parameters are above national averages. Some areas of the state are still less well served. According to simple geographic analysis and hospital discharge data analyzed for the DOH, opportunity exists to further refine the trauma system. The data regarding patient access and need for additional trauma centers has been extensively reviewed. Diametrically different conclusions have been reached by the opposing factions and even by the same authors at different points in time. Attempts by the DOH to gain consensus for changes in the apportionment rules have been ongoing since about 2005, but the efforts have failed to produce any new rules.

Data from the American Hospital Association reveals that Florida has 208 acute care hospitals with emergency departments. Of these 13 are critical access hospitals.

At the time of the TSC visit, Florida had 24 verified trauma centers and 4 provisionally designated trauma centers in operation, including the 2 new verified designations announced in February, 2013. Florida had 8 Level I trauma centers, 11 Level II trauma centers, 3 Level II and pediatric trauma centers, one joint pediatric center, and one stand-alone pediatric center.

Of the non-designated hospitals, 108 meet minimal state standards for EMS to deliver injured patients, leaving approximately 80 hospitals entirely outside the trauma system. The ratio of 28 designated trauma centers to 108 hospitals eligible to receive injured patients by EMS is more consistent with an exclusive trauma system model. The trauma center coverage mapping website from the University of Pennsylvania (www.traumamaps.org) reports that 89% of the land area and 98% of the population of Florida are within 1 hour of a Level I or Level II trauma center, compared to 35% of land area and 90% of population for the nation as a whole. Data supplied by the DOH estimates that Florida's population in 2011 as slightly over 19 million. Including provisional centers, this yields a ratio of 1.47 Level I or Level II trauma centers per million people on an aggregate basis. Review of specific metropolitan areas yields ratios as follows:

- 4.4 trauma centers per million in the Pensacola area,
- 2.7 trauma centers per million in the Tallahassee area,

- 1.8 trauma centers per million in the Tampa region,
- 1.4 trauma centers per million in South Florida and
- 1.4 trauma centers per million in the Orlando area.

These population ratios are roughly in the middle of national ratios, which range from about 0.3 to 6.6 trauma centers per million people.

The Trauma Program has a well-defined process for application, provisional designation, and verification of trauma centers at either Level I or Level II, including provisions that the designation of new trauma centers be based upon system need as well as facility capacity. System need has not been fully re-assessed since 1990, and the updated assessment in 2005 did not touch on all areas. As a result, significant disagreement has occurred over areas of need and the appropriateness of new provisional designations approved under the 1990 structure. To be provisionally designated, a hospital must submit a letter of intent to the DOH. If the hospital matches a "slot" identified in the 1990 plan, it is allowed to complete an application. The application is reviewed, and if found acceptable, the hospital is opened for treatment of trauma patients and local EMS transport protocols are adjusted. No on-site verification of capacity is required prior to allowing the facility to treat trauma patients. Verification is then granted after successful review approximately one year later.

The period for re-verification is set at 7 years, the longest interval for re-verification specified for any state in the nation. The standards for Level I and Level II trauma centers are roughly based on standards promulgated by the ACS-COT Trauma Center Verification program circa 1990, though the Florida standards are less comprehensive. The ACS-COT standards have been extensively reviewed and updated in the intervening years, while the Florida standards have not been revised.

Florida has no provisions for designation of trauma centers below Level II and no requirements for other hospitals that want to participate in the trauma system. Some EMS agencies have established minimal services that a hospital must have in order to receive injured patients from the field. No uniformity of these minimal hospital services exists, as some EMS service areas allow the transporting EMS providers to over-ride trauma transport protocols based upon their judgment. Statute authorizes the DOH to collect a minimum data set for all injured patients from all acute care hospitals, but no rule has been established for this statute, so data submission does not occur. The Trauma Program should establish the standards for all hospitals participating in the trauma system, including submission of data. Additionally the Trauma Program should consider whether development of Level III and Level IV trauma centers would be of benefit to the trauma system.

Florida was among the first states to require a needs analysis prior to trauma center designation, and the state established a comprehensive set of parameters upon which to make that judgment. However, the Trauma Program has not been able to keep pace with the needs assessment process required by statute. As a result, the process for trauma center designation has been based on an outdated model that no longer reflects the trauma system status or stakeholder perception. This mismatch in vision is

combined with a funding scheme that intensifies competition between trauma centers for patient volume. It has additionally caused the recent interest in new trauma center development to be highly contentious, and it is viewed as threatening to existing trauma centers. Intense disagreement about areas needing trauma centers has paralyzed the trauma system and disrupted cooperation between trauma centers.

Although Florida statute correctly identifies the attributes of an inclusive and integrated trauma system, the present system structure is that of an exclusive trauma system, with only Level I and Level II trauma centers having identified standards and data submission requirements. As noted above, the designation of new trauma centers is viewed as a threat to existing centers, when ideally these new centers could allow for better matching of patients to hospitals with appropriate capabilities. Rather than creating a threat to current trauma centers, the development of a true regional network of facilities with known capability will improve availability and efficiency of care to injured patients. Matching patients to the lowest level trauma center able to provide necessary care will ultimately optimize trauma system efficiency. It will decrease utilization of EMS resources and prevent the overload of higher level trauma centers resulting from the transfer of patients with minor injuries. Florida should realign its focus to facilitate a statutorily required goal of providing the most cost-efficient trauma care possible.

- Conduct an assessment of the current trauma system, including the parameters outlined in Florida statute 395.402, to inform decisions regarding the location and level of new trauma center designations.
- Establish a transparent and broadly-accepted process for future provisional trauma center designation based upon both capacity and trauma system need.
  - Work with stakeholder advisory groups to establish criteria for need.
  - Utilize findings from a newly conducted need assessment.
- Establish a transparent, broadly accepted process for initial full designation and ongoing re-designation based upon system participation, center performance, and participation in quality improvement programs.
  - Work with Florida Trauma System Advisory Committee (FTSAC) to establish criteria for initial and ongoing trauma center designation.
- Impose a moratorium on any new provisional or full trauma center designation until these new processes are in place.
- Require that all acute care facilities participate in the inclusive and integrated trauma system as a condition of licensure.
  - Designate each acute care facility at an appropriate level, either as a trauma center or a participating facility.

## • Require all facilities to submit at least a minimal set of data on every injured patient to the state registry.

- Revise current criteria for Level I and Level II trauma centers to reflect current national standards.
- Establish minimal standards and a minimal trauma dataset for hospitals participating in the trauma system that are not trauma centers.
- Consider the establishment of Level III and potentially Level IV trauma center designation status to more accurately reflect the capacity of designated facilities.
- Shorten the period of trauma center verification from 7 years to 3-5 years.
- Consider adoption of an external process, such as that provided by the American College of Surgeons, for trauma center verification to reduce the workload on Trauma Program personnel.
- Strengthen requirements for initial provisional trauma center designation to include on-site verification of institutional capacity and commitment.

#### **Purpose and Rationale**

To achieve the best possible outcomes, the system must be designed so that the right patient is transported to the right facility at the right time. Although on the surface this objective seems relatively straightforward, patients, geography, and transportation systems often conspire to present significant challenges. The most critically injured trauma patient is often easy to identify at the scene by virtue of the presence of coma or hypotension. However, in some circumstances, the patients requiring the resources of a Level I or II center may not be immediately apparent to prehospital providers. Primary or field triage criteria aid providers in identifying which patients have the greatest likelihood of adverse outcomes and might benefit from the resources of a designated trauma center. Even if the need is identified, regional geography or limited air medical (or land) transport services might not allow for direct transport to an appropriate facility.

Primary triage of a patient from the field to a center capable of providing definitive care is the goal of the trauma system. However, there are circumstances (for example, airway management, rural environments, inclement weather) when triaging a patient to a closer facility for stabilization and transfer is the best option for accessing definitive care. Patients sustaining severe injuries in rural environments might need immediate assessment and stabilization before a long-distance transport to a trauma center. In addition, evaluation of the patient might bring to light severe injuries for which needed care exceeds the resources of the initial receiving facility. Some patients might have specific needs that can be addressed at relatively few centers within a region (for example, pediatric trauma, burns, severe TBI, SCI, and reimplantation). Finally, temporary resource limitations might necessitate the transfer of patients between acute care facilities.

Secondary triage at the initial receiving facility has several advantages in systems with a large rural or suburban component. The ability to assess patients at non-designated or Level III to V centers provides an opportunity to limit the transfer of only the most severely injured patients to Level I or II facilities, thus preserving a limited resource for patients most in need. It also provides patients with lesser injuries the possibility of being cared for within their community.

The decision to transfer a trauma patient should be based on objective, prospectively agreed-on criteria. Established transfer criteria and transfer agreements will minimize discussions about individual patient transfers, expedite the process, and ensure optimal patient care. Delays in transfer might increase mortality, complications, and length of stay. A system with an excess of transferred patients might tax the resources of the regional trauma facility. Conversely, inappropriate retention of patients at centers without adequate facilities or expertise might increase the risk of adverse outcomes. Given the importance of timely, appropriate interfacility transfers, the time to transfer, as well as the rates of primary and secondary overtriage basis, and corrective actions should be instituted when problems are identified. Data derived from tracking and

monitoring the timeliness of access to a level of trauma care commensurate with injury type and severity should be used to help define optimal system configuration.

A central communications center with real-time access to information on system resources greatly facilitates the transfer process. Ideally, this center identifies a receiving facility, facilitates dialogue between the transferring and receiving centers, and coordinates interfacility transport.

To ensure that the system operates at the greatest efficiency, it is important that patients are repatriated back to community hospitals once the acute phase of trauma care is complete. The process of repatriation opens up the limited resources available to care for severely injured patients. In addition, it provides an opportunity to bring patients back into their local environment where their social network might help reintegrate patients into their community.

#### **Optimal Elements**

I. The trauma system is supported by an EMS system that includes communications, medical oversight, prehospital triage, and transportation; the trauma system, EMS system, and public health agency are well integrated. **(B-302)** 

- a. There are mandatory system-wide prehospital triage criteria to ensure that trauma patients are transported to an appropriate facility based on their injuries. These triage criteria are regularly evaluated and updated to ensure acceptable and system-defined rates of sensitivity and specificity for appropriately identifying a major trauma patient. (I-302.6)
- b. There is a universal access number for citizens to access the EMS/trauma system, with dispatch of appropriate medical resources. There is a central communications system for the EMS/trauma system to ensure field-to- facility bidirectional communications, interfacility dialogue, and all-hazards response communications among all system participants. **(I-302.7)**
- c. There is a procedure for communications among medical facilities when arranging for interfacility transfers, including contingencies for radio or telephone system failure. **(I-302.9)**

II. Acute care facilities are integrated into a resource-efficient, inclusive network that meets required standards and that provides optimal care for all injured patients. **(B-303)** 

a. When injured patients arrive at a medical facility that cannot provide the appropriate level of definitive care, there is an organized and regularly monitored system to ensure that the patients are expeditiously transferred to the appropriate system-defined trauma facility. **(I-303.4)** 

#### **Current Status**

Components of Florida's trauma transport protocols (TTPs) are described in rules Chapter 64J-2. The rules cover both adult and pediatric trauma patients. The rules state that TTPs will use the Adult Trauma Scorecard Methodology and the Pediatric Trauma Scorecard Methodology to establish "trauma alert" patients -- patients who will be transported to a trauma center. Florida does not use Centers for Disease Control (CDC) Trauma Field Triage Guidelines. The rule does not address interfacility transport or the use of air medical services.

The *Florida Regional Common EMS Protocols* manual includes the Trauma Transport Protocol (1.10) that uses the Adult and Pediatric Trauma Scorecard Methodologies. The protocol includes a brief section on interfacility transport as well as a section on helicopter transport procedures. The use of the protocols listed in the manual is not mandated by the state. Each EMS agency must develop a TTP, have it approved by the EMS agency's medical director and submit it to BEMO for review and approval. Some stakeholders expressed concern that often the TTPs are developed and submitted to BEMO without any input from the regional trauma centers. BEMO has no process to determine if the TTPs were developed with appropriate input from regional trauma centers and non-trauma center hospitals or if appropriate harmonization among TTPs for different EMS agencies has occurred within a specific trauma region.

No specific state mandated protocols address air medical transport of the trauma patient. Each EMS agency enters into a specific agreement with an air medical agency. That air medical service is required to follow the TTP of the EMS agency to which they are responding. No regular evaluation or performance improvement of rotor-wing trauma transport is conducted by BEMO or the Trauma Program.

Interfacility trauma transfer agreements are arranged independently between hospitals. The sending physician is responsible for arranging the transfer. No centralized real-time electronic information system or centralized communication center provides EMS providers or physicians with information regarding the availability of medical resources at various trauma centers or of the availability and location of EMS resources that could be of assistance with transport. Participants at the TSC meeting stated that, in general, they have little trouble transferring patients from a lower level facility to a higher level facility in a timely fashion. However, no representatives from non-trauma center hospitals were present.

Reports prepared by various academic trauma centers over the last several years using hospital discharge data found that a substantial number of trauma patients, who should go to a trauma center are not being transferred. This would suggest that the current TTP process in Florida is not optimal. Neither the state Trauma Program nor EMS Program regularly identifies the following through a performance improvement process:

- The frequency of EMS providers not complying with TTPs,
- The factors associated with episodes of non-compliance, and
- The outcomes of patients associated with episodes of non-compliance.

From a hospital perspective, the Trauma Program does not regularly determine the frequency of inappropriate decisions made by non-trauma center hospitals to transfer or not transfer patients to a trauma center, the reasons behind those decisions, or the outcomes associated with those patients. The state trauma system also does not

regularly evaluate the timeliness of interfacility trauma transfers, and its relationship to patient outcomes.

Additionally, the Trauma Program does not conduct performance improvement to determine if the appropriate application of the TTPs adequately identifies patients who need to go to trauma centers. Such information is needed to identify strategies to improve compliance with TTPs and the performance of appropriate and timely interfacility transport.

- Evaluate the content, implementation, and method of enforcement of the trauma transport protocols (TTPs) to assure uniformity and efficiency of patient flow both within trauma regions as well as statewide.
  - Engage the EMS and Trauma programs, the Florida Trauma System Advisory Council and the EMS Advisory Council.
  - Implement and adhere to the current Centers for Disease Control Trauma Field Triage Criteria.
- Task the Trauma Program with annual reporting on trauma center and nontrauma center destination and patient outcomes (initial destination and transfer).
  - Correct identified deficiencies in trauma system coordination and patient flow using structured performance improvement processes identified by the Trauma Program.
- Produce an annual report that evaluates the current status of air medical transport of trauma patients for both scene response and interfacility transport.

#### **Purpose and Rationale**

As an integral component of the trauma system, rehabilitation services in acute care and rehabilitation centers provide coordinated care for trauma patients who have sustained severe or catastrophic injuries, resulting in long-standing or permanent impairments. Patients with less severe injuries may also benefit from rehabilitative programs that enhance recovery and speed return to function and productivity. The goal of rehabilitative interventions is to allow the patient to return to the highest level of function, reducing disability and avoiding handicap whenever possible. The rehabilitation process should begin in the acute care facility as soon as possible, ideally within the first 24 hours. Inpatient and outpatient rehabilitation services should be available. Rehabilitation centers should have CARF (Commission on Accreditation of Rehabilitation Facilities) accreditation for comprehensive inpatient rehabilitation programs, and accreditation of specialty centers (SCI and TBI) should be strongly encouraged.

The trauma system should conduct a rehabilitation needs assessment (including specialized programs in SCI, TBI, and for children) to identify the number of beds needed and available for rehabilitation in the geographic region. Rehabilitation specialists should be integrated into the multidisciplinary advisory committee to ensure that rehabilitation issues are integrated into the trauma system plan. The trauma system should demonstrate strong linkages and transfer agreements between designated trauma centers and rehabilitation facilities located in its geographic region (in or out of state). Plans for repatriation of patients, especially when rehabilitation centers across state lines are used, should be part of rehabilitation system planning. Feedback on functional outcomes after rehabilitation should be made available to the trauma centers.

#### **Optimal Elements**

I. The lead agency ensures that adequate rehabilitation facilities have been integrated into the trauma system and that these resources are made available to all populations requiring them. **(B-308)** 

- a. The lead agency has incorporated, within the trauma system plan and the trauma center standards, requirements for rehabilitation services, including interfacility transfer of trauma patients to rehabilitation centers. **(I-308.1)**
- b. Rehabilitation centers and outpatient rehabilitation services provide data on trauma patients to the central trauma system registry that include final disposition, functional outcome, and rehabilitation costs and also participate in performance improvement processes. **(I-308.2)**

II. A resource assessment for the trauma system has been completed and is regularly updated. **(B-103**)

 a. The trauma system has completed a comprehensive system status inventory that identifies the availability and distribution of current capabilities and resources. (I-103.1)

#### **Current Status**

Florida has at least 38 in-patient rehabilitation facilities that are accredited by the Commission on Accreditation of Rehabilitation Centers (CARF). Of these, 29 are statedesignated inpatient rehabilitation facilities that specifically meet the needs for adult and pediatric patients with traumatic brain injury (TBI) and spinal cord injury (SCI). The majority of adult trauma centers have a rehabilitation facility within each geographic catchment area; however, the Panhandle area has more limited access to rehabilitation centers. The pediatric rehabilitation facilities are geographically situated to cover the North (Jacksonville), Central (Tampa), and South (Miami) areas of the state.

The rehabilitation community appears to be well integrated with the trauma system, and it is adequately represented in committees at multiple levels. The Brain and Spinal Cord Injury Program (BSCIP) has responsibility for overseeing the programs that specialize in the care of TBI and SCI populations. Although an inventory of rehabilitation facilities specializing in the care of TBI and SCI patients exists, no such comprehensive inventory of all rehabilitation facilities for care of other injured patients was reported. Therefore, the total number of rehabilitation beds for injured patients in Florida is not available. No waiting list for in-patient rehabilitation beds is currently being maintained. An estimated 33% to 50% of TBI patients are admitted to rehabilitation facilities specialized in TBI care. Insurance status was reported as the major determinant of the rehabilitation center/program to which patients are transferred. Participants also expressed concerns that older adults may have sub-optimal access and delivery of rehabilitation services.

Florida has a strong emphasis on TBI and SCI within the rehabilitation community, and these prominent programs have a committed constituency. Significant program successes include the following:

- The immediate reporting of TBI and SCI in-patients to the BSCIP registry,
- Referral of TBI and SCI patients to a regional case manager who begins providing an innovative process of care,
- An experimental and innovative program for surgical implantation of diaphragmatic pacers for SCI patients who are unable to wean from mechanical ventilation (many have been subsequently weaned from ventilation), and
- A well-funded trust fund to help pay for TBI and SCI patient services.

#### Recommendations

• Maintain and regularly update a comprehensive inventory of licensed rehabilitation centers and beds available to treat trauma patients.

- Evaluate the access to and delivery of rehabilitation services for the geriatric trauma population on a regional basis. Repeat every 3-5 years.
- Evaluate the access to and delivery of rehabilitation services to uninsured patients.

#### **Purpose and Rationale**

As critically important resources for state, regional, and local responses to MCIs, the trauma system and its trauma centers are central to disaster preparedness. Trauma system leaders need to be actively involved in public health preparedness planning to ensure that trauma system resources are integrated into the state, regional, and local disaster response plans. Acute care facilities (sometimes including one or more trauma centers) within an affected community are the first line of response to an MCI. However, an MCI may result in more casualties than the local acute care facilities can handle, requiring the activation of a larger emergency response plan with support provided by state and regional assets.

For this reason, the trauma system and its trauma centers must conduct a resource assessment of its surge capacity to respond to MCIs. The resource assessment should build on and be coupled to a hazard vulnerability analysis. An assessment of the trauma system's response to simulated incident or tabletop drills must be conducted to determine the trauma system's ability to respond to MCIs. Following these assessments, a gap analysis should be conducted to develop statewide MCI response resource standards. This information is essential for the development of an emergency management plan that includes the trauma system.

Planning and integration of the trauma system with plans of related systems (public health, EMS, and emergency management) are important because of the extensive impact disasters have on the trauma system and the value of the trauma system in providing care. Relationships and working cooperation between the trauma system and public health, EMS, and emergency management agencies support the provision of assets that enable a more rapid and organized disaster response when an event occurs. For example, the EMS emergency preparedness plan needs to include the distribution of severely injured patients to trauma centers, when possible, to make optimal use of trauma center resources. This plan could optimize triage through directing less severely injured patients to lower level trauma centers or nondesignated facilities, thus allowing resources in trauma centers to be spared for patients with the most severe injuries. In addition, the trauma system and its trauma centers will be targeted to receive additional resources (personnel, equipment, and supplies) during major MCIs.

Mass casualty events and disasters are chaotic, and only with planning and drills will a more organized response be possible. Simulation or tabletop drills provide an opportunity to test the emergency preparedness response plans for the trauma system and other systems and to train the teams that will respond. Exercises must be jointly conducted with other agencies to ensure that all aspects of the response plan have the trauma system integrated.

#### **Optimal Elements**

I. An assessment of the trauma system's emergency preparedness has been completed, including coordination with the public health agency, EMS system, and the emergency management agency. **(B-104)** 

- a. There is a resource assessment of the trauma system's ability to expand its capacity to respond to MCIs in an all-hazards approach. **(I-104.1)**
- b. There has been a consultation by external experts to assist in identifying current status and needs of the trauma system to be able to respond to MCIs. (I-104.2)
- c. The trauma system has completed a gap analysis based on the resource assessment for trauma emergency preparedness. **(I-104.3)**

II. The lead agency ensures that its trauma system plan is integrated with, and complementary to, the comprehensive mass casualty plan for natural and manmade incidents, including an all-hazards approach to planning and operations. **(B-305)** 

- a. The EMS, the trauma system, and the all-hazards medical response system have operational trauma and all-hazards response plans and have established an ongoing cooperative working relationship to ensure trauma system readiness for all-hazards events. **(I-305.1)**
- b. All-hazards events routinely include situations involving natural (for example, earthquake), unintentional (for example, school bus crash), and intentional (for example, terrorist explosion) trauma-producing events that test the expanded response capabilities and surge capacity of the trauma system. **(I-305-2)**
- c. The trauma system, through the lead agency, has access to additional equipment, materials, and personnel for large-scale traumatic events. (I-305.3)

#### **Current Status**

As a result of 9/11 and the devastation from multiple hurricanes, Florida has developed impressive health and medical response plans and amassed caches of medical assets. With stakeholder support, the DOH has developed a mass casualty incident (MCI) plan and surge capacity plan. The DOH, EMS, hospitals, and the community have regularly exercised these plans, generated after-action reports, and acted upon some of the recommendations. An example of their efforts was the Tempest Guards exercise where hospitals were found to need increased security and decontamination procedures.

The DEPCS administers the Public Health Emergency Preparedness (PHEP) and ASPR funding to support various public health and healthcare provider disaster planning and response. Over the past 10 years, \$46 million have been provided to trauma centers from the ASPR grant to build response capabilities for burn and surge capacity planning, exercises, training, and equipment. This grant funding has also

supported the development of six state medical teams and mobile medical assets including 3 Gateway shelter systems.

Florida is also in the process of implementing a disaster management system (e.g., EMResource and HavBed) that includes healthcare resources and patient tracking. However, the disaster management system is not yet inclusive of all healthcare providers (EMS, dispatch, hospitals) statewide. The Trauma Program should investigate the application of these resources for monitoring patient flow and coordination on a regional and statewide basis.

Florida has developed a wonderful model for telemedicine called Florida Emergency Trauma Telemedicine Network (FETTN) and SPARROWnet. The telemedicine system provides urgent consultation and educational capabilities, and it was used to provide care following the Haiti earthquake disaster. The first state activation occurred as tropical storm Isaac approached the Florida coast. The successful activation of the telemedicine system demonstrated the benefit of the state's ability to enhance communications for state health, trauma, and healthcare systems. Future expansion of the FETTN system should include the integration of more trauma centers and participating trauma hospitals, as well as developing protocols for use of the system.

Through the ASPR grant, the DEPCS is working to establish healthcare coalitions. These coalitions should include all healthcare providers: EMS, dispatch, hospitals, trauma centers, burn centers, nursing homes, emergency management, local public health, and public safety. Seven Regional Domestic Security Task Force Regions (RDSTFR) were created after 9/11 with Homeland Security funding. These regions offer a natural structure for the further development of healthcare coalitions, TSAs, and EMS regions. The healthcare coalitions, along with a state Medical Advisory Committee, can form the infrastructure to support development of crisis standards of care guidelines for hospitals and EMS. Bringing trauma stakeholders together to participate in this process may help launch, and provide a focus for, regional trauma system planning.

EMS agencies and the state fire chiefs have also been active in statewide disaster planning efforts. The DOH has developed an ambulance deployment plan which is well integrated with the State Fire Emergency Response Team plans.

The state EMS and Trauma Program staff members are trained in the National Incident Management System (NIMS) and the Incident Command Structure. They have taken numerous courses to support the ESF 8 leadership role for the DOH in the event of a disaster. The BEMO staff members have response roles and responsibilities in the event of a disaster and serve at the SEOC on the SERT.

Florida has developed a communications system that is both redundant and provides interoperability. This communications capability includes – operation radar and mobile field communication teams with trailer assets that can establish voice communications.

- Develop the healthcare coalitions and align with the seven Regional Domestic Security Task Force Regions.
  - Ensure that the disaster medical response plans are integrated through regional planning between members of the healthcare coalition (hospitals, EMS, fire, public health, dispatch, emergency management and law enforcement).
- Seek additional funding for further development and implementation of the Florida Emergency Trauma Telemedicine Network (FETTN) and SPARROWnet systems to support disaster response.
- Establish a state medical advisory council, including the state EMS and trauma medical directors, to develop crisis standards of care guidelines.
- Seek funding for further development of the real-time resources such as the EMresource and HAvBED systems for disaster resource management and patient tracking.
  - o Include all acute care hospitals, EMS agencies, and dispatch agencies.

#### **Purpose and Rationale**

The trauma lead agency has responsibility for instituting processes to evaluate the performance of all aspects of the trauma system. Key aspects of system-wide effectiveness include the outcomes of population based injury prevention initiatives, access to care, as well as the availability of services, the quality of services provided within the trauma care continuum from prehospital and acute care management phases through rehabilitation and community reintegration, and financial impact or cost. Intrinsic to this function is the delineation of valid, objective metrics for the ongoing quality audit of system performance and patient outcomes based on sound benchmarks and available clinical evidence. Trauma management information systems (MISs) must be available to support data collection and analysis.

The lead agency should establish forums that promote inclusive multidisciplinary and multiagency review of cases, events, concerns, regulatory issues, policies, procedures, and standards that pertain to the trauma system. The evaluation of system effectiveness must take into account the integration of these various components of the trauma care continuum and review how well personnel, agencies, and facilities perform together to achieve the desired goals and objectives. Results of customer satisfaction (patient, provider, and facility) appraisals and data indicative of community and population needs should be considered in strategic planning for system development. System improvements derived through evaluation and quality assurance activities may encompass enhancements in technology, legislative or regulatory infrastructure, clinical care, and critical resource availability.

To promote participation and sustainability, the lead agency should associate accountability for achieving defined goals and trauma system performance indicators with meaningful incentives that will act to cement the support of key constituents in the health care community and general population. For example, the costs and benefits of the trauma system as they relate to reducing mortality or decreasing years of productive life lost may make the value of promoting trauma system development more tangible. A facility that achieves trauma center verification/designation may be rewarded with monetary compensation (for example, ability to bill for trauma activation fees) and the ability to serve as a receiving center for trauma patients. The trauma lead agency should promote ongoing dialog with key stakeholders to ensure that incentives remain aligned with system needs.

#### **Optimal Elements**

I. The trauma MIS is used to facilitate ongoing assessment and assurance of system performance and outcomes and provides a basis for continuously improving the trauma system, including a cost-benefit analysis. **(B-301)** 

a. The lead trauma authority ensures that each member hospital of the trauma system collects and uses patient data, as well as provider data, to assess system performance and to improve quality of care. Assessment data are routinely submitted to the lead trauma authority. **(I-301.1)** 

II. The jurisdictional lead agency, in cooperation with other agencies and organizations, uses analytic tools to monitor the performance of population based prevention and trauma care services. **(B-304)** 

III. The financial aspects of the trauma system are integrated into the overall performance improvement system to ensure ongoing fine tuning and cost-effectiveness. **(B-309)** 

a. Financial data are combined with other cost, outcome, or surrogate measures, for example, years of potential life lost, quality-adjusted life years, and disability adjusted life years; length of stay; length of intensive care unit stay; number of ventilator days; and others, to estimate and track true system costs and costbenefits. **(I-309.4)** 

#### **Current Status**

A review of the *Florida Trauma Registry Report*, the *State Trauma System Annual Report*, *Trauma Service Area Analysis Report*, and the *Modes of Transportation Report*, revealed that the Trauma Program has done an excellent job in compiling the available trauma registry data to provide a framework for trauma system evaluation. However, the data analysis has some limitations because Florida does not currently collect trauma data from all hospitals and all EMS providers. As a result, a comprehensive and accurate picture of patient flow and appropriate patient destination (including over- and under-triage) is not possible. Ultimately, the trauma system data analysis should make it possible to determine if the right patient gets to the right facility at the right time.

Even with limitations in data quality and completeness, the *Annual Report of Florida Trauma System Performance* was published. This report applied the Trauma Quality Improvement Program (TQIP) methodology, which is an assessment of trauma center performance as a ratio of expected outcome. It was determined that many trauma centers were operating within expectations. All trauma centers should be encouraged to use the TQIP process for facility PI. TSC participants expressed strong support for using TQIP for trauma center performance improvement, and then using this methodology as a platform for state trauma system evaluation. The Trauma Program is investigating the addition of TQIP data elements into the next generation Florida Trauma Registry.

The Trauma Program does not currently have an active trauma system advisory council or a multidisciplinary PI committee to provide oversight for management of a state PI process. Even though the PI, trauma registry, and research planning teams continue to meet, the agendas reflect a focus on the next generation trauma registry, data dictionary updates, injury prevention activities, and the timeliness of data submission. However, some prior systemwide PI efforts led to changes in protocols for tourniquets, burn care, TBI care, and rural trauma care.

Florida has not developed a regional infrastructure to implement and support PI activities for an inclusive trauma system. Additionally, a state PI plan has not yet been developed to provide strategic guidance to evaluate issues affecting the trauma system, including defined processes and measures.

- Reactivate the state Performance Improvement Committee as a subcommittee of the Florida Trauma System Advisory Council (FTSAC) to develop a statewide performance improvement (PI) plan.
  - Ensure that the PI plan outlines the PI process at the provider, regional, and state levels and includes process, structure and outcome measures.
  - Review PI plan templates from other states to guide development of the Florida PI plan.
  - Ensure that the PI plan includes all aspects of trauma care and trauma system performance.
  - Use data from all continuum-of-care participants including trauma centers, non-trauma hospitals, rehabilitation centers, EMS providers and dispatch for system evaluation.
  - Include population-based data.
- Continue efforts to integrate the Trauma Quality Improvement Program (TQIP) data elements into the next generation Florida Trauma Registry to provide a baseline for the state trauma system performance improvement.
- Establish a regional PI infrastructure consistent with the Regional Domestic Security Task Force Regions, providing medical representation and state and/or regional staff support.
  - Routinely monitor the EMS triage and transport guidelines and protocols for compliance.
  - Conduct regional PI workshops to educate the continuum-of-care providers on the statewide PI plan, process and measures.
  - Include the assessment of over and under triage in the systemwide performance improvement process as the data system becomes more inclusive.

• Require all Florida trauma centers to participate in a statewide or national riskadjusted benchmarking process.

#### **Purpose and Rationale**

Hospital-based trauma registries developed from the idea that aggregating data from similar cases may reveal variations in care and ultimately result in a better understanding of the underlying injury and its treatment. Hospital-based registries have proven very effective in improving trauma care within an institution but provide limited information regarding how interactions with other phases of health care influence the outcome of an injured patient. To address this limitation, data from hospital-based registries should be collated into a regional registry and linked such that data from all phases of care (prehospital, hospital, and rehabilitation) are accessible in 1 data set. When possible, these data should be further linked to law enforcement, crash incident reports, ED records, administrative discharge data, medical examiner records, vital statistics data (death certificates), and financial data. The information system should be designed to provide system-wide data that allow and facilitate evaluation of the structure, process, and outcomes of the entire system; all phases of care; and their interactions. This information should be used to develop, implement, and influence public policy.

The lead agency should maintain oversight of the information system. In doing so, it must define the roles and responsibilities for agencies and institutions regarding data collection and outline processes to evaluate the quality, timeliness, and completeness of data. There must be some means to ensure patient and provider confidentiality is in keeping with federal regulations. The agency must also develop policies and procedures to facilitate and encourage injury surveillance and trauma care research using data derived from the trauma MIS. There are key features of regional trauma MISs that enhance their usefulness as a means to evaluate the quality of care provided within a system. Patient information collected within the management system must be standardized to ensure that noted variations in care can be characterized in a similar manner across differing geographic regions, facilities, and EMS agencies. The composition of patients and injuries included in local registries (inclusion criteria) should be consistent across centers, allowing for the evaluation of processes and outcomes among similar patient groups. Many regions limit their information systems to trauma centers. However, the optimal approach is to collect data from all acute care facilities within the region. Limiting required data submission to hospitals designated as trauma centers allows one to evaluate systems issues only among patients transported to appropriate facilities. It is also important to have protocols in place to ensure a uniform approach to data abstraction and collection. Research suggests that if the process of case abstraction is not routinely calibrated, practices used by abstractors begin to drift.

Finally, every effort should be made to conform to national standards defining processes for case acquisition, case definition (that is, inclusion criteria), and registry coding conventions. Two such national standards include the National Highway Traffic Safety Administration's National Emergency Medical Services Information System (NEMSIS), which standardizes EMS data collection, and the American College of

Surgeons National Trauma Data Standard, which addresses the standardization of hospital registry data collection. Strictly adhering to national standards markedly increases the value of state trauma MISs by providing national benchmarks and allowing for the use of software solutions that link data sets to enable a review of the entire injury and health care event for an injured patient.

To derive value from the tremendous amount of effort that goes into data collection, it is important that a similar focus address the process of data reporting. Dedicated staff and resources should be available to ensure rapid and consistent reporting of information to vested parties with the authority and vision to prevent injuries and improve the care of patients with injuries. An optimal information reporting process will include standardized reporting tools that allow for the assessment of temporal and/or system changes and a dynamic reporting tool, permitting anyone to tailor specific "views" of the information.

#### **Optimal Elements**

I. There is an established trauma MIS for ongoing injury surveillance and system performance assessment. **(B-102)** 

- a. There is an established injury surveillance process that can, in part, be used as an MIS performance measure. **(I-102.1)**
- b. Injury surveillance is coordinated with statewide and local community health surveillance. (I-102.2)
- c. There is a process to evaluate the quality, timeliness, completeness, and confidentiality of data. **(I-102.4)**
- d. There is an established method of collecting trauma financial data from all health care facilities and trauma agencies, including patient charges and administrative and system costs. **(I-102.5)**

II. The trauma MIS is used to facilitate ongoing assessment and assurance of system performance and outcomes and provides a basis for continuously improving the trauma system, including a cost-benefit analysis. **(B-301)** 

- a. The lead trauma authority ensures that each member hospital of the trauma system collects and uses patient data, as well as provider data, to assess system performance and to improve quality of care. Assessment data are routinely submitted to the lead trauma authority. **(I-301.1)**
- b. Prehospital care providers collect patient care and administrative data for each episode of care and not only provide these data to the hospital, but also have a mechanism to evaluate the data within their own agency, including monitoring trends and identifying outliers. **(I-301.2)**
- c. Trauma registry, ED, prehospital, rehabilitation, and other databases are linked or combined to create a trauma system registry. **(I-301.3)**

d. The lead agency has available for use the latest in computer/technology advances and analytic tools for monitoring injury prevention and control components of the trauma system. There is reporting on the outcome of implemented strategies for injury prevention and control programs within the trauma system. (I-301.4)

#### **Current Status**

The management information system that supports the planning and evaluation of the Florida trauma system is, clearly, a work in progress. Multiple datasets are available, but the most essential of these for trauma system planning and evaluation are in evolutionary stages.

The current Florida trauma registry has existed since 2008. It was originally developed in a common database program (MS Access<sup>™</sup>). Challenges were encountered when attempting to import data from various hospital-based trauma registries. This precluded routine reporting back to the trauma centers and use of the data for trauma system planning. Recently, an annual report was produced that mirrors the ACS National Trauma Data Bank (NTDB) report. This provided a high level overview of the demographic characteristics of the Florida trauma centers with some limited comparisons to national data in NTDB.

Due to the acknowledged limitations in the existing trauma registry, including its inability to produce meaningful information in a timely manner, the Trauma Program, in collaboration with trauma data stakeholders, has undertaken a process to upgrade the state trauma registry. Reportedly, the new registry will be NTDB compliant, and it will have embedded transaction capabilities to facilitate data transfers from individual trauma centers and uploads to the NTDB. A well-known vendor with clients in multiple states has received the contract to create the next generation trauma registry. The projected implementation date is July 1, 2013. Once the new trauma registry is operational, training should be offered to all trauma registrars along with inter-rater reliability assessment to ensure the consistency of data submitted.

While waiting for the trauma registry to become operational and have adequate data for analysis, work should begin on identifying a list of reports that will be useful for assessment of the trauma system, development of the trauma system plan, and system PI. One or more work groups of trauma medical directors, trauma program managers, EMS providers, and system leadership could be selected. Involving the epidemiologist early in the process will provide opportunities for sample reports to be run once some data are available so that it can be determined if additional refinement is needed.

- Complete the implementation of the next generation trauma registry.
  - Ensure participation by all hospitals.
- Provide training to trauma registrars to ensure consistency in data entry.

- Complete and report inter-rater reliability checks between and among hospital trauma registrars.
- Identify and convene a work group consisting of trauma medical directors, trauma program managers, EMS providers, and trauma system planners (possibly under the Florida Trauma System Advisory Committee (FTSAC) or trauma program managers group) to:
  - Develop a list of reports that will be essential to the revision of the trauma system plan (distribution of patients, transfer patterns, time to definitive care [field and transfer], etc.)
  - Conduct modeling of changes in distribution of patients, transfer patterns, and times to definitive care (field and transfer) (may need to work with urban planners or similar for modeling techniques).
- Assign the FTSAC with the development of a list of standardized reports to be run on a quarterly basis that will assist in ongoing performance monitoring of the trauma system.
  - Maintain the same list of reports for at least one full year before adaptation, deletion, or substitution.
  - Distribute the reports widely to stakeholders and advisory bodies.
- Continue to work toward data linkage of the Emergency Medical Services Tracking and Reporting System (EMSTARS), the hospital discharge data, motor vehicle crash, and other datasets to better inform trauma system planning, development, monitoring, and evaluation.

#### **Purpose and Rationale**

#### **Overview of Research Activity**

Trauma systems are remarkably diverse. This diversity is simply a reflection of authorities tailoring the system to meet the needs of the region based on the unique combination of geographic, economic, and population characteristics within their jurisdiction. In addition, trauma systems are not fixed in their organization or operation. The system evolves over years in response to lessons learned, critical review, and changes in population demographics. Given the diversity of organization and the dynamic nature of any particular system, it is valuable when research can be conducted that evaluates the effectiveness of the regional or statewide system. Research drives the system and will provide the foundation for system development and performance improvement. Research findings provide value in defining best practices and might alter system development. Thus, the system should facilitate and encourage trauma-related research through processes designed to make data available to investigators. Competitive grants or contracts made available through lead authorities or constituencies should provide funds to support research activities. All system components should contribute to the research agenda. The extent to which research activities are required should be clearly outlined in the trauma system plan and/or the criteria for trauma center designation.

The sources of data used for research might be institutional and regional trauma registries. As an alternative, population-based research might provide a broader view of trauma care within the region. Primary data collection, although desirable, is expensive but might provide insights into system performance that might not be otherwise available.

#### Trauma Registry-based Research

Investigators examining trauma systems can use the information recorded in trauma registries to great advantage to determine the prevalence and annual incidence rate of injuries, patterns of care that occur to injured patients in the system's region, and outcomes for the patients. These data can be compared with standards available from other trauma registries, such as the NTDB. Such comparisons can then enable investigators to determine if care within their region is within standards and can allow for benchmarking. Initiating and sustaining injury prevention initiatives is a vital goal in mature trauma systems. Investigators can take a leadership role in performing research using trauma registry data that identify emerging threats and instituting public health measures to mitigate the threats. For example, a recent surge in death and disability related to off -road vehicles can be identified and the scope of the problem defined in terms of who, where, and how riders are injured, and then, through presentations and publications, the public can be informed of a new threat.

Trauma system administrators have a responsibility to control investigators' access to the registry. The integrity and reliability of data in a trauma systems registry are essential if accurate research and valid conclusions are to be reached using the data. Trauma system administrators should have a process that screens data entered into the system's composite registry from individual institutions. There should be a mechanism that ensures that the information is stored in a secure manner. Investigators who seek access to the trauma registry must follow a written policy and procedure that includes approval by an authorized institutional review board. Trauma registry data may include unique identifiers, and system administrators must ensure that patient confidentiality is respected, consistent with state and federal regulations.

#### Population-based Trauma System Research

A major disadvantage of using only trauma registry data to conduct research that evaluates injured patients in a region is the bias resulting from missing data on patients not treated at trauma centers. Specifically, most registry data are restricted to information from hospitals that participate in the trauma system. Although ideally all facilities participate in the form of an inclusive system, many systems do not attain this goal. Thus, a population-based data set provides investigators with the full spectrum of patients, irrespective of whether they have been treated in trauma centers or nondesignated centers or were never admitted to the hospital owing to death at the scene of incident or because their injuries were insufficiently severe to require admission. The state and national hospital discharge databases are examples of population-based data. These discharge databases contain information that was abstracted from medical records for billing purposes by hospital employees who enter these data into an electronic database. For investigators seeking a wider perspective on the care of injured patients in their region, these more inclusive data sets, compared with registries, are essential tools. Other population based data that may be of help include mortality vital statistics data recorded in death certificates. Selected regions might have outpatient data to capture patients who are assessed in the ED and then released.

Investigators can use these population-based data to study the influence of a regional trauma system on the entire spectrum of patients within its catchment area.

#### Participation in Research Projects and Primary Data Collection

Multi-institutional research projects are important mechanisms for learning new knowledge that can guide the care of injured patients. Investigators within trauma systems can participate as coinvestigators in these projects. Investigators can participate by recruiting patients into prospective studies, being leaders in the design and administration of grants, and preparing manuscripts and reports. Evidence of this collaboration is that investigators within a trauma system are recognized in announcements of grants or awards. Lead agency personnel should identify and reach out to resources within the system with research expertise. These include academic centers and public health agencies.

#### Measures of Research Activity

Research can be broadly defined as hypothesis-driven data analysis. This analysis leads the investigators to a conclusion, which might become a recommendation for system change. Full manuscripts published in peer reviewed research journals are an exemplary form of research activity. Research reported in annual reviews or in public information formats intended to inform the trauma system's constituency can also be considered legitimate research activity.

#### **Optimal Elements**

I. The trauma MIS is used to facilitate ongoing assessment and assurance of system performance and outcomes and provides a basis for continuously improving the trauma system, including a cost-benefit analysis. **(B-301)** 

a. The lead agency has available for use the latest in computer/technology advances and analytic tools for monitoring injury prevention and control components of the trauma system. There is reporting on the outcome of implemented strategies for injury prevention and control programs within the trauma system. (I-301.4)

II. The lead agency ensures that the trauma system demonstrates prevention and medical outreach activities within its defined service area. **(B-306)** 

- a. The trauma system has developed mechanisms to engage the general medical community and other system participants in their research findings and performance improvement efforts. **(I-306.1)**
- b. The effect or impact of outreach programs (medical community training/support and prevention activities) is evaluated as part of a system performance improvement process. **(I-306.3)**

III. To maintain its state, regional, or local designation, each hospital will continually work to improve the trauma care as measured by patient outcomes. **(B-307)** 

a. The trauma system implements and regularly reviews a standardized report on patient care outcomes as measured against national norms. (I-307.2)

#### **Current Status**

Many of the Florida trauma centers have an extensive history of conducting trauma research. Additionally, many EMS agencies have a long history of being involved in EMS research, including trauma-related EMS research. Currently, several trauma research studies being conducted at Florida trauma centers are being supported by federal funding. Participants described how the Florida COT had a research subcommittee which provided some advice to the Trauma Program regarding research issues and priorities, but that subcommittee is no longer active. Some participants stated that they are attempting to independently form trauma regions to conduct translational research.

The State Surgeon General stated that he plans to develop a Trauma Research Agenda. However, within the PRQ, the Trauma Program stated it did not have a role in conducting trauma research. The PRQ further states that trauma research, whether clinical or focused on injury prevention, is the responsibility of the state's trauma centers. No role was reported for the Trauma Program to plan a strategy to identify trauma system research priorities, to facilitate trauma system research collaboration, or to use its infrastructure and data for research. No information was provided to indicate if or how the Trauma Program would work with trauma center researchers to identify funding opportunities or collaborations with state agencies that could result in potential funding of trauma system research.

Data from the current trauma system registry are not available to researchers. The Trauma Program anticipates that data from the next generation trauma registry will be available to researchers in the near future. Minimal consideration has been given to formatting data or developing various types of datasets that would reduce technical and regulatory burdens for investigators.

Recent state reports regarding the Florida trauma system do not highlight the research being conducted by the designated trauma centers. Including such information in such reports could help demonstrate some of the important contributions made by the trauma system to the health and well-being of Florida residents and to the nation.

Many stakeholders, especially the younger trauma center medical directors, are eager to conduct research within the trauma system. The Trauma Program has tremendous opportunities to facilitate research that will benefit the Florida residents, and also underscore the value of the trauma system.

- Create a research committee of the Florida Trauma System Advisory Council.
  - Develop a state Trauma Research Agenda.
  - Develop state, regional, and facility policies and operating procedures to limit administrative and regulatory burdens for investigators to use trauma system data.
  - o Identify potential opportunities for research funding.
  - Reach out to potential research collaborators with funding sources.
- Identify potential resources and potential collaborators for research within the state.
- Compile a list of on-going and recently completed trauma research within the state on an annual basis and publish it on the Trauma Program website.
- Seek guidance to ensure that data submitted to the next generation trauma registry are stored and formatted in a way that will facilitate analysis and data sharing.

#### **Focus Questions**

#### Focus Question 1

Geographical areas: Florida has 19 trauma service areas (TSAs) per s. 395.402 (4)(a), Florida Statutes. Florida also has seven Domestic Security Task Force (DSTF) regions, which are stated in s. 395.402 (2)(e), Florida Statutes. Statute requires that this regional structure be included as a geographical consideration in trauma system planning and integration with emergency and disaster planning.

# • Which geographical representation (TSAs or DSTF or other) would best promote an inclusive, sustainable trauma system with safe, effective, and efficient care?

A strong regional infrastructure will be a critical element in the implementation of a more integrated inclusive trauma system in Florida. A regional structure is necessary to allow for local adaptation of the core policies that form the basis of the trauma system. The regions will also provide the primary structure for a systemwide PI program. The need for a regional structure was recognized in the original 1990 plan, but the regions created were too small in most cases. Additionally, no funding was provided for the necessary administrative support of the regions. The existing TSAs bear no geographical or political relationship to regional structures established for EMS, disaster, or other related activities. Therefore, efforts to simply re-invigorate or re-develop the original TSA structure are unlikely to be efficient or effective.

As stated in the report, the TSC team recommends that the DSTF regions be adopted as the regional template for further trauma system development. A smaller number of regions covering a larger geographic area will enable more effective regional development. Alignment with the domestic security program may help identify additional resources (personnel and fiscal) to support regional trauma system development. The alignment of regional structures for the various overlapping elements of trauma systems, disaster response, and domestic security will facilitate a more integrated and cooperative relationship that will strengthen each of the component parts.

 What geographical characteristics (e.g., county groups, geographic measurement, proximity to existing trauma centers, EMS distances) are most relevant in apportionment of trauma centers?

Historically, simple geographic proximity and acceptably short transport times to a trauma center have been primary factors in the assessment of trauma center distribution, at least on a theoretical basis. While the notion of concentric rings around trauma centers representing distance or transport time provides a very gross measure of likely placement, it does offer a starting point for discussions. Common benchmarks use a 60 minute maximum transport time (based upon the relatively arbitrary concept of the "golden hour") and a maximum transport distance of 50 to 100 miles. Planning must also take into account issues such as natural barriers, transportation resources, the

potential for extreme weather conditions, man-made barriers (traffic, crashes, parades, etc.), and real or perceived threats of terrorism. Several computer-based modeling approaches can be used to evaluate these factors and to assess the effect of placing a trauma center at a given geographical location.

Evaluation of geographical catchment areas must be conducted. A balance between a sufficient population base to justify the resource expenditure for a new trauma center must be determined while at the same time ensuring that sufficient trauma center capacity exists to care for the injured population. The population base needed to support a Level I or Level II trauma center is dependent upon a number of factors, including the type and frequency of injuries, population demographics, and policy based decisions around system redundancy, surge capacity, and financial investment. As a result, the population base may range between 350,000 to more than 1,000,000 persons per Level I or Level II trauma center.

Both of the analyses above focus primarily upon high-level centers (Level I and II). However, with an inclusive model it is likely that trauma system access through lower level centers (Level III and possibly Level IV) is a more important metric, allowing for initial evaluation and stabilization prior to transport to higher level centers as needed. The location and capacity of these lower level trauma system resources modifies and enhances the optimal distribution of high level centers. By filling in the background information with these resources (Level III and Level IV trauma centers plus participating non-trauma center facilities), the need, location, and level of higher level trauma centers may become more focused.

## • What non-geographical characteristics should be considered in apportionment of trauma centers?

From a practical standpoint, geographical characteristics for decision making are inherently limited by the fact that almost all trauma systems have existing facilities with relatively fixed capabilities. It is quite difficult to either build a new trauma center at a desired location, or to remove one from an undesired location. Some degree of geographic or temporal maldistribution occurs in all states, but this can be compensated for by optimizing patient flow. For example, initial access to the trauma system can be provided through the inclusive network of lower level trauma centers or trauma participating facilities with appropriate interfacility transfer processes. Longer distance primary transport to high-level centers can be reserved for appropriate cases.

Other issues that must be considered are during discussions of placement and levels of trauma centers include:

- The balance between system redundancy and patient volume per trauma center. This is especially critical in areas of high vulnerability, either to mass casualty events or to the potential loss of individual centers
- Social support systems for injured persons and facilitating their return to the community. Patients who are displaced long distances from home face significant challenges in follow-up, rehabilitation, and reintegration

- Support for training/teaching missionsSystem costs and efficiencies

Appendix D provides additional information pertaining to this focus question.

#### Focus Question 2

# Trauma Center Surgeon Salaries and On-call Pay: Provide national benchmarks for trauma surgeon salaries and on-call pay for Trauma Surgeons, Neurosurgeons, and Orthopedic surgeons.

Data on salary and on-call pay for trauma surgeons is confounded by differing reporting methodologies, varying sample sizes, and regional influences. In addition, compensation may be complex and dependent on a variety of practice parameters and incentives. The data shown below should therefore be considered useful approximations and subject to adjustment secondary to local market conditions and contract scope. Since compensation varies over time and by location, national data sources should be accessed periodically to update the information.

#### Trauma Surgeon Salaries:

No data specific to trauma surgeon salaries are available prior to this publication:

Fakhry SM, Watts DD: What's a Trauma Surgeon Worth? A Salary Survey of the Membership of the Eastern Association for the Surgery of Trauma. *Journal of Trauma, 49*:833-38, 2000.

A subsequent update was performed by Fakhry et al. in 2005 and presented at the 2006 American Association for the Surgery of Trauma (AAST) meeting. An additional salary survey was published in 2009 that provided mean data for midlevel faculty, plus bonus and call pay:

Cohn, SM, Price, MA, Villareal, CL: Trauma and Surgical Critical Care Workforce in the United States: A Severe Surgeon Shortage Appears Imminent. *Journal of the American College of Surgeons, 209*(4):446-452, 2009.

Data are also available from the American Association for Medical Colleges (AAMC) for academic salaries. The Medical Group Management Association (MGMA), Sullivan Cotter and Associates, along with other sources have data for for non-academic surgeons.

Fakhry 2000 data:Mean salary \$229,142 ± 78,045Fakhry 2005 data:Mean salary \$285,236 ± 104,543Cohn 2009 data:Approximate mean salary \$350,000, including bonus and call pay

The AAMC reported total compensation in 2011-12 to be a mean of approximately \$359,000 (50<sup>th</sup> percentile for Associate Professor). The MGMA data are essentially similar.

On Call Pay:

Data aggregated from several sources are provided below, but as stated in the introduction, on-call pay varies significantly by region, the size and type of hospital, as well as other variables. One of these sources is Sullivan, Cotter and Associates, and this group conducts an annual survey. The most recent can be purchased on their website: <a href="http://www.sullivancotter.com/">www.sullivancotter.com/</a>:

Trauma Surgeons:\$800-\$2000 per dayNeurosurgeons:\$1000-\$4000 per dayOrthopedic Surgeons:\$1000-\$2000 per day

#### Focus Question 3

# Integration of EMS, Rehabilitation, and Injury Prevention: What can be done to strengthen the integration of EMS, trauma centers, non-trauma hospitals, rehabilitation facilities, and injury prevention programs in Florida's trauma system?

Numerous opportunities exist to improve the integration of the Trauma Program with EMS, injury prevention, and rehabilitation. Many are described within the body of the report. Representatives from each of these specialty focus areas should feel engaged in trauma system planning, development, and performance improvement. Rather than thinking about these groups as unique entities, they should be recognized as essential partners for the Trauma Program with which relationships are built and maintained. One method is to ensure that each partner has a voice on work groups and within the voting membership of the FTSAC. Methods to keep all partners regularly informed about trauma system policies and activities should be developed. Email alerts directing partners to important updates on the Trauma Program website could be one strategy.

Non-trauma hospitals care for many injured patients, most often those with less serious injuries. However, it was reported that these hospitals do receive trauma alert patients when EMS identifies the hospital as the closest appropriate facility according to the trauma destination protocol. These non-trauma hospitals need to be integrated into the EMS and trauma system. Health professionals in these non-trauma hospitals need an organized response team in the emergency department, as well as communication with trauma center experts to guide resuscitation, and to facilitate the interfacility transfer. Feedback about the care provided by the non-trauma hospital is also essential to improve performance. The regional infrastructure provides an opportunity for collaboration between EMS, the non-trauma hospitals, and the trauma centers that will ultimately enhance the care provided to seriously injured patients.

Non-trauma hospitals need recognition for their role within the trauma system and identifying them as participating trauma hospitals is one mechanism. Data about the care provided to injured patients by these hospitals are essential to the trauma system for planning, performance improvement, and evaluation at the regional and state level. A minimal dataset for participating trauma hospitals should be identified so that Florida has more comprehensive data regarding care to all injured patients.

- Ensure a representative from EMS, trauma centers, non-trauma hospitals, rehabilitation, and injury prevention as a voting member on the newly formed Florida Trauma System Advisory Committee (FTSAC).
- Create an Injury Prevention subcommittee of the FTSAC and include key representatives from EMS, trauma centers, non-trauma hospitals, rehabilitation facilities, and injury prevention programs in the membership.

- Include representation from each of the 7 Regional Domestic Security Task Force Regions should be included as well.
- Identify a representative from each non-trauma hospital to receive updates sent by the Trauma Program to all trauma stakeholders.
- Develop a regional infrastructure and ensure that all non-trauma hospitals, EMS agencies, trauma centers, and other interested groups are invited to meetings and have a voice during the regional needs assessment, planning, performance improvement, and system evaluation processes.
- Engage EMS agencies, non-trauma hospitals, and trauma centers within each region in discussions and decisions regarding trauma destination protocols, consultation for the care of seriously injured patients, trauma interfacility transfer guidelines, and transfer agreements.

## How should prehospital, trauma center, and post-hospital data be linked to improve the trauma system (prevention and care) at the local and state levels?

The key to being successful for data linkage and concatenating (aggregating) various data sets is to ensure that the data contained in each source are as reliable and valid as possible. The Division of Emergency Preparedness and Community Support (DEPCS) controls two of the most essential databases -- the state's trauma registry and the EMSTARS.

Population-based datasets are very important for understanding the overall injury prevention and control system in Florida. Vital records (death certificates), census data, hospital discharge, emergency department, and highway safety datasets are all prime targets for analysis and linkage. The initial goal of such linkages and analyses is to overcome what the TSC team characterized by the familiar statement "you don't know what you don't know". However, the linkage with these various datasets are secondary to the focus of bringing the next generation trauma registry on-line, having all acute care hospitals submit data to the state trauma registry, and the build out of the EMSTARS to include all "high-volume" EMS agencies.

- Concentrate on the timely and full implementation of the next generation trauma registry.
- Increase participation in the Emergency Medical Services Tracking and Reporting System (EMSTARS), concentrating on high volume EMS agencies that do not currently contribute.
- Develop a web-based abbreviated trauma registry input process for use by the non-trauma acute care hospitals, and require them to submit data.

- Explore the development of a unique trauma patient identifier (such as the trauma band being used in Arkansas, or the central registry available in California) to enable linkages between the trauma registry (transferring hospital and trauma center) and EMSTAR.
- Provide training opportunities for the staff members in the Health Information and Policy Analysis Program to gain skills in probabilistic data linkage, International Classification of Disease-9 Injury Severity Score mapping, and Geographic Information System mapping.

### What EMS-trauma structure promotes accountability for local and state system outcomes?

The Florida EMS and trauma system provides a good opportunity for promoting accountability for local and state trauma system outcomes. Although trauma centers have well established internal PI programs, no statewide standard approach for measuring trauma system or patient outcomes currently exists. No evidence was provided to suggest that most EMS personnel are engaged in their local hospital PI programs. Only in very limited areas of the state are EMS personnel integrated with regional or multi-county hospital PI programs.

To promote accountability for state trauma system outcomes, the Trauma Program should take the initiative to work collaboratively with the trauma centers, local EMS agencies, the Florida COT, EMS Medical Directors, and the State EMS Advisory Council to establish statewide quality benchmarks for the trauma system. Trauma centers will need to establish or expand their current PI program to include both the local EMS providers and those EMS agencies outside the county that have routine referrals into their facilities.

Many data sources are available to assist in establishing a statewide data-driven PI program. The EMSTARS, state trauma registry, Hospital Discharge data, Highway Safety Crash Data, and Uniform Data System for Rehabilitation are examples of data that can be made accessible to the local and regional trauma centers. Since BEMO has re-organized and formed the Health Information and Policy Analysis Program, resources exist to support a statewide PI initiative.

It may be necessary to review existing legislation to ensure privacy protection is provided to the trauma centers and EMS agencies participating in the local and regional PI programs.

- Establish statewide quality benchmarks for the state trauma system in collaboration with system stakeholders.
- Have the staff members of the Health Information and Policy Analysis Program develop regional and statewide reports to measure the identified benchmarks and potential contributing factors using appropriate datasets.

- Share the findings (both regional and statewide) regarding the trauma system status regarding benchmarks with stakeholders.
  - Encourage multidisciplinary stakeholders to discuss findings at regional meetings and identify potential opportunities to improve the trauma system.
  - Help all health care providers to understand the importance of their role in the trauma system for the improvement of care to injured patients.

## What is the best timeline for integrating new destinations (new trauma centers or specialty care) into trauma transport protocols?

The regulatory process for trauma center designation, as it is stated in the regulatory standard and timeline, appears to take approximately 12 months. The provisional trauma centers need time to establish call schedules, to train staff on protocols, and to develop the internal infrastructure and resources needed to provide trauma services. The new trauma centers do not know the exact date when provisional status or full designation status will be achieved. In addition, the local EMS agencies and their medical directors need time to meet with the new trauma center to develop or modify their transport protocols and train their personnel on the modifications.

#### Recommendation

• Allow at least 90 days for integrating new facilities as trauma center/specialty care destinations into the EMS transport protocols.

### **Appendix A: Acronyms**

AAMC – American Association of Medical Colleges ACS – American College of Surgeons ASPR – Assistant Secretary for Preparedness and Response

BEMO – Bureau of Emergency Medical Oversight

BIS – Benchmarks, Indicators, and Scoring

BSCIP – Brain and Spinal Cord Injury Program

CARF - Commission on Accreditation of Rehabilitation Facilities

CDC – Centers for Disease Control

CME - continuing medical education

COPN - certificate of public need

COT – Committee on Trauma

CQI – continuous quality improvement

DEPCS - Division of Emergency Preparedness and Community Support

DOH - Department of Health

DOT – Department of Transportation

ECO – Emergency Coordination Officer

EMS – Emergency Medical Services

EMSTARS - Emergency Medical Services Tracking and Reporting System

ENPC – Emergency Nursing Pediatric Course

ESF – Emergency Support Function

FETTN - Florida Emergency Trauma Telemedicine Network

FTE - full-time equivalent

FTSAC – Florida Trauma System Advisory Council

GIS - Geographic Information System

HRSA – Health Resources and Services Administration

ICISS - International Classification of Disease-9 Injury Severity Score

MCI – mass casualty incident

MGMA – Medical Group Management Association

NHTSA – National Highway Traffic Safety Administration NIMS – National Incident Management System NTDB – National Trauma Data Bank

PHEP – Public Health and Emergency Preparedness

PI – Performance Improvement

PRQ - Pre-Review Questionnaire

RDSTFR - Regional Domestic Security Task Force Regions RTTDC – Rural Trauma Team Development Course

SCI – spinal cord injury

SCO – State Coordinating Officer

SEOC – State Emergency Operation Center

SERT – State Emergency Response Team

STEMI – ST-Elevation Myocardial Infarction

TBI – traumatic brain injury

TNCC – Trauma Nurse Core Curriculum

TQIP – Trauma Quality Improvement Program

TSA – Trauma Service Area

TSC – trauma system consultation

TSPAC – Trauma System Plan Advisory Council

TTP – trauma transport protocol

### Appendix B: Methodology

The Florida Department of Health (DOH) requested this trauma system consultation, which was conducted under the auspices of the American College of Surgeons (ACS), Trauma System Consultation (TSC) program. The multi-disciplinary Trauma System Consultation (TSC) team consisted of: two trauma/general surgeons, one emergency physician, a state EMS/trauma director, a trauma program manager, a rural trauma and prehospital specialist, and a public health and injury specialist. Biographical sketches for team members are included as Appendix C of this report.

The primary objective of this ACS trauma system consultation was to guide and help promote a sustainable effort in the graduated development of an <u>inclusive and</u> <u>integrated</u> system of trauma care for the State of Florida. The format of this report correlates with the public health framework of assessment, policy development, and assurance outlined in the ACS *Regional Trauma Systems Optimal Elements, Integration, and Assessment: System Consultation Guide.* Prior to the visit, the TSC team reviewed the ACS Pre-Review Questionnaire (PRQ) submitted by the DOH, along with a number of related supporting documents provided by the DOH and information available on government websites.

The TSC team convened in Tallahassee, FL on February 2-5, 2013, to review the Florida trauma system. The meetings during the four-day visit consisted of plenary sessions during which the TSC team engaged in interactive dialogue with a broad range of representative trauma system participants. There was also an opportunity for informal discussion with the participants and time devoted to questions and answers. During the survey, the TSC team also met in sequestered sessions for more detailed reviews and discussion, and for the purpose of developing a team consensus on the various issues, preparing a report of their findings, and developing recommendations for future development of the trauma system in Florida. This report was developed independently of any other trauma system consultations or assessments.

### **Appendix C: Review Team Biographical Sketches**

### ROBERT J. WINCHELL, MD, FACS- TEAM LEADER

Dr. Robert Winchell is currently head of the Division of Trauma and Burn Surgery at the Maine Medical Center and Associate Professor of Surgery at the Tufts University School of Medicine. He received his undergraduate degree from the California Institute of Technology, his M.D. from Yale University, and did his internship, General Surgery residency, and Trauma and Critical Care Fellowship at the University of California, San Diego, where he remained on the faculty as Associate Professor of Clinical Surgery in the Division of Trauma through 1999. After leaving the University of California, Dr. Winchell established and subsequently directed the Tacoma Trauma Center in Tacoma, Washington. The trauma center continues to operate successfully as a joint venture between two previously competing hospitals. In 2001, Dr. Winchell moved to the Maine Medical Center and assumed his current post in 2004.

Dr. Winchell has been involved in trauma center and trauma system design and operation in a wide variety of settings covering the spectrum of system development. He was instrumentally involved with both the day-to-day operations and ongoing development of the San Diego County trauma system for over ten years and served as chair of the San Diego and Imperial County Committee on Trauma. He participated in the operation and ongoing development of the Washington state trauma system, serving on the state advisory board, and as chair of the Southwest EMS region. Since moving to Maine, Dr. Winchell has worked to develop the Maine state system, is a member of the state advisory board, and is a past chairman of the Maine State Committee on Trauma. He is Chair of the Trauma Systems Evaluation and Planning Committee of the American College of Surgeons and also serves as a senior site reviewer for the trauma center verification program of the College.

Dr. Winchell is Board certified in General Surgery, with added qualifications in Surgical Critical Care. Dr. Winchell is a Fellow of the American College of Surgeons as well as a member of the American Association for the Surgery of Trauma, the Association for Academic Surgery, the Southwest Surgical Congress, and the Society of Critical Care Medicine. He is author of more than 50 scientific papers and book chapters, and has given over 100 regional, national, and international presentations.

#### JANE W. BALL, RN, DRPH

Dr. Jane W. Ball served as the Director of the National Resource Center (NRC) at the Children's National Medical Center in Washington, D.C. from 1991 through 2006. The NRC provided support to two Federal Programs in the U. S. Department of Health and Human Services' Health Services and Resources Administration (HRSA): the Emergency Medical Services for Children (EMSC) Program and the Trauma-Emergency Medical Services Systems Program. As director of the NRC, she coordinated the support provided to the Federal Program Directors as well as the provision of technical assistance to state grantees. Support to the Federal Program

Directors often included meeting facilitation, preparation of special reports (such as the Model Trauma Systems Evaluation and Planning document), and consultation on Program issues. Technical assistance often included strategic planning, providing guidance in securing funding, developing and implementing grants, developing injury prevention plans and programs, building coalitions, shaping public policy, conducting training, and producing educational resource materials.

Dr. Ball has authored numerous articles and publications as well as several health care textbooks, including *Mosby's Guide to Physical Examination* (7 editions), *Child Health Nursing* (2 editions), *Pediatric Nursing: Caring for Children* (5 editions), *Maternal and Child Nursing Care* (3 editions), and *Pediatric Emergencies: A Manual for Prehospital Care Providers* (2 editions). One of these texts, Pediatric Nursing: Caring for Children, received the1999 and 2001 Robert Wood Johnson Foundation Last Acts Coalition Outstanding Specialty Book Award. *Child Health Nursing* was recognized as an American Journal of Nursing Book of the Year in 2010. As an expert in the emergency care of children, Dr. Ball has frequently been invited to join committees and professional groups that address the unique needs of children.

Dr. Ball served as the President of the National Academies of Practice, an organization composed of distinguished health care practitioners from 10 disciplines that promote education, research, and public policy related to improving the quality of health care for all through interdisciplinary care.

Dr. Ball graduated from the Johns Hopkins Hospital School of Nursing. She obtained her master's degree and doctorate in Public Health from John Hopkins University School of Hygiene and Public Health. She is a Certified Pediatric Nurse Practitioner. She received the Distinguished Alumni Award from the Johns Hopkins University in 2010.

#### SAMIR M. FAKHRY, MD, FACS

Dr. Fakhry graduated from the American University of Beirut, School of Medicine in 1981. He completed his residency in general surgery and his fellowship in critical care and trauma at the University of North Carolina at Chapel Hill in 1988.

From 1988 until 1991 he led the trauma program as Director for Trauma Services at George Washington University Medical Center in Washington D.C. In 1991, he became Director of Surgical Critical Care Services at UNC Hospitals in Chapel Hill, NC. While at UNC, he rose to the rank of Associate Professor of Surgery with Tenure and was awarded several teaching awards by the medical students and the surgical residents. He remained there until 1997 when he was recruited to the Inova Regional Trauma Center at Inova Fairfax Hospital in Falls Church, Virginia as the Chief of Trauma Services.

From August 1997 until December 2008, he held the position of Chief, Trauma and Surgical Critical Care Services at the Inova Regional Trauma Center. He was also

Associate Chair for Research and Education, Department of Surgery; Medical Director for the Inova Regional Trauma Center Injury Prevention Program and Professor of Surgery, Virginia Commonwealth University - Inova Campus. In January of 2009, Dr. Fakhry was appointed Professor of Surgery and Chief of the Division of General Surgery at the Medical University of South Carolina (MUSC) in Charleston, South Carolina. He is also the Physician Leader of the Surgical Acute and Critical Care Service line at MUSC.

Dr. Fakhry has been heavily involved in trauma and surgical critical care research and in injury prevention. His research interests include trauma systems, medical informatics applications, traumatic brain injury, intestinal injury, motor vehicle crashes, aggressive driving and surgical education. He has authored over 100 peer-reviewed publications, abstracts and book chapters. He is a member of many national societies and serves on several national committees and boards. Dr. Fakhry was Principal Investigator (PI) for the Crash Injury Research and Engineering Network (CIREN) Center at Inova Fairfax Hospital from May, 2000 until December, 2008. He is currently PI together with Dee Ford MD on an NIH funded research project entitled "Critical Care Excellence in Sepsis and Trauma" (CREST). The goal of CREST is to improve patient outcomes for sepsis and trauma by educating providers and providing access to specialist consultation via telemedicine technology to participating rural hospitals in South Carolina.

#### RONALD F. MAIO, D.O., M.S., FACEP

Dr. Maio received DO degree, in 1976, from Michigan State University's College of Osteopathic Medicine (MSUCOM). After completing his internship and serving in the US Army in Germany as general medical officer, he did an Emergency Medicine Residency at MSU affiliated hospitals in Lansing, Michigan, and is board certified in Emergency Medicine. In 1988 he received an MS in Clinical Research Design and Statistical Analysis from UM SPH.

Dr. Maio is the Director of the Office of Human Research Compliance Review (OHRCR) for the University of Michigan, and is a Professor of Emergency Medicine and former Associate Chair for Research for the Department of Emergency Medicine. Prior to being appointed Director he was the Assistant Dean for Research Regulatory Affairs at the Medical School and also was the founder and Director of the University of Michigan's Injury Research Center, based in the Department of Emergency Medicine.

Dr. Maio has practiced emergency medicine in both the rural and non-rural setting, was an assistant medical director for two EMS systems in Michigan, and, served on the board of the Huron Valley Ambulance Association based in Ann Arbor, Michigan. Dr. Maio has also served on numerous state and federal committees and panels and has served as the chair for the National Association of EMS Physicians' (NAEMSP) Research Committee.

Dr. Maio's primary areas of research have been in traumatic injury and also the effectiveness of EMS systems. His research has ranged from epidemiologic studies and observational studies to randomized controlled trials (RCTs) and he has conducted

studies in children and adults. In regard to injury he has particular interests in the relationship of alcohol and other drugs to the occurrence and severity of injury and the outcomes following injury and also in regional variation in motor-vehicle crash morality.

#### DREXDAL PRATT

Chief Drexdal Pratt heads the Division of Health Service Regulation of the North Carolina Department of Health and Human Services. His agency also manages the Emergency Medical Services and Trauma and the Assistant Secretary for Preparedness and Response (ASPR) Hospital Preparedness Cooperative Agreement.

Mr. Pratt is a graduate of the Institute of Government at the University of North Carolina at Chapel Hill, the EMS Management Institute at the University of North Carolina at Charlotte, and Forsyth Technical Community College. He is also a Certified Emergency Manager (CEM) and a Certified Public Manager (CPM).

Mr. Pratt joined the North Carolina Office of Emergency Medical Services in 1987 as a Regional Coordinator. He was promoted through the ranks, first to Regional Supervisor, and then to Chief of the agency in 1999.

Mr. Pratt served two terms as Chair of the Region I EMS Advisory Council. He received the National Association of County Commissioner's Achievement Award for coordinating the development of the Stokes County NC computer-aided dispatch program.

Mr. Pratt serves has served as a Commissioner on the Governor's State Emergency Response Commission and served as Chairman of the Commission's Homeland Security Medical Committee. In addition, Mr. Pratt served as Chairman of the NC Hospital Preparedness Committee. Currently Mr. Pratt is Chair of the State Medical Response System Executive Committee.

#### NELS D. SANDDAL, PHD, MS, REMT-B

Dr. Sanddal is currently the Manager of the American College of Surgeons (ACS) Trauma Systems and Verification Programs. Prior to his current position, he served as President of the Critical Illness and Trauma Foundation (CIT), in Bozeman, Montana for 25 years. He worked as the training coordinator for the EMS and Injury Prevention Section of the Montana Department of Public Health and Human Services in the late 1970's. He has served as the Chairperson of the National Council of State EMS Training Coordinators and as the lead staff member for that organization, and similarly for the National Association of EMT.

Dr. Sanddal completed his undergraduate work at Carroll College, received his Master's degree in psychology from Montana State University and his doctorate in Health Science from Walden University. He has been a co-investigator for six state or regional rural preventable trauma mortality studies and has conducted research in the areas of

training for medical personnel, suicide, and rural injury prevention and control. Nels served on the Institute of Medicine's Committee on the Future of Emergency Care in the U.S. Healthcare System.

He received his EMT training in Boulder, Montana, in 1973 and has been an active EMT with numerous volunteer ambulance services since that time and has managed three EMS agencies. When he is at his home in Montana, Nels responds with the Gallatin River Ranch Volunteer Fire Department where he serves as the Chief Medical Officer and Assistant Fire Chief.

#### JOLENE R. WHITNEY, MPA

Jolene R. Whitney has worked with the Bureau of Emergency Medical Services and Preparedness, Utah Department of Health for 30 years. She spent the first 6 years of her career as a regional EMS consultant. She became Assistant Training Coordinator in1986. She has been a program manager for EMS systems and trauma system development since 1991. She is currently the Deputy Director for the Bureau, which includes managing 20 staff and several programs including Trauma System Development, state grants program, fiscal reporting, Chemical Stockpile Emergency Preparedness, EMS Strike teams, ED, Trauma and Pre-hospital databases, CISM, medical direction coordination, EMS Licensing and Operations, and EMS for Children.

Ms. Whitney has a Masters in Public Administration from Brigham Young University and a B.S. in Health Sciences, with an emphasis in Community Health Education from the University of Utah. She was certified as an EMT-Basic in 1979. She also obtained certification as an EMT instructor and became certified as an EMT III (Intermediate) in 1983. She has attended numerous conferences, courses, and workshops on EMS, trauma, and disaster planning and response.

Ms. Whitney is a co-author of five publications on preventable trauma mortality, domestic violence, challenges of rural trauma in the western states and medical surge capacity planning. She is the previous past Chair for the State Trauma Managers Council for the National Association of State EMS Officials. She is currently serving on the Highway Information and Traffic Safety Committee for NASEMSO and participated in the development of a rural MCI assessment tool. She is a member of the American Trauma Society and Utah Emergency Managers Association.

In 2010, Ms. Whitney participated on an Institute of Medicine planning committee and served as a panel Chair for a rural response to MCI workshop. She was recently nominated to serve on the Crisis Standards of Care Committee with the IOM.

Ms. Whitney spent 250 hours in the Olympic Command Center, serving as an EMS liaison for the 2002 Winter Olympics in Salt Lake City, Utah. Jolene has completed the ICS training for 100, 200, 300, 700 and 800 series. She is currently working on the development of the Utah DMAT-1 and serves as the acting planning chief for the team.

She has been involved with all aspects of EMS including ambulance licensure, EMS council implementation, certification and training, computer testing, and curricula development. She has experience in statute and rule development, grant writing, system plan development, coalition building, and disaster preparedness. She has served on several national committees and teams, including five state EMS system assessments for NHTSA, five trauma system consultations for ACS, reviewed rural trauma grant applications for HRSA, contributed to the HRSA model trauma system plan, the National Trauma Data Standards, the NASMESO trauma system planning guide, and the NHTSA curriculum for an EMT refresher course.

**Appendix D: Needs Assessment Process and Tools** 

American College of Surgeons – Committee on Trauma Trauma Systems Evaluation and Planning Committee

**Trauma Center Needs Assessment Process and Tools** 

Version 1 May 1, 2013



AMERICAN COLLEGE OF SURGEONS Inspiring Quality: Highest Standards, Better Outcomes



### **Trauma System Needs Assessment**

### **Overarching Concept**

Individual states ensure optimal care of injured persons in their State by establishing criteria through their executive and legislative branches that define a trauma system within the state's geographic boundaries. The state agency responsible for the trauma system translates the statutes by developing rules or regulations, policies, and procedures which are then implemented by the regional or state trauma system within the constraints of funding.

The American College of Surgeons Committee on Trauma (ACS-COT) represents surgeons with expertise in the optimal care of injured patients, inclusive of trauma system development, prehospital care, trauma center development, direct patient care, research, and injury prevention. The ACS-COT has established the guidelines that define the essential elements that identify a hospital as a trauma center, as well as trauma care within a system.

The ACS-COT has now proposed a strategy to help states to assess and consider the needed distribution of trauma centers within its boundaries, using an inclusive care model for the trauma system. Such an effort is important because of the need to prevent excessive duplication of Level I and Level II trauma centers that have high costs in which it is important to maintain adequate patient volume to promote optimal quality of care, cost-effectiveness of care, and the training mission. Equally important is ensuring that patients have access to trauma centers that are matched to their level of injury severity. Patients with mild and moderate injuries can have high quality care at a designated lower level trauma center that is closer to their community. Patients with severe injuries may be served by timely access to high level trauma centers, many times by transfer from a lower level trauma center that performs the initial resuscitation and stabilization.

#### **Guidance for Trauma System Needs Assessment**

Many factors are important to consider when determining an optimal geographic distribution (the number and location) of trauma centers within a state or region. Important considerations are terrain, the transportation infrastructure, local weather patterns, the mass casualty assessment (terror threat, industrial risk), and population (absolute count, dispersal). Capability (level of trauma care) includes important considerations such as population, the medical infrastructures in a region (trauma surgeons, surgeon subspecialists, availability for the call schedule, intensive care resources), transportation assets for interfacility transfer, and the communication systems.

The attached document provides individual assessment parameters that can be used to help a state or regional trauma system to conduct a needs assessment and estimate the number and location of trauma centers required for its population and visitors. Since this is the first version of the document, it is possible that more assessment parameters will be identified and developed in the future.

These assessment parameters fall into several categories such as patient access, discovery/ dispatch, training mission, education, EMS response, and capacity. The leaders of the regional or state trauma system should make an effort to use as many of the assessment parameters for which data are available; however, it is unlikely that a trauma system will be able to use all the parameters. Each of the assessment parameters is stated as a benchmark or desired outcome. In many cases recommendations for a desirable outcome have been proposed, based either from the literature or common practice in other systems. As there are generally a range of potential values for each parameter, the desired outcomes will likely be different for each trauma system and must be determined by the trauma system's decision makers – choosing targets that are acceptable or desirable based upon local public opinion, policy, and infrastructure. For example, not every trauma system will have the resources to place trauma centers in every location necessary to achieve a goal of transporting 90% of patients to a level 1 trauma center within 1 hour, a goal that may well be achievable in some systems. In this case, the benchmark for system access might be better chosen to establish a threshold for transport to a level I or level II center, or transport to a participating system hospital within 1 hour.

When selecting a desired outcome, the potential gaps in the trauma system should be considered as they could potentially affect ability of the trauma system to meet the desired outcome. Additionally, trade-offs have been identified that should be considered when selecting a desired outcome.

Specific datasets are suggested to perform the assessment for each parameter, along with some strategies or considerations when analyzing the data. Several different datasets may be needed to assess each parameter, and some datasets can be used for several parameters. The list of datasets that have been identified to help perform this assessment includes the following:

- State trauma registry
- Individual trauma center registries
- State EMS registry
- Hospital discharge data (HDD)
- Emergency department data (EDD)
- State NEMSIS data
- State or Regional 911 data sets, local 911 data
- Trauma data reported by non trauma hospitals
- Computer-aided dispatch (CAD) registries
- Trauma system status management data (e.g. time hospitals are on diversion)

The following criteria represent the current state of an ongoing project to quantify metrics that are of potential utility in assessing trauma-related resource needs within a region. Further refinements are expected as the Committee continues its development efforts and various states and regions apply these metrics. Users are encouraged to check back with the Trauma System Evaluation and Planning Committee to ensure they have the most recent version of the tools.

	Desired State xx % of all injured patients meeting step one or two field triage criteria will receive care at a LI or LII trauma yy minutes of injury.					
Category - Access	Parameters	xx - No data available for percentage of injured patients, suggested range 80%-100% yy - No data available for correct time to arrival, suggest 60 min				
	Current State	Determine:         • Injury time         • Field triage step         • Arrival time at facility         • Destination facility, if other than level I or level II center, then need time to transfer         • Arrival time at 2nd facility				
	Data Sources	<ul> <li>EMS registry</li> <li>Trauma registry at receiving trauma centers</li> <li>Trauma data from intermediate facilities:         <ul> <li>Trauma specific data</li> <li>HDD or EDD data</li> </ul> </li> </ul>				
	Gaps	<ul> <li>Delay in EMS dispatch</li> <li>Delay in EMS arrival</li> <li>Long transport time</li> <li>No appropriate center</li> </ul>				
	Strategies	Include both ground and air medical transport time/ distance in calculations (add no-fly days into the calculations)				
	Trade-Offs	Over designation likely to improve access but increases cost and volume at individual trauma centers Under-designation maintain higher volume at individual trauma centers but potentially decreases access and places greater burdens of transformer resources, both for field and inter-facility transports.				

		American College of Surgeons – Trauma Center Needs Assessment Tool
	Desired State	xx % of patients meeting step three triage criteria will receive care at a level III or higher trauma center within yy minutes of injury
	Parameters	xx - No data available, suggested range 80%-100% yy - No data available, suggest 60 min
Category - Access	Current State Data Sources	Determine:         Injury time         Field triage step         Arrival time at facility         Destination facility, if other than level I or level II center, then need         Time to transfer         Arrival time and 2nd facility         Destination facility         EMS registry         Trauma registry at receiving trauma centers
		<ul> <li>Trauma data from intermediate facilities:</li> <li>Trauma specific data</li> <li>HDD or EDD data</li> </ul>
	Gaps	<ul> <li>Delay in EMS dispatch</li> <li>Delay in EMS arrival</li> <li>Long transport time</li> <li>No appropriate center</li> </ul>
	Strategies	Determine the number of injured patients without head injury to verify that a Level III trauma center is warranted. Ensure institutional commitment to trauma.
	Trade-Offs	Level III trauma centers improve access for minor to moderately injured patients. Essential in rural areas for immediate stabilization prior to transfer. Level III centers in urban and suburban areas may adversely affect both system efficiency and cost without significantly improving access

	Desired State	xx % of patients not meeting any field triage criteria treated at an appropriate facility without inter-facility transfer	
	Parameters	xx - No data available, suggested range 80%-100%	
Category - Access	Current State	Determine: Injury time Field triage step Arrival time at facility Disposition	
	Data Sources	<ul> <li>EMS registry</li> <li>Trauma registry at receiving trauma centers</li> <li>Injury data from non-trauma centers (community hospitals)         <ul> <li>Trauma registry specific data</li> <li>Hospital discharge or ED discharge data</li> </ul> </li> </ul>	
	Gaps	<ul> <li>Over-utilization of transfer</li> <li>Failure to transfer</li> <li>Under-triage</li> </ul>	
	Strategies	This approach requires injury data from all acute care centers. It must be monitored to ensure minimal under-triage or mi triage. Outcomes must also be monitored to ensure that patients are getting appropriate care in a timely manner.	
	Trade-Offs	In an inclusive and integrated trauma system it is acknowledged that most minor injury is treated appropriately at Level IV- trauma centers and community acute care hospitals.	

	American College of Surgeons – Trauma Center Needs Assessment Tool				
	Desired State	xx% of injured patients with ISS > 15 treated without transfer at facilities other than designated trauma centers			
	Parameters	xx - no data, suggest < 5%			
Category - Access	Current State	<ul> <li>Determine:</li> <li>% of patients with ISS &gt; 15 treated in designated trauma centers compared with total number of injured patients with ISS &gt;15 in the state</li> </ul>			
	Data Sources	<ul> <li>State trauma registry</li> <li>Facility trauma registries</li> <li>Hospital discharge data</li> <li>Vital records (death certificates)</li> </ul>			
	Gaps	Limited enforcement of system guidelines for interfacility transfer			
	Strategies	Identify hospitals not appropriately transferring seriously injured patients on a consistent basis (e.g., keep paying patients neurosurgeon available daytime hours only). Identify as a potential location where trauma center or trauma participating hospital is needed. Monitor and enforce transfer guidelines and policies.			
	Trade-Offs	In rural areas access to specialty care, e.g. neurosurgeon, may be occasionally life-saving. However, the resources supporting that sporadic care such as a qualified ICU may be lacking and the lack of their inclusion in the trauma center through a designation/verification process reduces oversight and performance improvement monitoring. Selective triage by ability to pay places a greater burden on higher level centers. Failure to recognize that all acute care facilities treat some level of injury negates the opportunity to collect data from those facilities and to more fully integrate them into an inclusive trauma system designed to meet the needs of the entire spectrum of injured patients.			

	American College of Surgeons – Trauma Center Needs Assessment Tool				
	Desired State xx% of injured patients meeting step one or step field triage criteria are appropriately transported to the closest designated or verified trauma center regardless of state boundaries				
Category – Access	Parameters	xx - no data, suggest transfer to out-of-state trauma center is it is more than 15 minutes closer than a trauma center designated or verified at the same or higher level in-state.			
	Current State	<ul> <li>Determine:</li> <li>Number of trauma patients receiving care in surrounding states</li> <li>Document and analyze transport time differences against in state resources</li> </ul>			
	Data Sources	<ul> <li>State trauma registry data from neighboring state</li> <li>Trauma registry data from home state</li> <li>HDD from neighboring state</li> <li>EMS registry in home state</li> <li>Vital records from home and neighboring states (death certificates)</li> </ul>			
	Gaps	<ul> <li>Need to dual recognition of border facilities as part of the trauma system in both states</li> <li>Need for contributions to trauma registry data in both states</li> <li>Reciprocal support for non-paying patients</li> <li>Structured plan for repatriation to an in-state facility, if appropriate</li> </ul>			
	Strategies	Identify patients receiving appropriate care at out-of-state trauma centers. May reduce the need for duplication of resources within near proximity.			
	Trade-Offs	In the neighboring center is not part of the home state's trauma system, there may be limited opportunities for formal confirmation of capabilities during verification or designation reviews. Likewise there may not be ongoing monitoring throu system performance improvement processes. Out-of-state facilities may represent the only logical option for access to tim care if they abut rural areas in the home state.			

	Desired State	Each level I center will see a sufficient volume of injured patients to support continued competence of trauma staff and the training mission of the center	
sion	Parameters	<ul> <li>Limit by admissions: COT 1200</li> <li>Limit by severe injuries: COT 250 with ISS &gt; 15</li> <li>Limit by geographical proximity: One LI per region or catchment area</li> </ul>	
raining Mission	Current State	Determine: <ul> <li>Required volume for competency mission</li> <li>Required volume for training mission</li> </ul>	
- Trainir	Data Sources	<ul> <li>EMS registry</li> <li>Trauma registry at receiving trauma centers</li> <li>Trauma data from intermediate facilities:         <ul> <li>Trauma registry specific data</li> <li>Hospital discharge or ED discharge data</li> </ul> </li> </ul>	
Category –	Gaps	<ul> <li>Over-triage to LI center</li> <li>Underutilization and commensurate experience at LII-III trauma centers</li> </ul>	
	Strategies	If the training need cannot be met by standard patient flow, the field triage criteria may need to be adjusted to ensure the agreed upon volume. If patient transport is determined by geographic catchment area, boundary modifications may be necessary. The training mission should be factored into the model for trauma center number, location, and level.	
	Trade-Offs	May result in under-designation of supporting facilities that would be necessary for surge or large scale events. This could, potentially, reduce redundancy in the event of a LI facility catastrophe such as a flood, tornado, earthquake, fire or act of terrorism.	

	American College of Surgeons – Trauma Center Needs Assessment Tool		
	Desired State	xx% of population covered by E911 or Next Generation 911, yy% of geographical coverage by E911 or Next Generation 911	
/٨	Parameters	xx - no data available, suggested 95-100% of population yy - no data available, suggested >90% of geography	
Category – Discovery	Current State	Determine: • % of population covered • % of geography covered	
	Data Sources	<ul> <li>State 911 Office</li> <li>Regional/Local 911 Offices</li> </ul>	
	Gaps	<ul> <li>Delay in ability to notify dispatch by cell phone</li> <li>Inability to locate caller results in delayed response</li> </ul>	
	Strategies	Continued national and statewide efforts to upgrade 911 capacity is ongoing. Trauma stakeholders should be knowledgeable of such efforts in their state or region and should support legislative or grant efforts to secure sufficient funding for such improvements.	
	Trade-Offs	While delays in discover do occasionally occur, delays in notification are far more common and may affect need for additional trauma centers in order to meet time to definitive care guidelines. Failure to identify caller location (E911 and Next Gen 911) may delay response times and may also suggest the need for additional trauma centers.	

	American College of Surgeons – Trauma Center Needs Assessment Tool					
	Desired Statexx% of population covered by advanced life support personnel within zz minutes; yy% of population covered by basic life support ambulance within aa minutes					
Category – EMS Response	Parameters	xx - no data available, zz - in urban systems fractal response time of < 9 minutes >95% yy - no data available aa - in rural systems fractal response time of <20 minutes >90%				
	Current State	Determine:         • % of urban population covered by ALS within established response times parameters         • % of rural population covered by ALS within established response times parameters         • % of rural population covered by BLS within established response time parameters				
	Data Sources	State EMS Office:   State NEMSIS databases  Computer aided dispatch (CAD) databases				
	Gaps	<ul> <li>Limited availability of ALS resources in rural areas         <ul> <li>Can be of high value due to extended transport or transfer times.</li> </ul> </li> <li>Local agencies may be reluctant to transport patients to distant trauma centers         <ul> <li>Takes limited resources out of primary response area</li> <li>If volunteer staffed takes people away from primary vocations</li> </ul> </li> </ul>				
	Strategies	Computer aided dispatch may help identify the correct response type/mode. Pre-arrival instructions are essential in area with extended response times but rural dispatch centers often do not have the resources to provide certification for their dispatchers. Trained emergency medical responders (EMR) such as law enforcement, fire department or freestanding qui response units may be essential to provide immediate medical care prior to the ambulance arrival in rural and remote are				
	Trade-Offs	Properly positioned EMS agencies reduce response time. It may not be practical to expect high level prehospital resources every community. Regionalization of EMS systems may help control costs and helps keep local resources within standard response areas. ALS rendezvous and hand-offs may improve system efficiency.				

	American College of Surgeons – Trauma Center Needs Assessment Tool				
e e	Desired State	Use of air medical resources reduces initial transport time by xx minutes for patients meeting step one or step two field triage criteria beyond a yy ground transport radius. Use of air medical resources reduces inter-hospital transport time by aa minutes for patients meeting step one or step two field triage criteria beyond a bb ground transport radius.			
Category – Air Medical Response	Parameters	xx - no data available, suggest 15-30 minutes yy - no data available, suggest a 20-30 mile radius aa - no data available, suggest >30 minutes (assumes full ALS ground capabilities) bb - no data available, suggest greater than 50 mile radius (assumes full ALS ground capabilities)			
	Current State	<ul> <li>Determine:</li> <li>Number, location and type of air medical resources in the region or state</li> <li>Average length of time from dispatch to airborne</li> <li>Average length of time for patient preparation for flight (scene and inter-hospital)</li> <li>Average time savings by distance from the nearest appropriate trauma center (may not be the air medical assets home base).</li> <li>Requires assessment and comparison of ground transport times</li> </ul>			
	Data Sources	<ul> <li>Statewide trauma registry</li> <li>Individual trauma registry</li> <li>Acute care facility ED discharge data</li> <li>NEMSIS statewide database</li> </ul>			
	Gaps	<ul> <li>Overabundance of resources in some metropolitan areas</li> <li>Paucity of resources stationed or immediately available in rural/remote areas</li> <li>May not operate in a manner that best supports the trauma system</li> </ul>			
	Strategies	Establish clear expectations through rule, regulation or policy concerning the use of air medical resources for the initial transport or transfer of trauma patients. Ensure that data are collected and analyzed and that air medical providers are fully engaged in performance improvement activities.			
	Trade-Offs	The use of rotor wing aircraft may result in the ability to increase the time/distance radius surrounding high level trauma centers. If "stationed" at the trauma center results in fly out – fly back time considerations that lessen the radius. Rotor wing aircraft affiliated with a hospital may result in over flights of closer appropriate trauma centers resulting in delays to care. Minor/moderate injuries may be transported resulting in increased individual and systems costs and significant risks to providers and patients. Fixed wing aircraft often take significant time from dispatch to launch but may be the only reasonable alternative for remote transfers. Air medical data are often not available for incorporation into other trauma data sets, for system planning, or performance improvement activities.			

	American College of Surgeons – Trauma Center Needs Assessment Tool			
no	Desired State	xx% of time EMS takes patients meeting field triage criteria to the correct facility and yy% of time step one or step two criteria notification by EMS results in trauma team activation.		
Triage/Trauma Activation	Parameters	<ul> <li>xx - no data available</li> <li>yy - no data available</li> <li>ACS Resources for Optimal Care of the Injured Patient suggests</li> <li>xx &lt;50% over-triage</li> <li>xx &lt;05% under-triage</li> <li>yy Trauma surgeon immediately (&lt;15 minutes) available (LI and LII trauma centers, promptly [&lt;30 minutes] for LIII) for the highest level of trauma team activation upon prior notification by EMS.</li> </ul>		
/Traum	Current State	<ul> <li>Determine:</li> <li>% of over-triage</li> <li>% of under-triage</li> <li>% of mistriage</li> <li>% of mistriage</li> <li>Percent of failure to require the highest level of trauma team activation for patients meeting step one or step two trauma triage criteria with appropriate notification by EMS prior to arrival.</li> </ul>		
– Triage	Data Sources Gaps	<ul> <li>State trauma registry</li> <li>Facility trauma registries</li> <li>State NEMSIS database</li> <li>Hospital discharge data</li> <li>Vital records (death certificates)</li> <li>System (multi-disciplinary) performance improvement minutes</li> </ul>		
Category	Gaps	<ul> <li>Establish and enforce field triage guidelines         <ul> <li>Adopt or refine CDC/ACS guidelines</li> </ul> </li> <li>Ensure facilities adopt and adhere to trauma team activation policies         <ul> <li>Continuously monitored through PIPS processes</li> </ul> </li> </ul>		
ate	Strategies	Develop "Cribari grid" for each facility to determine rates of over- and under-triage. Develop model criteria for trauma team activation at the regional or state level. Monitor compliance of both triage and activation.		
Ü	Trade-Offs	Over-triage ensures injured patients do not have occult injuries, however it increases system costs. Under-triage/mistriage contributes to poorer outcomes. Failure to initiate trauma team activations delays access to care.		

	American College of Surgeons – Trauma Center Needs Assessment Tool			
	Desired State	xx% of time trauma centers are on diversion; yy% of time trauma centers are 10% over capacity		
	Parameters	xx - no data available - suggest <5% total time on diversion		
		yy - no data available - suggest <10% total time over-capacity		
t)	Current State	Determine:		
cit		% of time on diversion		
с С		% of time overcapacity		
ap	Data Sources	Individual trauma registries		
		Statewide or regional system/bed status management data		
ory	Gaps	Limited trauma centers may result in excess diversion and subsequent delays in care.		
		Persistent overcapacity issues may result in inability meet unexpected demands during catastrophic events.		
	Strategies	Establish and monitor diversion and capacity benchmarks as part of verification/designation process. Monitor system/bed		
atego	status management data (such as EMSystem installed for use during catastrophic events) on an ongoing basis.			
Ü	Trade-Offs	Excessive diversion or over-capacity issues impact the system's ability to flex for surges and large scale events. It may indicate a need for additional trauma centers in an region or state. This could include lower level centers to relieve some burden for minor and moderate injuries.		

### Appendix E: Participant List

Last Name	First Name	Organization
Anderson	Mark	Regional Medical Center Bayonet Point
Ang	Darwin	Ocala Regional
Armstrong	John	Department of Health
Aucutt	Brittney	Department of Health
Barnhill	Kim	Department of Health
Barquist	Erik	Osceola Regional Medical Center
Behmke	Bernadette	Department of Health
Bifler	John	Department of Health Emergency Medical
		Services
Bixler	John	Florida Department of Health Emergency
		Medical Services
Blank	Phill	Blank & Meenan
Block	Ernest	Health First Holmes Regional Medical Center
Card	Karen	Department of Health
Carrillo	E.M.	Memorial Regional Hospital
Collins	Janet	Trauma Program
Cookro	Dennis	Department of Health
Cummings	Dylan	Department of Health
Daughtery	Stephanie	Department of Health/BEMU
DeCastro	Martha	Florida Hospital Association
Ecenia	Steve	Rutledge Ecenia
Emmanuel	Stephan	Ausley McMullen
Epstein	Steven	Bayfront Medical Center
Fennell	Jennifer	Core Message
Frazier	Seann	Parker Hudson Rainer & Dobbs
Frehn	Jeff	Radey Thomas / Tampa General Hospital
Garrino	Eddy	Memorial Regional Hospital
Gill	Karan	Sacred Heart Hospital
Glazer	Michael	Ausley McMullen
Harman	Aaron	Department of Health
Harper	Genevieve	Sacred Heart Hospital
Harvey	Carma	Department of Health
Hilsenbeck	Julie	Tenet Health
Кау	Nathan	SHS
Kushner	David	UMJ Chair
Lyon	Freda	Tallahassee Memorial Hospital
Macvezzi	Leopoldo	Miami Children's Hospital
МсСоу	Steve	Department of Health
McHargue	Mike	Department of Health
McKenney	Mark	HCA Healthcare
Moore	Frederick	UF Shauds
Newsome	Bonnie	Department of Health
Norwood	Scott	Regional Medical Center Bayonet Point

Osborne	David	Blank & Meenan		
Richter	Cory	Indian River Fire Rescue/EMS Advisory		
		Council		
Roberts	James	Shands JAX & Shands Gailesulle		
Roberts	James	Shands Healthcare		
Shouppe	Clint	Baycare Health System		
Smith	John	City of Kissimmee		
Smith	John	City of Kissimmee		
Stadler	Patricia	Tallahassee Memorial Hospital		
Tepas	J.J.	University of Florida		
Tyndall	Joseph	University of Florida, Department of		
		Emergency Medicine		
Warren	Gabriel	Rutledge Ecenia		
Zhang	Roy	Department of Health		
Ziglan	Michele	HCA Healthcare		

## Trauma System

David Joseph Ciesla MD, FACS Medical Director, Regional Trauma Program Tampa General Hospital

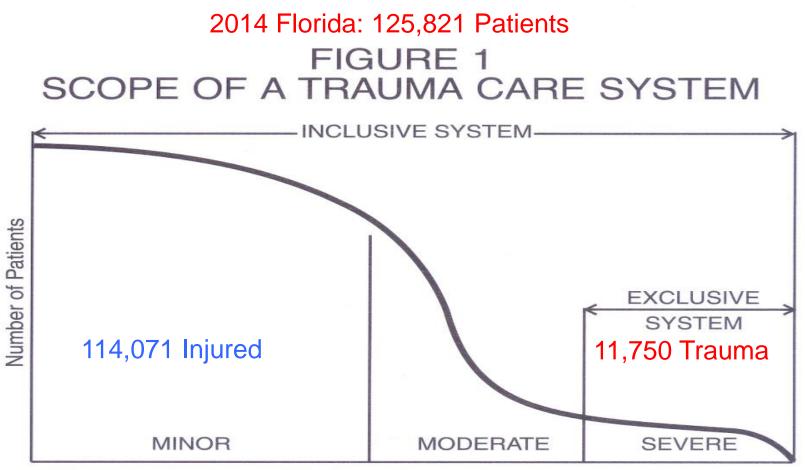
## Improve... Don't Dismantle

- 1. <u>Re-establish</u> the FL Trauma System Planning Advisory Committee
- 2. Place a **moratorium on new trauma** center designation until working collaboratively with FTSPAC the DOH.
- 3. Conduct an <u>a</u>ssessment of current trauma system inclusive of EMS capabilities,
- 4. Develop a transparent **objective data** driven needs assessment methodology that measures "demand" and "capacity" to identify number, level, and location of "needed" new trauma centers
- Adopt the National Trauma Data Bank (NTDB) as the FL Trauma Registry or adopt the NTDB reporting criteria and standards for Florida.
- 6. Appoint the immediate past chair of the FL Committee on Trauma as the DOH Trauma Medical Director

# Trauma System

- Organized coordinated effort in a defined geographic area that delivers the full range of care to all injured patients and is integrated with the local public health system
  - The number, level, and location of trauma centers are <u>critical elements</u> of trauma system function and disaster response.
  - The importance of controlling the allocation of trauma centers, as well as, the need for a process to designate trauma centers based upon need, has been recognized as <u>an essential component of trauma</u> <u>system design since the 1980s</u>

## What is a Trauma Patient?



Injury Severity Risk

Reprinted with permission from Bureau of Health Services Resources, Division of Trauma and Emergency Medical Services: *Model Trauma Care System Plan*. Health Resources and Services Administration, U.S. Department of Health and Human Services, Rockville, MD, 1992.

# What is a Trauma Center?

### **Hospital**

- Multiple Specialties
- Emergency capabilities
- Local resource
- Access point into Trauma System
- Capable of providing routine injury care to minor/moderate injuries

### **Major Trauma Center**

- Multiple specialties
- Dedicated Trauma Resuscitation Team
- Immediately Available Trauma OR
- Admission Priority for Injured patients
- Organized Trauma Services
- Destination for Pre-Hospital Triage
- Regional Resource
- Routinely cares for all degrees of injury
- Specifically organized for the Major Trauma Patient
- Major Trauma Patient Volume is directly related to survival and quality

# What is a Trauma Center?

### **Hospital/Major Trauma Center**

- Large community hospitals
- Population dense areas
- Treat full range of injured patients
- Most injured patients in trauma centers have minor or moderate injuries
- Major injuries account for only 15% of trauma center patients



## What is a Major Trauma Center?

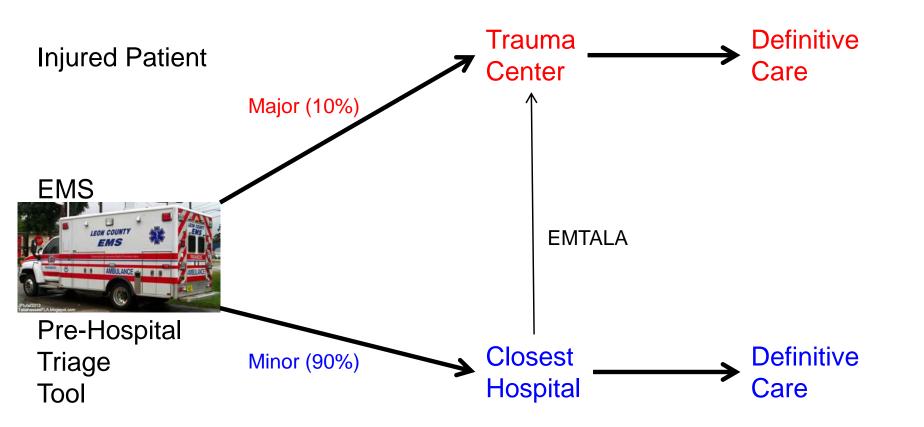
### Level II Trauma Center

- Quality assessment program
- Trauma resuscitation team
- 24h specialty availability
- Local resource
- Tertiary care needs may be referred
- No research/training expectation
- No annual minimum volume requirement

### Level I Trauma Center

- Quality assessment program
- Trauma resuscitation team
- 24h specialty availability
- Regional resource
- Comprehensive specialty services
- Organized research, training and education
- Minimum annual severe injury volume requirement

# Trauma System



## **Pre-Hospital Trauma Triage Tool**

12/4/2002

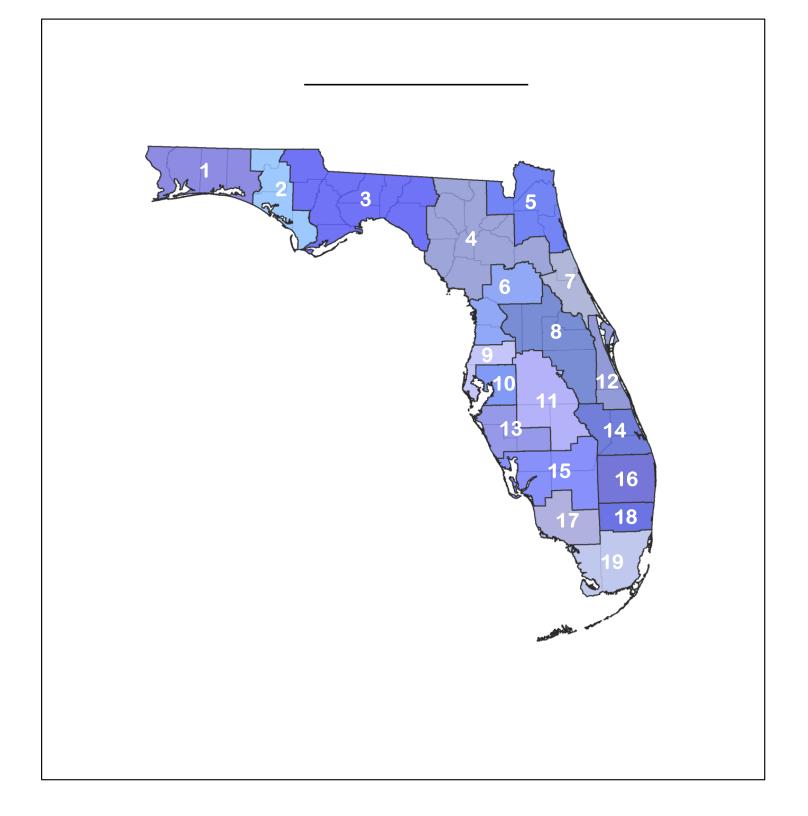
#### Adult Trauma Triage Criteria & Methodology

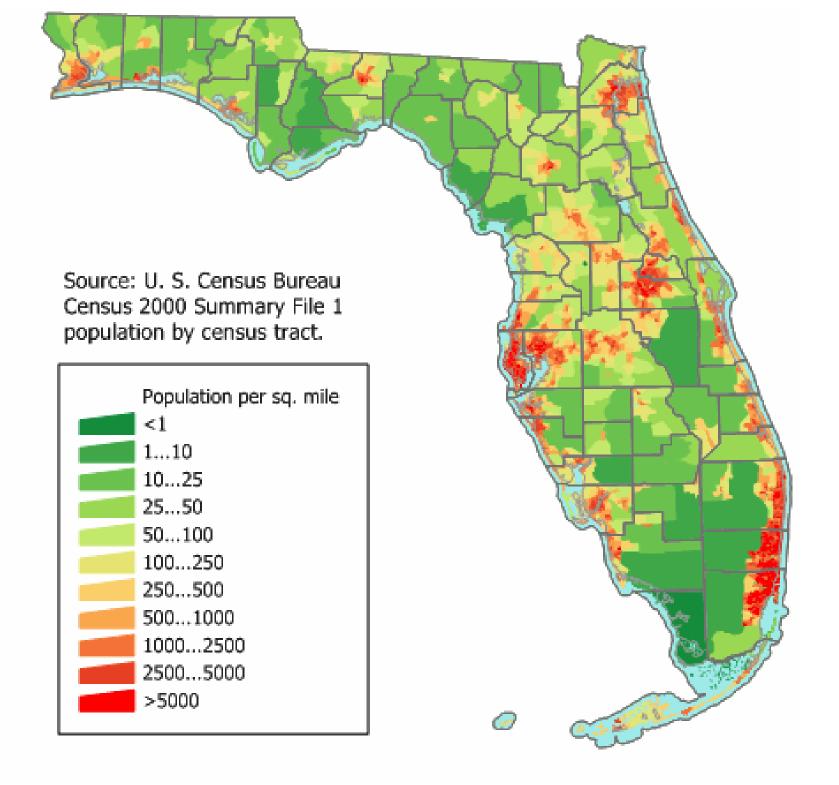
The EMT or paramedic shall assess the condition of those injured persons with anatomical and physiological characteristics of a person sixteen (16) years of age or older for the presence of at least one of the following four (4) criteria to determine whether to transport as a trauma alert. These four criteria are to be applied in the order listed, and once any one criterion is met that identifies the patient as a trauma alert; no further assessment is required to determine the transport destination.

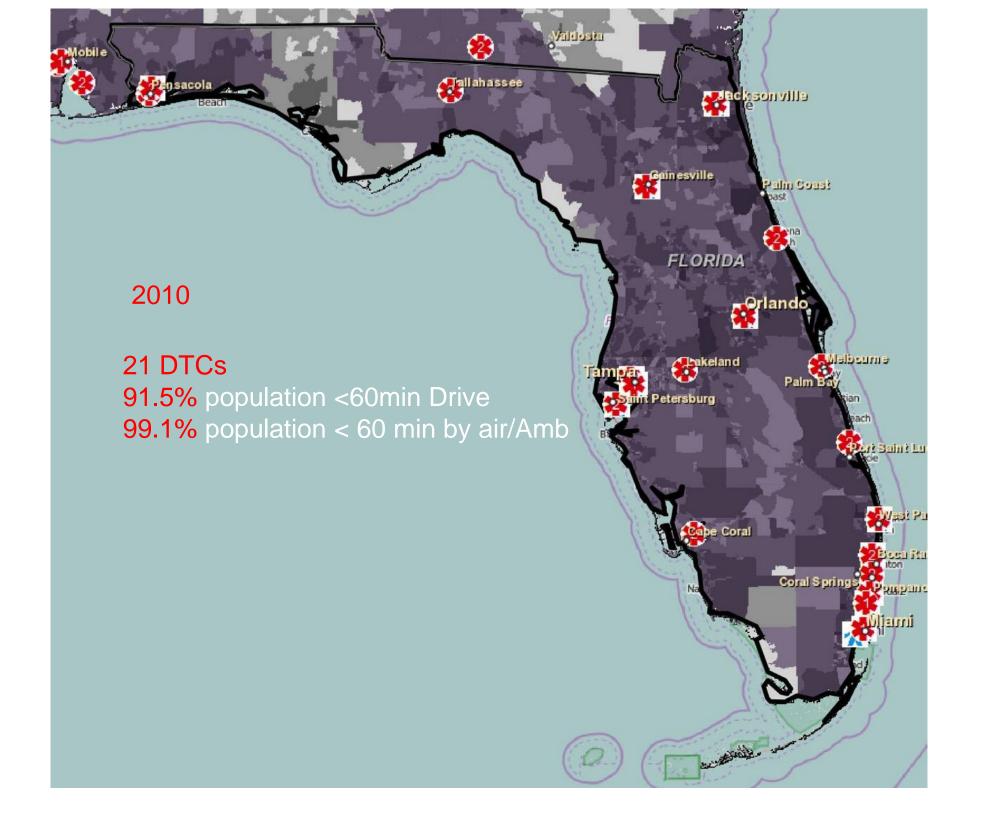
Criteria:         □       1. Meets color-coded triage system (see below)         □       2. GCS ≤ 12 (Patient must be evaluated via GCS if not identified as a trauma alert after application of criterion 1.)         □       3. Meets local criteria (specify):         □       4. Patient does not meet any of the trauma criteria listed above but, in the judgement of the						
	aramedic, should be transported as					
COMPONENT						
AIRWAY	RESPIRATORY RATE OF 30 or GR	EATER				
		в		R		
CIRCULATION	SUSTAINED HR OF 120 BEATS PE MINUTE or GREATER	R	LACK OF RADIAL PULSE WITH SUSTAINE HEART RATE (>120) or BP <90 mmHg	D		
		в		R		
BEST MOTOR RESPONSE	BMR =5		BMR = 4 or LESS or PRESENCE OF PARALYSIS, or SUSPICION OF SPINAL CC INJURY or LOSS OF SENSATION	RD		
		В	—	R		
CUTANEOUS	SOFT TISSUE LOSS <sup>2</sup> or GSW TO THE EXTREMETIES		2ND OR 3RD <sup>0</sup> BURNS TO 15% or MORE TBSA or AMPUTATION PROXIMAL TO THE WRIST or ANKLE or ANY PENETRATING INJURY TO HEAD, NECK, or TORSO <sup>3</sup>			
		В		2		
LONGBONE FRACTURE <sup>4</sup>	SINGLE FX SITE DUE TO MVA or F 10 ' or MORE	ALL	FRACTURE OF TWO or MORE LONGBONE	S		
FRACTURE		в		R		
AGE	55 YEARS or OLDER					
		в				
MECHANISM OF INJURY	EJECTION FROM VEHICLE <sup>S</sup> or DEFORMED STEERING WHEEL <sup>6</sup>					
		в				
	ransport as a trauma alert		B = any two (2) - transport as a trauma alert			

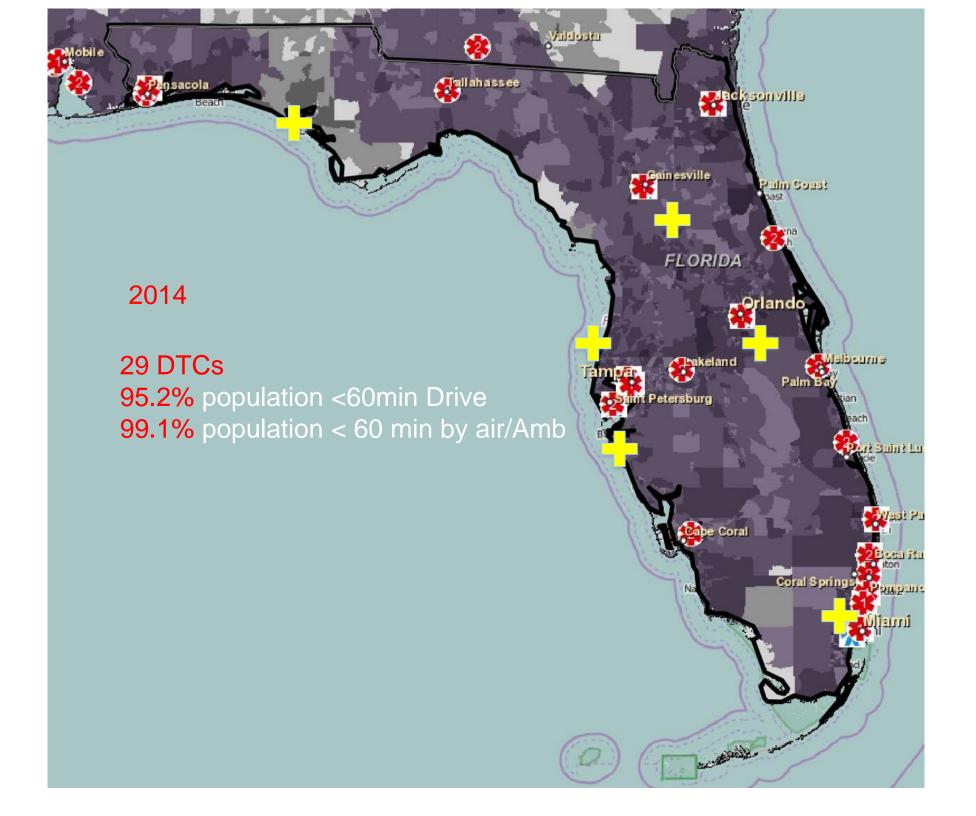
- Major degloving injures, or major flap avulsion (>5 in.)
- 3. Excluding superficial wounds in which the depth of the wound can be determined
- 4. Longbone (Including humerus, (radius, ulna), femur, (tibia or fibula).
- 5. Excluding motorcycle, moped, all terrain vehicle, bicycle, or open body of a pickup truck
- Only applies to driver of vehicle)

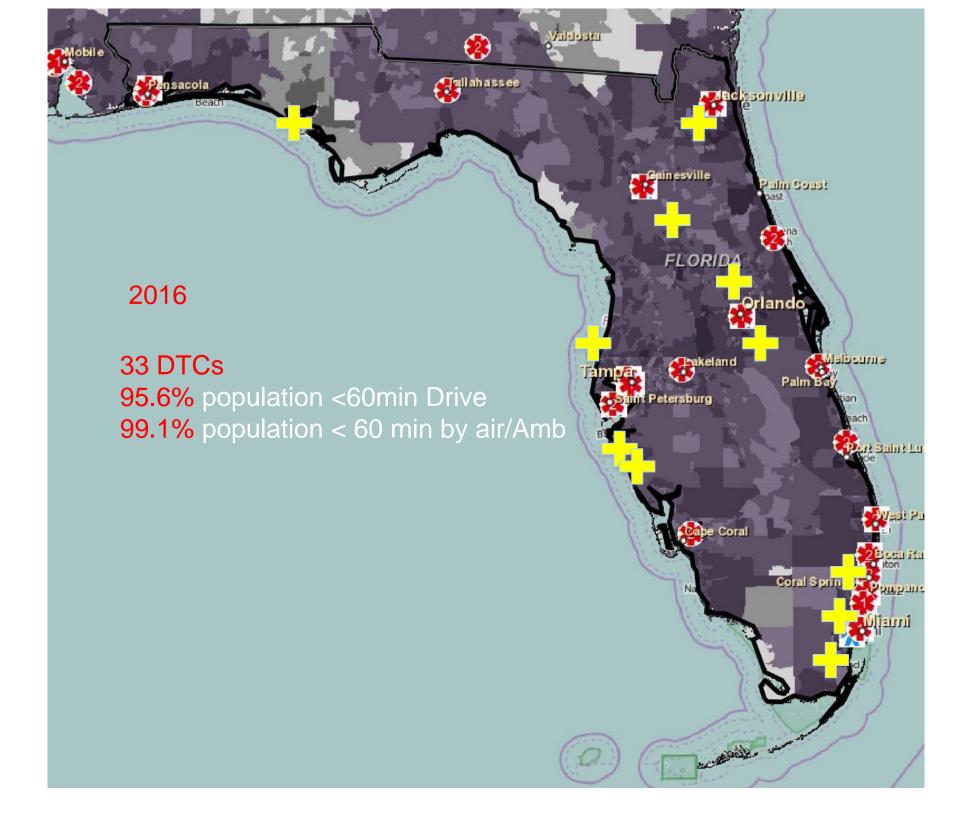
- Identifies Major Trauma Patients
- Directs transport to nearest trauma center
- Does not differentiate between Level I and Level II Centers

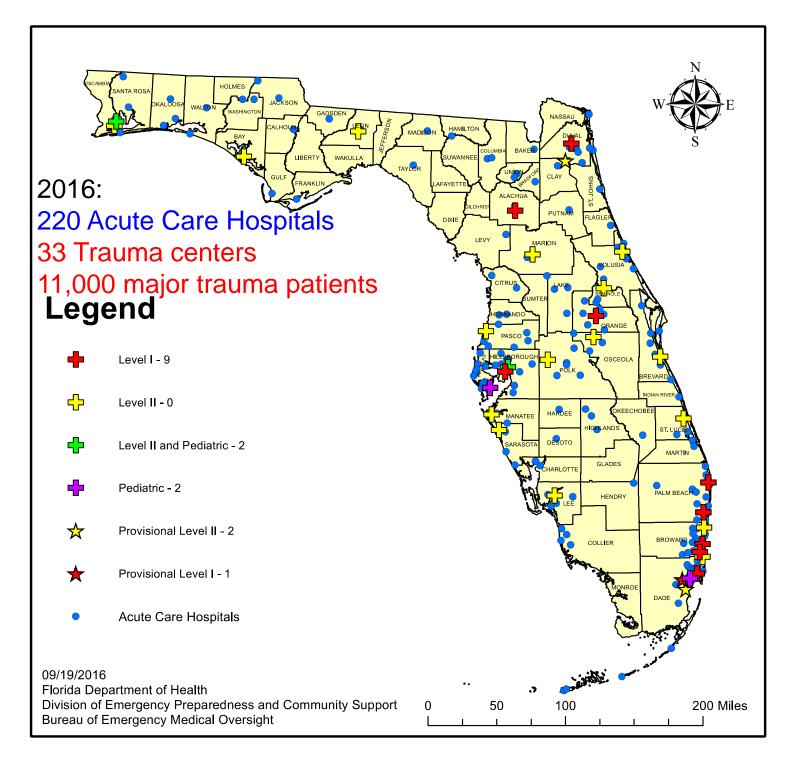








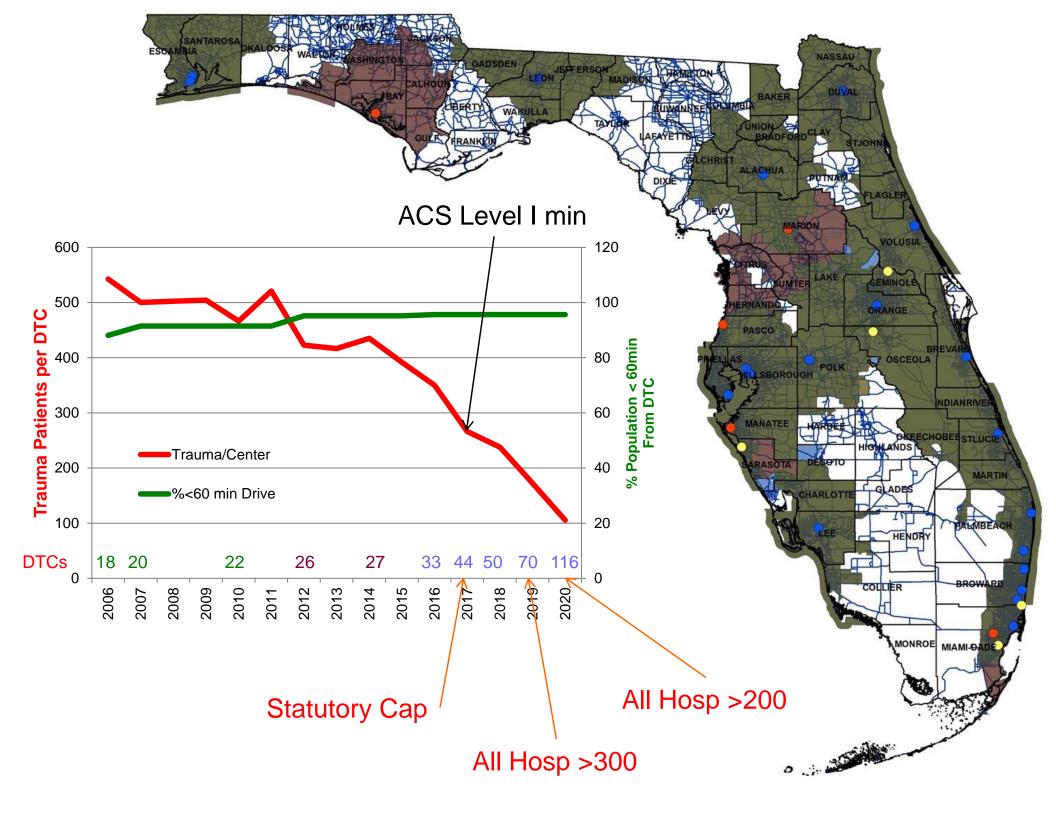




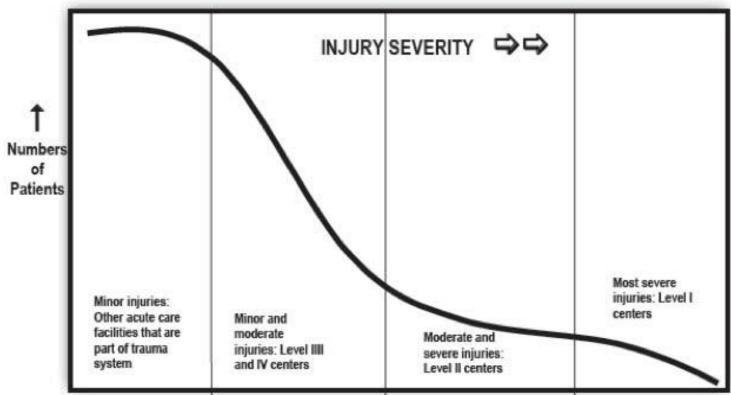


#### Trauma Centers and Acute Care Hospitals

Disclaimer: This thematic map is for reference purposes. Any reliance on the information contained herein is at the user's own risk. The Florida Department of Health and its agents assume no responsibility for any use of the information contained herein or any loss resulting there from.



## Inclusive Trauma Systems... Are Best



The inclusive trauma system uses the full spectrum of acute care facilities to provide trauma care.

## **Proficiency... Why It Matters**

### • High Volume = High Quality

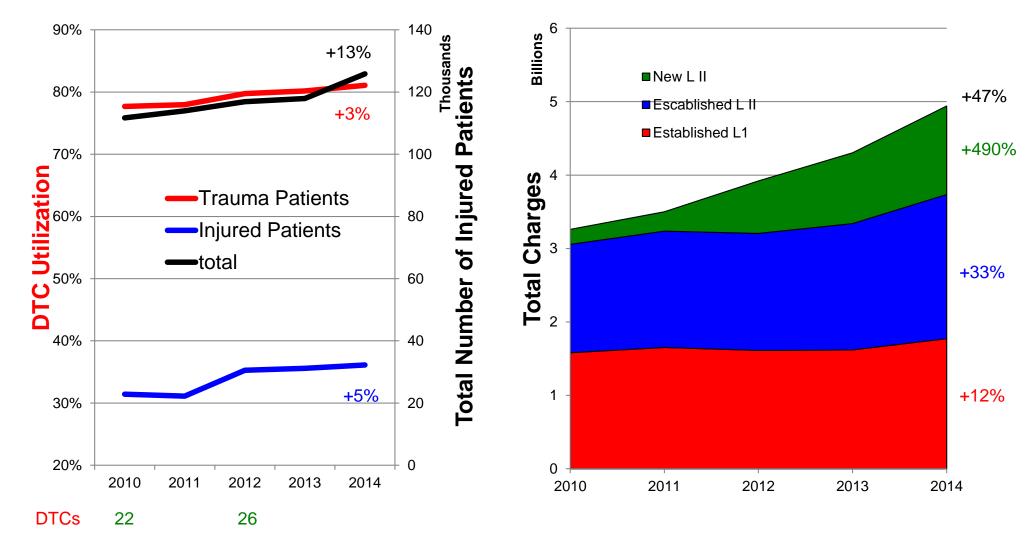
- Trauma center volume is a predictor of patient mortality.
- Increased trauma center volume is directly correlated to increased quality.
- Increased trauma center volume is directly correlated to increased survival and reduced post injury complications.
- Trauma system planning avoids duplication of services, dilution of volume, and mediocre quality.

## Trauma Center Allocation... Should Be Managed

- The number, level, and location of trauma centers are <u>critical elements</u> of trauma system function and disaster response.
- The importance of controlling the allocation of trauma centers, as well as, the need for a process to designate trauma centers based upon need, has been recognized <u>as an essential component</u> of trauma system design since the 1980s.
- Uncontrolled growth of trauma centers undermines quality and proficiency.
- Uncontrolled growth detrimental to the long-term stability of a statewide trauma system and to the population it serves.

## **Trauma Center Economics**

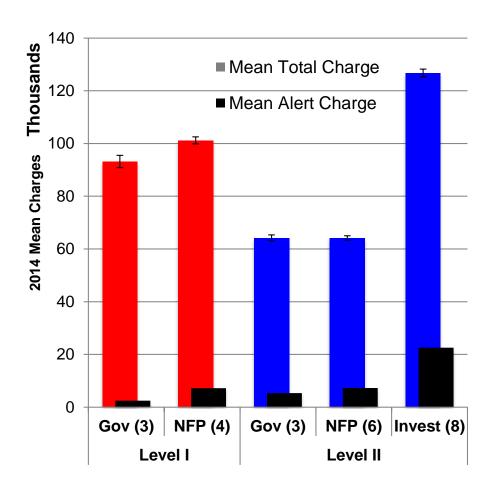
### **Annual Patient Volume**



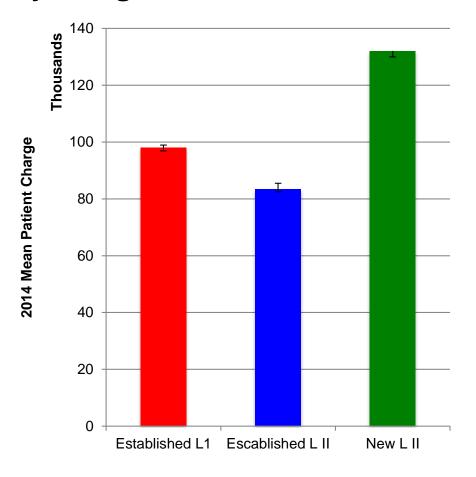
### **Annual Patient Charges**

# Variability in Patient Charges

**By Ownership** 



#### By designation Year > 2010



# Summary

## By 2010

- 22 Trauma Centers
  - 7 Level I
  - 13 Level II
  - 2 pediatric
- Statewide Coverage
  - Triage 69 % accurate
    - 29% overtriage
    - 2% undertriage
  - 93% live in covered area
  - 91% 60 min drive
  - 99% 60 min Air/Ground
- No trauma centers operating beyond capacity
  - 466 trauma patients/center

## Since 2010

- 33 Trauma Centers
  - 10 Level I
  - 21 Level II
  - 2 Pediatric
- Statewide coverage
  - Triage 65% accurate
    - 33% overtriage
    - 2% undertriage
  - All new centers in areas already covered
  - All but 1 new center < 35mi from existing center
  - 95% 60 min drive
  - 99% 60 min air/ground
- Trauma Centers operating below optimal
  - 350 trauma patients/center

# Summary

## Beyond 2017

- Current state
- Level I Center
  - Decreased patient volume and acuity
  - Academic mission threatened
  - Less favorable payer mix
  - Less differentiation
- Established Level II
  - Decreased volume of centers in proximity
- New Level II
  - Increased volume and acuity as patients redistributed
  - Substantially higher charges
  - Substantially higher payments
  - Overall increased costs

## Beyond 2017

- De-regulation threatens to dismantle the 40 years of Florida trauma system development
- The current rule is insufficient to measure need
- The current law is out of date and must be revised

## FLs Trauma System Model... Nationally Commended

- Trauma center access in Florida is above the national average.
- 96% of Floridians lived in an area already routinely served by at least one established trauma center in 2010 (before the proliferation). The national average is 82% of population.
- Florida's incidence of major trauma has also been decreasing for decades.
- No data exists indicating that Florida's severely injured children and adults needing a trauma center were not able to be treated in trauma centers (before the proliferation began in 2010.)
- Florida has already increased the number of trauma centers by 50% while the population has only grown 8% since 2010.

## Conclusion... Don't Dismantle FLs Trauma System

- Do not take up SB 746, a bill that would dismantle Florida's nationally recognized trauma system and is diametrically opposed to national standards.
- Re-establish the FL Trauma System Planning Advisory Committee (FTSPAC)
- Place a moratorium on new trauma center designation until working collaboratively with FTSAC the Department of Health (DOH):
  - Conducts an assessment of current trauma system inclusive of EMS capabilities
  - Develops a transparent objective data driven needs assessment methodology that measures "demand" and "capacity" to identify number, level, and location of "needed" new trauma centers
- Appoint the immediate past chair of the FL Committee on Trauma as the DOH Trauma Medical Director
- Adopt the National Trauma Data Bank (NTDB) as the FL Trauma Registry or adopt the NTDB reporting criteria and standards for Florida.

APPEARANCE RECORD
3-22-17 Meeting Date (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) Bill Number (if applicable)
opic Trauma Care Amendment Barcode (if applicable)
lame Lynda Tirte (Tee-tel)
ob Title <u>NUISE</u>
ddress 420 NAdams Stunit 502 Phone 250-980-1146
Tallahuse FL City State Zip Email LTIEFELOgnal Com
peaking: For Against Information Waive Speaking: In Support Against ( <i>The Chair will read this information into the record.</i> )
Representing Plurida Emergency Nurses association
ppearing at request of Chair: Yes X No Lobbyist registered with Legislature: Yes X No

THE FLORIDA SENATE

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLOR	IDA SENATE
APPEARAN	CE RECORD
MARCH 22, 2014 Peliver BOTH copies of this form to the Senator of	or Senate Professional Staff conducting the meeting)
Meeting Date	Bill Number (if applicable)
Topic TRAVMA	Amendment Barcode (if applicable)
Name STEVEN G. EPSTEIN, M	FunE, MD, FACS
Job Title TRAVMA MEDICAL DIRECT	OR, BAVEROUT HEALTH
Address 701 6th Gr. S. St. Btush	2Vrg, Fl. Phone 727 843-6254
Street	Email
City State	Zip
Speaking: For Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing BAY FRONT HEALTH	ST. PETERBURG, F/
Appearing at request of Chair: Yes No	Lobbyist registered with Legislature: 🗌 Yes 📝 No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
Current low-THC Law		Builds on current low-THC structure and incorporates conforming changes into the right to try act.	Builds on current low-THC structure and incorporates conforming changes into the right to try act.	act but keeps the ability to receive marijuana delivery	Builds on current low-THC structure. Eliminates cannabis from the right to try act but keeps the ability to receive marijuana delivery devices. (Terminal patients are incorporated in s. 381.986)	
Legislative Intent				rules are adopted pursuant to ch. 120, with emergency rulemaking if necessary. 3. Legislature Intends that all registrations are in	<ol> <li>Legislature intends to implement Amendment</li> <li>Legislature intends that all rules are adopted pursuant to ch. 120, with emergency rulemaking if necessary.</li> <li>Legislature Intends that all registrations are in accordance with this section and rules.</li> </ol>	<ul> <li>(a) PUBLIC POLICY.</li> <li>(1) The medical use of marijuana by a qualifying patient or caregiver is not subject to criminal or civil liability or sanctions under Florida law.</li> <li>(2) A physician shall not be subject to criminal or civil liability or sanctions under Florida law solely for issuing a physician certification with reasonable care.</li> <li>(3) Actions and conduct by a Medical Marijuana Treatment Center registered with the Department, or its agents or employees, and in compliance with this section and Department regulations, shall not be subject to criminal or civil liability or sanctions under Florida law</li> </ul>

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
			Definitio	ns		
Debilitating Medical Conditions (DBM)	1. Adds terminal conditions, paraplegia, and quadriplegia to the amendment definition.	Uses amendment definition.	Uses amendment definition.	3. Adds conditions that	<ol> <li>Uses amendment definition.</li> <li>Adds terminal conditions.</li> <li>Adds conditions that produce seizures and muscle spasms</li> </ol>	Cancer, epilepsy, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), post-traumatic stress disorder (PTSD), amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, multiple sclerosis, or other debilitating medical conditions of the same kind or class as or comparable to those enumerated, and for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient. <i>(b)(1)</i>
Chronic pain	Not addressed	Allowed, but must be related to a listed DBM.	Not addressed.	Not addressed.	Not addressed.	

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
Medical Use	Uses Amendment Definition	<ol> <li>Uses amendment definition;</li> <li>Restricts smoking;</li> <li>Restricts use of other types of marijuana not specified on a certification;</li> <li>Restricts use of marijuana not purchased from an MMTC;</li> <li>Restricts use in certain public places.</li> </ol>	Uses amendment definition.	2. Restricts use of marijuana not purchased from an MMTC;	<ol> <li>Restricts smoking;</li> <li>Restricts use of marijuana not purchased from an MMTC;</li> <li>Restricts use in certain public places.</li> </ol>	The acquisition, possession, use, delivery, transfer, or administration of an amount of marijuana not in conflict with Department rules, or of related supplies by a qualifying patient or caregiver for use by the caregiver's designated qualifying patient for the treatment of a debilitating medical condition. (b)(6)
Qualifying Patients	Uses Amendment Definition	1. Uses amendment definition. 2. Adds "eligible patients" as defined in the right to try act.	Uses amendment definition.	Uses amendment definition. Adds eligible patients as defined in the right to try act.	Uses amendment definition. Adds eligible patients as defined in the right to try act.	A person who has been diagnosed to have a debilitating medical condition, who has a physician certification and a valid qualifying patient identification card. If the Department does not begin issuing identification cards within nine (9) months after the effective date of this section, then a valid physician certification will serve as a patient identification card in order to allow a person to become a "qualifying patient" until the Department begins issuing identification cards. (b)(10)

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
			Prohibiti	ons		
<u> </u>	Applies the clean indoor air act to smoking.	Prohibits smoking	Smoking not addressed (allowed by default)	Prohibits smoking	Prohibits smoking	Nothing in this section shall require any accommodation of smoking medical marijuana in any public place. (c)(6)
Public Use/ Plain View	Prohibits use of marijuana in many public places	Prohibits use of marijuana in many public places, including maintaining criminal prohibitions on use in certain places.	Maintains current criminal penalties for use in plain view of public places in 381.986.		Maintains current criminal penalties for use in plain view of public places in 381.986.	See above, and nothing shall require any accommodation of any on-site medical use of marijuana in any correctional institution or detention facility or place of education or employment. (c)(6)
Advertising	Prohibits MMTCs from advertising its products.	Not addressed.	Not addressed.	advertising MMTC services.	<ol> <li>Prohibits anyone not registered as an MMTC from advertising MMTC services.</li> <li>MMTCs may not advertise services for which they are not registered.</li> </ol>	
Unlicensed Activity	Not addressed.	Not addressed.	Not addressed.	Includes specific prohibition on unlicensed MMTC activity.	Includes specific prohibition on unlicensed MMTC activity.	Only exempts MMTCs acting "in compliance with this section and Department regulations" from Florida law. (a)(3)

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
Other	States bill does not affect DUI laws	States that nothing in the bill affects workplace drug policies		Bills states that nothing affects malpractice laws;	Bills states that nothing affects malpractice laws;	<ol> <li>Nothing in this section shall permit the operation of any vehicle, aircraft, train or boat while under the influence of marijuana. (c)(4)</li> <li>Nothing in this section shall affect or repeal laws relating to negligence or professional malpractice on the part of a qualified patient, caregiver, physician, MMTC, or its agents or employees. (c)(8)</li> </ol>
			Physician Cert	ifications		
Who may write certifications	MD and DO s who have completed the 8-hour training and who do not have a financial interest in a MMTC or testing lab.	completed the 4-hour training and who are not MMTC	MD and DO s who have completed the 8-hour training and who are not MMTC medical directors.	MD and DO s who have completed the 4-hour training and who are not MMTC medical directors.	MD and DO s who have completed the 4-hour training and who are not MMTC medical directors.	"Physician" means a person who is licensed to practice medicine in Florida. <i>(b)(8)</i>

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
<b>Requirements for Certification</b>	Good faith medical judgement determination that the patient suffers from one or more debilitating medical conditions and that the medical use of marijuana would likely outweigh the potential health risks for the patient.	Must conduct a full exam of the patient.	<ol> <li>Must have seen the patient for 3 months prior to issuing certification.</li> <li>Must have determined that the patient will benefit from the treatment with marijuana.</li> </ol>		Must conduct a full exam of the patient.	<ol> <li>"Physician certification" means a written document signed by a physician, stating that in the physician's professional opinion, the patient suffers from a debilitating medical condition, that the medical use of marijuana would likely outweigh the potential health risks for the patient, and for how long the physician recommends the medical use of marijuana for the patient.</li> <li>A physician certification may only be provided after the physician has conducted a physical examination and a full assessment of the medical history of the patient. (b)(9)</li> </ol>
Physician Registration	The registry must include a file for certifying physicians with the physician's name and license number.	Physician must register with the compassionate use registry.	, ,	Physician must register with the compassionate use registry.	Physician must register with the compassionate use registry.	
Informed Consent	Minors must have parent or guardian written consent.	Must obtain written consent from the patient, or parent or guardian of minor patients	Obtain voluntary written informed consent from patient or patient's caregiver.	for informed consent from minors. Note: Amendment requires	<ol> <li>Strikes language requiring informed consent.</li> <li>Does not include language for informed consent from minors.</li> <li>Note: Amendment requires parent or guardian consent for minors.</li> </ol>	In order for a physician certification to be issued to a minor, a parent or legal guardian of the minor must consent in writing. (b)(9)

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
Two Physicians for Minors			2 physicians must concur for persons under 18.	<ol> <li>Two physicians must concur for persons under 18.</li> <li>Patients under 18 may not purchase marijuana.</li> <li>Only parent, legal guardian, caregiver, or health care provider may purchase marijuana for patients under 18.</li> </ol>		
Residency	Florida residents only.	Florida residents only.	Not specifically limited to Florida residents.	Specifically allows out of state patients	Florida residents only.	
Treatment Plan		Must maintain treatment plan with UF college of pharmacy.	Must maintain treatment plan with UF college of pharmacy.	Treatment plan not required.	Treatment plan not required.	

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
Patient and Order Grandfathering		Current Low-THC and eligible patients are grandfathered in as qualifying patients and current orders are grandfathered in as certifications.		Current Low-THC and eligible patients are grandfathered in as qualifying patients and current orders are grandfathered in as certifications.	patients are grangtathered in	
Certification Renewal	-	Annual, or shorter if specified. Patient must be reexamined.	Unspecified. (Amendment requires annual renewal of ID cards).	At least annual and patient must be reexamined.	At least annual and patient must be reexamined.	
Out of State Patient Requirements				<ol> <li>Must be physically present for initial and follow up exams.</li> <li>Patient must:         <ul> <li>Be staying in Florida for at least 30 days;</li> <li>Wait at least 2 weeks after obtaining a physician certification prior obtaining marijuana; or</li> <li>Have a state issued ID card or certification from another state for marijuana.</li> </ul> </li> </ol>		

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
Allowed Supply	90 Day supply (under the definition of allowed amount of marijuana)	90 Day supply	45 day supply	90 day supply, but physician may certify more with a reasonable belief that the patient will use it appropriately.	45-day supply, but physician may certify more with a reasonable belief that the patient will use it appropriately.	The DOH is required to adopt a regulation that defines the amount of marijuana that could reasonably be presumed to be an adequate supply for qualifying patients' medical use, based on the best available evidence. This presumption as to quantity may be overcome with evidence of a particular qualifying patient's appropriate medical use. (d)(1)d.
			Caregive	ers		
Requirements	<ol> <li>21 or older;</li> <li>Level 2 BG screening;</li> <li>Exception to age and BG screen for spouse, parent, guardian, child, or sibling;</li> <li>Must complete a 2-hour training course.</li> </ol>	<ol> <li>21 or older;</li> <li>Level 2 BG screening;</li> <li>Exception to age and BG screen for close family;</li> <li>Must agree in writing to be the caregiver;</li> <li>May not receive compensation.</li> </ol>	1. 21 or older; 2. Agree to assist the patient; 3. Be issued a DOH ID card.	<ol> <li>Be 21 or older;</li> <li>Agree in writing to be caregiver;</li> <li>Cannot receive compensation;</li> <li>Pass a Level 2 BG screening unless patient is a close relative;</li> <li>Take and pass a 1-hour course and exam offered by the DOH;</li> </ol>	<ol> <li>Be 21 or older;</li> <li>Agree in writing to be caregiver;</li> <li>Cannot receive compensation;</li> <li>Pass a Level 2 BG screening unless patient is a close relative.</li> </ol>	"Caregiver" means a person who is at least twenty-one (21) years old who has agreed to assist with a qualifying patient's medical use of marijuana and has qualified for and obtained a caregiver identification card issued by the Department. Caregivers are prohibited from consuming marijuana obtained for medical use by the qualifying patient. (b)(7)

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
<b>Caregiver to Patient Ratio</b>	or spouses or if the caregiver is a healthcare worker and the patients are residents in a healthcare facility. 2. One unrelated caregiver per patient and up to 2 additional	unless all patients are close relatives or the caregiver is a healthcare worker and the patients are residents in a healthcare facility. 2. One caregiver per patient	Unspecified. (Amendment grants direct rule authority to the DOH to determine caregiver number and qualifications).	<ol> <li>One patient per caregiver unless all patients are close relatives or the caregiver is a healthcare worker and the patients are residents in a healthcare facility.</li> <li>One caregiver per patient unless they are close relatives.</li> </ol>	<ol> <li>One patient per caregiver unless all patients are close relatives or the caregiver is a healthcare worker and the patients are residents in a healthcare facility.</li> <li>One caregiver per patient unless they are close relatives.</li> </ol>	The Department may limit the number of qualifying patients a caregiver may assist at one time and the number of caregivers that a qualifying patient may have at one time. (b)(7)
Other Requirements	Minor patients must have consenting parent/guardian as a caregiver, or, if that person is unable or unwilling, another parent or guardian.					
	1. Bill specifies what	1. Bill specifies what	Patient and Caregiver Regi			
	information ID cards must contain. 2. Photo required. 3. DOH must receive written consent from parent or legal	information ID cards must contain. 2. Photograph is required. 3. DOH must receive written consent from parent or legal guardian before issuing to a minor	Bill eliminates the current-law rulemaking authority for patient ID cards. (Amendment grants direct rulemaking authority to DOH for patient and caregiver ID cards).	for ID cards. 2. No photograph is required. 3. DOH must receive written consent from parent or legal	<ol> <li>Bill specifies requirements for ID cards.</li> <li>No photograph is required</li> <li>DOH must receive written consent from parent or legal guardian before issuing to a minor</li> </ol>	1. "Identification card" means a document issued by the Department that identifies a qualifying patient or a caregiver. <i>(b)(3)</i>

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)		
	Department Responsibilities (text in Italics does not have to be completed by specified date )							
By <u>July 1, 2017</u>	patient registry. 2. Registry must include info on patient ID cards as well as additional cannabinoid and dispensing information	<ol> <li>Uses existing compassionate use registry.</li> <li>Expands access to the registry to all MDs and DOs and practitioners licensed to prescribe drugs to ensure proper care for patients.</li> </ol>	Uses existing compassionate use registry.	<ol> <li>Uses existing compassionate use registry.</li> <li>Expands access to the registry to all MDs and DOs and practitioners licensed to prescribe drugs to ensure proper care for patients.</li> </ol>	<ol> <li>Uses existing compassionate use registry.</li> <li>Expands access to the registry to all MDs and DOs and practitioners licensed to prescribe drugs to ensure proper care for patients.</li> </ol>			
By <u>July 3, 2017</u>	nermitting MIMIL(s	Adopt rules for patient and caregiver ID cards.	Eliminates current statutory authority for DOH to issue patient and caregiver ID cards. (Amendment 2 has constitutional authority for DOH to issue ID cards).	Adopt rules for patient and caregiver ID cards.	Adopt rules for patient and caregiver ID cards.	DOH must adopt rules for: 1. Procedures for the issuance and annual renewal of qualifying patient identification cards. 2. procedures establishing qualifications and standards for caregivers, including conducting appropriate background checks, and procedures for the issuance and annual renewal of caregiver identification cards. 3. Procedures for the registration of MMTCs that include procedures for the issuance, renewal, suspension and revocation of registration, and standards to ensure proper security, record keeping, testing, labeling, inspection, and safety. 4. A regulation that defines the amount of marijuana that could reasonably be presumed to be an adequate supply. (d)(1)ad.		

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
By <u>September 1, 2017</u>	<ol> <li>Create physician, patient, and caregiver registration form.</li> <li>Create the 2-hour caregiver training course.</li> </ol>					
By <u>October 3, 2017</u>	Caregiver ID cards. 3. Begin issuing function licenses for MMTCs and permitting MMTC facilities. 4. Begin issuing ID cards to	<ol> <li>Begin registering patients, caregivers, and MMTCs.</li> <li>Begin issuing patient and caregiver ID cards.</li> <li>Grandfather in existing DOs as MMTCs.</li> </ol>	Does not grandfather existing DOs.	1. Begin issuing ID cards; 2. Register 10 additional applicants (see below) 3. Grandfathers in existing DOs.	Grandfathers in existing DOs	<ol> <li>The DOH must begin issuing patient and caregiver ID cards and registering MMTCs. (d)(2)</li> <li>If the Department does not issue regulations, or if the Department does not begin issuing identification cards and registering MMTCs within the time limits set in this section, any Florida citizen shall have standing to seek judicial relief to compel compliance with the Department's constitutional duties.</li> </ol>

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
	terminations, and return of ID	DOH must establish a process for approving changes of ownership for MMTCs.	<ol> <li>Authorize the establishment of medical marijuana testing facilities.</li> <li>Create a quality control program for testing of medical cannabis.</li> <li>For more details see Testing of Marijuana section.</li> </ol>	minute course for patients.	DOH must establish a process for approving changes of ownership for MMTCs.	1. The Department shall protect the confidentiality of all qualifying patients. All records containing the identity of qualifying patients shall be confidential and kept from public disclosure other than for valid medical or law enforcement purposes. (d)(4)
			MMTC Regu	lation		
nber of	<ol> <li>Unlimited.</li> <li>Retail facilities are limited to 1 per 25,000 residents in a county.</li> <li>Counties and cities may restrict retail facilities within their boundaries.</li> </ol>	<ol> <li>Must register 5 additional MMTCs when the compassionate use registry registers 250,000; 350,000; 400,000; and 500,000 patients.</li> <li>One registrant within the first additional 5 must be a member of the Black Farmers Agricultural Association.</li> <li>Must register 5 additional MMTCs for every additional 100,000 patients registered in the compassionate use registry over 500,000.</li> </ol>		the Black Farmers and Agriculturalists assoc. 2. Register 4 additional MMTCs each time the compassionate use registry adds 25,000 patients after Jan. 1, 2018. 3. All applicants must be registered to do business in Fl. For 5 years. 4. The DOH may not register	<ol> <li>Add 3 additional MMTCs at each instance of 250,000 patients in the compassionate use registry.</li> <li>Each additional 3 must include 1 applicant who is a member of the Black Farmers and Agriculturalists Association.</li> <li>All applicants must be registered to do business in Fl. For 5 years.</li> </ol>	

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
Vertical Integration	No.	Yes.	Yes.	Yes.	Yes.	
Performance Bond	\$1 million, specifies when forfeited.	\$5 million, reduced to \$2 million when MMTC serves 1,000 or more patients.	Same as SB 406	\$5 million, reduced to \$1 million when MMTC serves 1,000 patients.	Same as SB 406, but defines use for the bond	
General Registration / Licensure Requirements	<ol> <li>All MMTCs must register with the DOH.</li> <li>MMTCs must obtain licenses to perform any or all of: Cultivation, Processing, Retail Sale, and/or Transportation.</li> <li>Each MMTC facility must be inspected and permitted by the DOH.</li> <li>MMTCs may use contractors to assist with cultivation, processing, and transport.</li> <li>Employees, managers, principals and contractors must be registered with the DOH and issued a ID card.</li> <li>Access to "limited access", "restricted access", and "general access" areas per DOH rules.</li> </ol>	substantially similar to current regulation of DOs. 2. MMTCs are required to maintain compliance with all representations made in their applications. DOH may grant	<ol> <li>Regulation of MMTCs is substantially similar to current regulation of DOs.</li> <li>Eliminates the requirement to cultivate medical cannabis in a separate room from other plants.</li> <li>Eliminates the requirement that MMTCs store 9 months worth of medical cannabis for testing.</li> </ol>	<ol> <li>Substantially similar to SB 406.</li> <li>All MMTC owners and employees must register with the DOH</li> <li>MMTCs must present a floor plan to the department with designated "limited access" and "restricted" areas.</li> <li>Specifies when the DOH may suspend or revoke an MMTC license.</li> <li>Keeps 30 year nursery requirement.</li> <li>Authorizes DOH to adopt rules for administration facilities.</li> </ol>	<ol> <li>Substantially similar to SB 406.</li> <li>Specifies how an MMTC can lose its performance bond.</li> <li>Specifies when the DOH may suspend or revoke an MMTC license.</li> <li>Keeps 30 year nursery requirement but exempts members of the Black Farmers Assn.</li> </ol>	"Medical Marijuana Treatment Center" (MMTC) means an entity that acquires, cultivates, possesses, processes (including development of related products such as food, tinctures, aerosols, oils, or ointments), transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, or educational materials to qualifying patients or their caregivers and is registered by the Department.

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
Testing of Marijuana	by an Independent Testing	Requires self-testing by MMTCs with audits by independent testing labs.	3. Testing facilities must also	audits or can contract with an independent testing lab to	MMTCs can self test with audits or can contract with an independent testing lab to directly test the product.	

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
			DOH quality control program: 1. MMTCs must submit samples to a testing facility to ensure that the labeling of cannabinoid concentrations is correct and the cannabis is safe for human consumption. 2. MMTCs must maintain all records of tests conducted. 3. DOH must adopt rules to implement the program.			
			Miscellaneous I	Provisions		
Rulemaking				Requires rulemaking proceed pursuant to ch. 120, but DOH may use emergency rulemaking procedures.		
Local Ordinances	<ol> <li>Allows local control over retail facilities.</li> <li>Preempts cultivation and processing to the state.</li> </ol>		1. Maintains current law local control over zoning, etc., for retail facilities.	retail facilities. 2. Allows local governments to	<ol> <li>Maintains current law local control over zoning, etc., for retail facilities.</li> <li>Restricts local governments from banning retail facilities.</li> </ol>	

Topic	SB 614 (Sen. Brandes)	SB 406 (Sen. Bradley)	SB 1388 (Sen. Artiles)	SB 1666 (Sen. Braynon)	SB 1758 (Sen. Grimsley)	Amendment 2 (s. 29, Art. X of the State Constitution)
Taxation	<ol> <li>States that sales tax applies to marijuana.</li> <li>All sales tax revenue goes into a trust fund for marijuana safety and efficacy research.</li> <li>Local governments may assess a local option tax.</li> </ol>	Not specified.	Not specified.	Not specified.	Not specified.	
Miscellaneous				2. Prohibits importation of marijuana, allows exportation in accordance with federal law and the law of the state or countries to	<ol> <li>Exempts research institutions from criminal statutes related to marijuana for research purposes.</li> <li>Prohibits importation of marijuana, allows exportation in accordance with federal law and the law of the state or countries to which it is exported.</li> </ol>	Nothing in the section: 1. Allows for a violation of any law other than for conduct in compliance with the provisions of this section; (c)(1) 2. Affects or repeals laws relating to non-medical use, possession, production, or sale of marijuana; (c)(2) 3. Authorizes the use of medical marijuana by anyone other than a qualifying patient;(c)(3) 4. Requires the violation of federal law or purports to give immunity under federal law;(c)(5) 5. Requires any health insurance provider or any government agency or authority to reimburse any person for expenses related to the medical use of marijuana.(c)(7)
Effectiv e Date	Upon becoming law	Upon becoming law	July 1, 2017	Upon becoming law	Upon becoming law	3-Jan-17

SECTION 29. Medical marijuana production, possession and use.-

(a) PUBLIC POLICY.

(1) The medical use of marijuana by a qualifying patient or caregiver in compliance with this section is not subject to criminal or civil liability or sanctions under Florida law.

(2) A physician shall not be subject to criminal or civil liability or sanctions under Florida law solely for issuing a physician certification with reasonable care to a person diagnosed with a debilitating medical condition in compliance with this section.

(3) Actions and conduct by a Medical Marijuana Treatment Center registered with the Department, or its agents or employees, and in compliance with this section and Department regulations, shall not be subject to criminal or civil liability or sanctions under Florida law.

(b) DEFINITIONS. For purposes of this section, the following words and terms shall have the following meanings:

(1) "Debilitating Medical Condition" means cancer, epilepsy, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), post-traumatic stress disorder (PTSD), amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, multiple sclerosis, or other debilitating medical conditions of the same kind or class as or comparable to those enumerated, and for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient.

(2) "Department" means the Department of Health or its successor agency.

(3) "Identification card" means a document issued by the Department that identifies a qualifying patient or a caregiver.

(4) "Marijuana" has the meaning given cannabis in Section 893.02(3), Florida Statutes (2014), and, in addition, "Low-THC cannabis" as defined in Section 381.986(1)(b), Florida Statutes (2014), shall also be included in the meaning of the term "marijuana."

(5) "Medical Marijuana Treatment Center" (MMTC) means an entity that acquires, cultivates, possesses, processes (including development of related products such as food, tinctures, aerosols, oils, or ointments), transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, or educational materials to qualifying patients or their caregivers and is registered by the Department.

(6) "Medical use" means the acquisition, possession, use, delivery, transfer, or administration of an amount of marijuana not in conflict with Department rules, or of related supplies by a qualifying patient or caregiver for use by the caregiver's designated qualifying patient for the treatment of a debilitating medical condition.

(7) "Caregiver" means a person who is at least twenty-one (21) years old who has agreed to assist with a qualifying patient's medical use of marijuana and has qualified for and obtained a caregiver identification card issued by the Department. The Department may limit the number of qualifying patients a caregiver may assist at one time and the number of caregivers that a qualifying patient may have at one time. Caregivers are prohibited from consuming marijuana obtained for medical use by the qualifying patient.

(8) "Physician" means a person who is licensed to practice medicine in Florida.
(9) "Physician certification" means a written document signed by a physician, stating that in the physician's professional opinion, the patient suffers from a debilitating medical condition, that the medical use of marijuana would likely outweigh the potential health risks for the patient, and for how long the physician recommends the medical use of marijuana for the patient. A physician certification may only be provided after the physician has conducted a physical examination and a full assessment of the medical history of the patient. In order for a physician certification to be issued to a minor, a parent or legal guardian of the minor must consent in writing.

(10) "Qualifying patient" means a person who has been diagnosed to have a debilitating medical condition, who has a physician certification and a valid qualifying patient identification card. If the Department does not begin issuing identification cards within nine (9) months after the effective date of this section, then a valid physician certification will serve as a patient identification card in order to allow a person to become a "qualifying patient" until the Department begins issuing identification cards.

(c) LIMITATIONS.

(1) Nothing in this section allows for a violation of any law other than for conduct in compliance with the provisions of this section.

(2) Nothing in this section shall affect or repeal laws relating to non-medical use, possession, production, or sale of marijuana.

(3) Nothing in this section authorizes the use of medical marijuana by anyone other than a qualifying patient.

(4) Nothing in this section shall permit the operation of any vehicle, aircraft, train or boat while under the influence of marijuana.

(5) Nothing in this section requires the violation of federal law or purports to give immunity under federal law.

(6) Nothing in this section shall require any accommodation of any on-site medical use of marijuana in any correctional institution or detention facility or place of education or employment, or of smoking medical marijuana in any public place.

(7) Nothing in this section shall require any health insurance provider or any government agency or authority to reimburse any person for expenses related to the medical use of marijuana.

(8) Nothing in this section shall affect or repeal laws relating to negligence or professional malpractice on the part of a qualified patient, caregiver, physician, MMTC, or its agents or employees.

(d) DUTIES OF THE DEPARTMENT. The Department shall issue reasonable regulations necessary for the implementation and enforcement of this section. The purpose of the regulations is to ensure the availability and safe use of medical marijuana by qualifying patients. It is the duty of the Department to promulgate regulations in a timely fashion.

(1) Implementing Regulations. In order to allow the Department sufficient time after passage of this section, the following regulations shall be promulgated no later than six (6) months after the effective date of this section:

a. Procedures for the issuance and annual renewal of qualifying patient identification cards to people with physician certifications and standards for renewal of such identification cards. Before issuing an identification card to a minor, the Department must receive written consent from the minor's parent or legal guardian, in addition to the physician certification.

b. Procedures establishing qualifications and standards for caregivers, including conducting appropriate background checks, and procedures for the issuance and annual renewal of caregiver identification cards.

c. Procedures for the registration of MMTCs that include procedures for the issuance, renewal, suspension and revocation of registration, and standards to ensure proper security, record keeping, testing, labeling, inspection, and safety.

d. A regulation that defines the amount of marijuana that could reasonably be presumed to be an adequate supply for qualifying patients' medical use, based on the best available evidence. This presumption as to quantity may be overcome with evidence of a particular qualifying patient's appropriate medical use.

(2) Identification cards and registrations. The Department shall begin issuing qualifying patient and caregiver identification cards, and registering MMTCs no later than nine (9) months after the effective date of this section.

(3) If the Department does not issue regulations, or if the Department does not begin issuing identification cards and registering MMTCs within the time limits set in this section, any Florida citizen shall have standing to seek judicial relief to compel compliance with the Department's constitutional duties.

(4) The Department shall protect the confidentiality of all qualifying patients. All records containing the identity of qualifying patients shall be confidential and kept from public disclosure other than for valid medical or law enforcement purposes.

(e) LEGISLATION. Nothing in this section shall limit the legislature from enacting laws consistent with this section.

(f) SEVERABILITY. The provisions of this section are severable and if any clause, sentence, paragraph or section of this measure, or an application thereof, is adjudged invalid by a court of competent jurisdiction other provisions shall continue to be in effect to the fullest extent possible.

History.—Proposed by Initiative Petition filed with the Secretary of State January 9, 2015; adopted 2016.

#### The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT (This document is based on the provisions contained in the legislation as of the latest date listed below.)

	Prepa	ared By: The Profes	sional Staff of the 0	committee on H	lealth Policy
BILL:	SB 406				
INTRODUCER:	Senators B	radley and Young	g		
SUBJECT:	Compassio	onate Use of Low	-THC Cannabis	and Marijuar	ia
DATE:	March 20,	2017 REVI	SED:		
ANAL	YST	STAFF DIREC	TOR REFER	ENCE	ACTION
1. Looke		Stovall	Н	P Wa	orkshop
2.			Ał	IS	
3.			A	<u>р — — — — — — — — — — — — — — — — — — —</u>	

#### I. Summary:

SB 406 amends s. 381.986, F.S., to implement the provisions of s. 29, Art. X, of the State Constitution, Medical Marijuana Production, Possession, and Use. The bill makes numerous changes to the section including:

- Amending definitions to incorporate terms used in s. 29, Art. X, of the State Constitution and to add definitions for "chronic nonmalignant pain" and "close relative."
- Allowing allopathic<sup>1</sup> and osteopathic<sup>2</sup> physicians to certify the medical use of marijuana for patients with debilitating medical conditions and other specified patients.
- Establishing requirements that a physician must meet before certifying a patient and after certification. Reduces the required course a physician must take prior to certifying patients to a 4-hour course that must only be taken once.<sup>3</sup> Removes the 3 month patient treatment prerequisite.
- Amending current criminal penalties to conform with other changes in the bill and establishing new criminal violations for patients and caregivers cultivating or purchasing marijuana from a source other than a medical marijuana treatment center (MMTC) or who violate other provisions of the act.
- Establishing requirements for caregivers including limiting a patient to one caregiver and a caregiver to one patient with certain exceptions and requiring that caregivers pass a Level II background screening, with certain exceptions for a caregiver who is a close relative.
- Requiring the Department of Health (DOH) to begin issuing identification cards to patients and caregivers by October 3, 2017.

<sup>&</sup>lt;sup>1</sup> Licensed under ch. 458, F.S.

<sup>&</sup>lt;sup>2</sup> Licensed under ch. 459, F.S.

<sup>&</sup>lt;sup>3</sup> Current law requires that physicians take an 8-hour course annually.

- Grandfathering in existing dispensing organizations as MMTCs<sup>4</sup> and increasing the overall number of MMTCs that may be registered when certain numbers of patients are registered on the compassionate use registry.
- Requiring MMTCs to maintain compliance with the representations made in their applications for registration and allowing the DOH to grant variances in certain circumstances.

The bill also makes other conforming and technical changes to ss. 381.986, 381.987, 385.211, 499.0295, and 1004.411.

The bill's provisions take effect upon becoming law.

#### II. Present Situation:

#### Treatment of Marijuana in Florida

Florida law defines cannabis as "all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin,"<sup>5</sup> and places it, along with other sources of THC, on the list of Schedule I controlled substances.<sup>6</sup> The definition excludes "low-THC cannabis" as defined in s. 381.986, F.S., if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed in conformance with that section.

Schedule I controlled substances are substances that have a high potential for abuse and no currently accepted medical use in the United States.<sup>7</sup> As a Schedule I controlled substance, possession and trafficking of cannabis carry criminal penalties that vary from a first degree misdemeanor<sup>8</sup> up to a first degree felony with a mandatory minimum sentence of 15 years in state prison and a \$200,000 fine.<sup>9</sup> Paraphernalia<sup>10</sup> that is sold, manufactured, used, or possessed with the intent to be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance, is also prohibited and carries criminal penalties ranging from a first degree misdemeanor to a third degree felony.<sup>11</sup>

<sup>&</sup>lt;sup>4</sup> Including dispensing organizations that are currently in litigation but would qualify under ch. 2016-1236, L.O.F.

<sup>&</sup>lt;sup>5</sup> Section 893.02(3), F.S.

<sup>&</sup>lt;sup>6</sup> Section 893.03(1)(c)7. and 37., F.S.

<sup>&</sup>lt;sup>7</sup> Section 893.03(1), F.S.

<sup>&</sup>lt;sup>8</sup> This penalty is applicable to possession or delivery of less than 20 grams of cannabis. See s. 893.13(3) and (6)(b), F.S.

<sup>&</sup>lt;sup>9</sup> Trafficking in more than 25 pounds, or 300 plants, of cannabis is a first degree felony with a mandatory minimum sentence that varies from 3 to 15 years in state prison depending on the quantity of the cannabis possessed, sold, etc. *See* s. 893.135(1)(a), F.S.

<sup>&</sup>lt;sup>10</sup> Section 893.145, F.S.

<sup>&</sup>lt;sup>11</sup> Section 893.147, F.S.

# Medical Marijuana in Florida: the Compassionate Medical Cannabis Act of 2014

#### Patient Treatment with Low-THC Cannabis

The Compassionate Medical Cannabis Act of 2014<sup>12</sup> (act) legalized a low tetrahydrocannabinol (THC) and high cannabidiol (CBD) form of cannabis (low-THC cannabis)<sup>13</sup> for medical use<sup>14</sup> by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms. The act provides that a Florida licensed allopathic or osteopathic physician who has completed the required training<sup>15</sup> and has examined and is treating such a patient may order low-THC cannabis for that patient to treat such disease, disorder, or condition or to alleviate its symptoms, if no other satisfactory alternative treatment options exist for that patient. In order for a physician to order low-THC cannabis for a patient, all of the following conditions must apply:

- The patient is a permanent resident of Florida;
- The physician has treated the patient for at least 3 months immediately preceding the patient's registration and has determined that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient;<sup>16</sup>
- The physician registers as the orderer of low-THC cannabis for the patient on the compassionate use registry (registry) maintained by the DOH and updates the registry to reflect the contents of the order;
- The physician maintains a patient treatment plan that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to the low-THC cannabis;
- The physician submits the patient treatment plan quarterly to the University of Florida, College of Pharmacy (UFCP) for research on the safety and efficacy of low-THC cannabis on patients; and
- The physician obtains the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis after sufficiently explaining the current state of knowledge in the medical community about the effectiveness of treatment of the patient's condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects.<sup>17</sup>

<sup>&</sup>lt;sup>12</sup> Chapter 2014-157, L.O.F., codified in s. 381.986, F.S.

<sup>&</sup>lt;sup>13</sup> Section 381.986(b), F.S., defines "low-THC cannabis," as the dried flowers of the plant *Cannabis* which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight, or the seeds, resin, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin.

<sup>&</sup>lt;sup>14</sup> Section 381.986(1)(c), F.S., defines "medical use" as administration of the ordered amount of low-THC cannabis; and the term does not include the possession, use, or administration by smoking, or the transfer of low-THC cannabis to a person other than the qualified patient for whom it was ordered or the qualified patient's legal representative. Section 381.986(1)(e), F.S., defines "smoking" as burning or igniting a substance and inhaling the smoke; smoking does not include the use of a vaporizer.

<sup>&</sup>lt;sup>15</sup> Section 381.986(4), F.S., requires such physicians to successfully complete an 8-hour course and examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses the clinical indications for the appropriate use of low-THC cannabis, appropriate delivery mechanisms, contraindications for such use, and the state and federal laws governing its ordering, dispensing, and processing.

<sup>&</sup>lt;sup>16</sup> If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient's medical record.

<sup>&</sup>lt;sup>17</sup> Section 381.986(2), F.S.

The act creates exceptions to existing law to allow qualified patients<sup>18</sup> and their legal representatives to purchase, acquire, and possess low-THC cannabis (up to the amount ordered) for that patient's medical use; and to allow dispensing organizations (DO) and their owners, managers, and employees to acquire, possess, cultivate, and dispose of excess product in reasonable quantities to produce low-THC cannabis and to possess, process, and dispense low-THC cannabis. DOs and their owners, managers, and employees are not subject to licensure and regulation under ch. 465, F.S., relating to pharmacies.<sup>19</sup>

### Patient Treatment with Medical Cannabis

Chapter 2016-123, L.O.F. amended the act to expand the regulatory structure relating to dispensing low-THC cannabis and authorized approved dispensing organizations to cultivate and dispense medical cannabis to eligible patients as defined under the Right to Try Act (RTTA).<sup>20</sup> In conjunction with s. 381.986, F.S., the RTTA allows physicians to treat eligible patients with terminal conditions with medical cannabis by including medical cannabis<sup>21</sup> within the definition of an "investigational drug, biological product, or device." Physicians must order the use of medical cannabis for those patients pursuant to the provisions of s. 381.986, F.S.

#### Dispensing Organizations under the Act

Section 381.986, F.S., requires that the DOH approve five DOs, one in each of five regions throughout the state. In order to be approved as a DO, an applicant must possess a certificate of registration issued by the Department of Agriculture and Consumer Services (DACS) for the cultivation of more than 400,000 plants, be operated by a nurseryman, and have been operating as a registered nursery in this state for at least 30 continuous years. Applicants are also required to demonstrate:

- The technical and technological ability to cultivate and produce low-THC cannabis;
- The ability to secure the premises, resources, and personnel necessary to operate as a DO;
- The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances;
- An infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department;
- The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department;
- That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04, F.S; and
- The employment of a medical director, who must be a physician and have successfully completed a course and examination that encompasses appropriate safety procedures and knowledge of low-THC cannabis.<sup>22</sup>

<sup>&</sup>lt;sup>18</sup> Section 381.986(1)(d), F.S., defines a "qualified patient" as a Florida resident who has been added by a physician licensed under ch. 458, F.S., or ch. 459, F.S., to the compassionate use registry to receive low-THC cannabis from a DO. <sup>19</sup> Section 381.986(7), F.S.

<sup>&</sup>lt;sup>20</sup> Section 499.0295, F.S.

<sup>&</sup>lt;sup>21</sup> "Medical cannabis" means all parts of any plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, sale, derivative, mixture, or preparation of the plant or its seeds or resin that is dispensed only from a DO for medical use by an eligible patient as defined in the Right to Try Act. <sup>22</sup> *Id.* 

An approved DO must post a \$5 million performance bond within 10 business days of approval. The DOH is authorized to charge an initial application fee and a licensure renewal fee, but is not authorized to charge an initial licensure fee.<sup>23</sup> An approved DO must maintain all approval criteria at all times.<sup>24</sup>

Beginning on July 7, 2014, the DOH held several rule workshops<sup>25</sup> to write and adopt rules implementing the provisions of s. 381.986, F.S., and the DOH put forward a proposed rule on September 9, 2014.<sup>26</sup> This proposed rule was challenged by multiple organizations involved in the rulemaking workshops and was found to be an invalid exercise of delegated legislative authority by an administrative law judge on November 14, 2014.<sup>27</sup> Afterward, the DOH held a negotiated rulemaking workshop in February of 2015, which resulted in a new proposed rule being published on February 6, 2015.<sup>28</sup> The new proposed rule was also challenged on, among other things, the DOH's statement of estimated regulatory costs and the DOH's conclusion that the rule will not require legislative ratification. Hearings were held on April 23 and 24, 2015, and a final order was issued on May 27, 2015, which found the rule to be valid.<sup>29</sup> The rules took effect June 17, 2015, and the DOH held an application period for DO approval which ended on July 8, 2015. Twenty-eight applications were submitted.<sup>30</sup>

On November 23, 2015, the DOH approved a DO in each of the following five regions as required by the act: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida.<sup>31</sup> Numerous petitions were filed challenging the DOH's selection process. In order to allow the approved DOs to begin dispensing products, the 2016 Legislature required the DOH to approve as a dispensing organization applicants that received the highest aggregate score through the department's evaluation process, notwithstanding any prior determination by the DOH that the applicant failed to meet the requirements of s. 381.986, F.S. The Legislature also provided that if the Division of Administrative Hearings, the DOH, or a court of competent jurisdiction makes a final determination that an applicant was entitled to be a DO, that both this DO and currently approved DOs may operate in the same region.<sup>32</sup> Currently, in addition to the five DOs originally approved, the DOH has since approved The Green Solution in Alachua County and Grow Health in Polk County. The following map depicts the currently approved DOs.

 $<sup>^{23}</sup>$  *Id*.

<sup>&</sup>lt;sup>24</sup> Section 381.986(6), F.S.

<sup>&</sup>lt;sup>25</sup> Audio recordings of the rule development workshops are available on the DOH website at:

http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/resources/rulemaking/index.html (last visited Mar. 20, 2017).

<sup>&</sup>lt;sup>26</sup> Proposed Rule ch. 64-4, F.A.C., ID 14941024, (Aug. 14, 2014) and changed, ID 15040352, (Sept. 9, 2014).

<sup>&</sup>lt;sup>27</sup> Tornello Landscape Corp. v. DOH, Case No. 14-4547RP; Fl. Medical Cannabis Assoc. v. DOH, Case No. 14-4517RP;

Plants of Ruskin, Inc. v. DOH, Case No. 14-4299RP; Costa Farms, LLC v. DOH, Case No. 14-4296RP (Fla. DOAH 2014).

A copy of each Final Order is available on the Division of Administrative Hearings website.

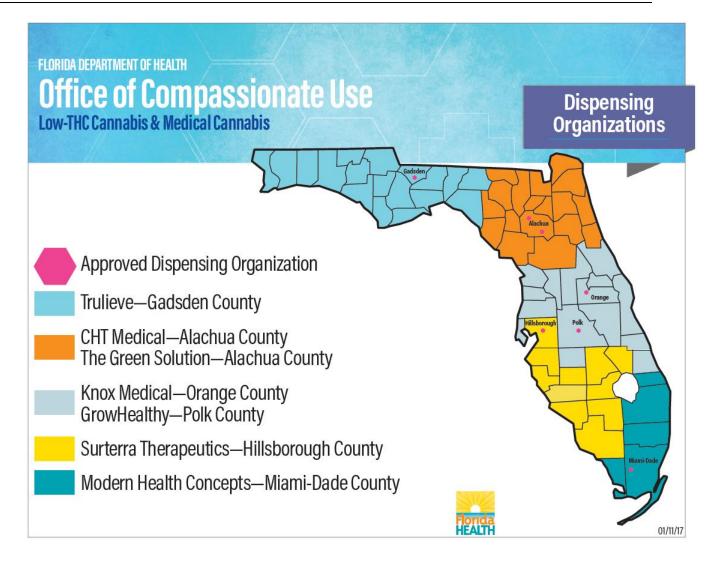
<sup>&</sup>lt;sup>28</sup> Proposed Rule ch. 64-4, ID 15645147, (Feb. 2, 2015).

<sup>&</sup>lt;sup>29</sup> Baywood Nurseries Co., Inc. v. DOH, Case No. 15-1694RP (Fla. DOAH 2015).

<sup>&</sup>lt;sup>30</sup> Information about the applications and the approved DOs is available on the DOH, Office of Compassionate Use, Resources website, available at: http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/dispensing-organizations/dispensing-application-process/index.html (last visited Mar. 20, 2017).

<sup>&</sup>lt;sup>31</sup> Section 381.986(5)(b), F.S. A map of the dispensing regions and approved dispensing organizations is available on the DOH website at: <u>http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/\_documents/ocu-dispensing-map.pdf</u> (last visited Mar. 20, 2017).

<sup>&</sup>lt;sup>32</sup> ch. 2016-123, L.O.F.



In addition to the currently approved DOs, s. 381.986(5)(c), F.S., requires the DOH to approve three additional DOs upon the registration of 250,000 active qualified patients in the compassionate use registry. At least one of the newly approved DOs must be an applicant that is a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999), or In Re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011), and a member of the Black Farmers and Agriculturalists Association. These additional applicants are not required to meet the requirement to possess a certificate of registration issued by the Department of Agriculture and Consumer Services (DACS) for the cultivation of more than 400,000 plants, be operated by a nurseryman, and have been operating as a registered nursery in this state for at least 30 continuous years.

# The Compassionate Use Registry

The act requires the DOH to create a secure, electronic, and online registry for the registration of physicians and patients and for the verification of patient orders by DOs, which is accessible to law enforcement.<sup>33</sup> The registry must allow DOs to record the dispensing of low-THC cannabis, and must prevent an active registration of a patient by multiple physicians. Physicians must

<sup>&</sup>lt;sup>33</sup> Section 381.986(5)(a), F.S.

register qualified patients with the registry and DOs are required to verify that the patient has an active registration in the registry, that the order presented matches the order contents as recorded in the registry, and that the order has not already been filled before dispensing any low-THC cannabis. DOs are also required to record in the registry the date, time, quantity, and form of low-THC cannabis dispensed.<sup>34</sup> The Compassionate Use Registry became operational on July 11, 2016.<sup>35</sup> As of the end of February, 2017, there were 4,079 patients registered with the Compassionate Use Registry.<sup>36</sup>

# The Office of Compassionate Use and Research on Low-THC Cannabis

The DOH was required to establish the Office of Compassionate Use under the direction of the deputy state health officer to administer the act.<sup>37, 38</sup>

The act includes several provisions related to research on low-THC cannabis and cannabidiol including:

- Requiring physicians to submit quarterly patient treatment plans to the UFCP for research on the safety and efficacy of low-THC cannabis;<sup>39</sup>
- Authorizing state universities to perform research on cannabidiol and low-THC cannabis and exempting them from the provisions in ch. 893, F.S., for the purposes of such research;<sup>40</sup> and
- Appropriating \$1 million to the James and Esther King Biomedical Research Program for research on cannabidiol and its effects on intractable childhood epilepsy.<sup>41</sup>

# Medical Marijuana in Florida: Amendment 2 (2016)

On November 4, 2016, Amendment 2 was voted into law and established s. 29, Art. X, of the State Constitution. This section of the State Constitution became effective on January 3, 2017, and creates several exemptions from criminal and civil liability for:

- Qualifying patients medically using (acquiring, possessing, using, delivering, transferring, or administering) marijuana in compliance with the amendment;
- Physicians, solely for issuing physician certifications with reasonable care and in compliance with the amendment; and
- Medical Marijuana Treatment Centers (MMTCs), their agents and employees for actions or conduct under the amendment and in compliance with DOH rules.

<sup>&</sup>lt;sup>34</sup> Section 381.986(6), F.S.

<sup>&</sup>lt;sup>35</sup> Implementation Timeline, Office of Compassionate Use, October 2016) available at

http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/ documents/ocu-timeline.pdf, (last visited on Mar. 21, 2017).

<sup>&</sup>lt;sup>36</sup> Revenue Estimating Conference report on Amendment 2, March 2, 2017, p. 3, (on file with the Senate Committee on Health Policy).

<sup>&</sup>lt;sup>37</sup> Section 385.212, F.S.

<sup>&</sup>lt;sup>38</sup> The Office of Compassionate Use is authorized to enhance access to investigational new drugs for Florida patients through approved clinical treatment plans or studies by: creating a network of state universities and medical centers recognized for demonstrating excellence in patient-centered coordinated care for persons undergoing cancer treatment and therapy in this state; making any necessary application to the United States Food and Drug Administration (FDA) or a pharmaceutical manufacturer to facilitate enhanced access to compassionate use for Florida patients; and entering into agreements necessary to facilitate enhanced access to compassionate use for Florida patients. *See* ss. 381.925 and 385.212, F.S.

<sup>&</sup>lt;sup>39</sup> Section 381.986(2)(e), F.S.

<sup>&</sup>lt;sup>40</sup> Section 385.211, F.S.

<sup>&</sup>lt;sup>41</sup> Chapter 2014-157, L.O.F.

- "Qualifying patient" meaning someone who:
  - Has been diagnosed with a "debilitating medical condition";
  - Has a "physician certification"; and
  - Has a valid qualifying patient identification card issued by the DOH.
  - Minor patients must also have the consent of a parent or legal guardian prior to both obtaining a physician certification and obtaining an identification card from the DOH.<sup>42</sup>
- "Debilitating Medical Condition" meaning:
  - Cancer;
  - Epilepsy;
  - o Glaucoma;
  - HIV/AIDS;
  - Post-Traumatic Stress Disorder (PTSD);
  - o ALS;
  - Crohn's Disease;
  - Parkinson's Disease;
  - o Multiple Sclerosis; or
  - Another debilitating medical condition of the same kind or class as, or comparable to, the enumerated conditions.
  - Additionally, a physician must believe that the medical use of marijuana would likely outweigh the potential health risks for the patient.
- "Marijuana" as having the meaning given cannabis in Section 893.02(3), Florida Statutes (2014), and, in addition, "Low-THC cannabis" as defined in Section 381.986(1)(b), Florida Statutes (2014), shall also be included in the meaning of the term "marijuana."
- "Medical Marijuana Treatment Center" or "MMTC" meaning an entity that acquires, cultivates, possesses, processes (including development of related products such as food, tinctures, aerosols, oils, or ointments), transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, or educational materials to qualifying patients or their caregivers and is registered by the Department.
- "Medical use" meaning the acquisition, possession, use, delivery, transfer, or administration of an amount of marijuana not in conflict with Department rules, or of related supplies by a qualifying patient or caregiver for use by the caregiver's designated qualifying patient for the treatment of a debilitating medical condition.
- "Physician Certification" meaning a written document signed by a person who is "licensed to practice medicine" in Florida stating:
  - The physician has conducted a medical examination of the patient and a full assessment of the patient's medical history;
  - That, in the physician's professional opinion, the patient has a debilitating medical condition;
  - That, in the physician's professional opinion, the medical use of marijuana will outweigh the health risks for the patient; and
  - For how long the physician recommends the medical use of marijuana for the patient.
- "Qualifying patient" meaning a person who has been diagnosed to have a debilitating medical condition, who has a physician certification and a valid qualifying patient

<sup>&</sup>lt;sup>42</sup> This provision is included in the definition of "physician certification."

identification card. If the Department does not begin issuing identification cards within nine (9) months after the effective date of this section, then a valid physician certification will serve as a patient identification card in order to allow a person to become a "qualifying patient" until the Department begins issuing identification cards.

Once certified, a patient may designate one or more caregivers to assist him or her with the medical use of marijuana. The amendment defines a "caregiver" as a person who is at least twenty-one (21) years old who has agreed to assist with a qualifying patient's medical use of marijuana and has qualified for and obtained a caregiver identification card issued by the Department. Caregivers:

- Are prohibited from consuming medical marijuana;
- Caregivers must obtain an ID card from the DOH;
- The DOH has authority to establish standards and qualifications for caregivers including:
  - Background checks;
  - o Procedures for issuing ID cards; and
  - Limitations on the number of caregivers per patient and the number of patients per caregiver.

The DOH is required to register Medical Marijuana Treatment Centers that will be authorized to acquire, cultivate, possess, process, transfer, transport, sell, distribute, dispense, or administer medical marijuana, related supplies, or educational materials to patients and caregivers. The DOH is required to adopt rules regarding MMTCs including:

- Procedures to register as an MMTC;
- Procedures for the issuance, renewal, suspension, and revocation of MMTC registrations; and
- Standards to ensure proper security, record keeping, testing, labeling, inspection, and safety.

The amendment requires the DOH to adopt rules no later than 6 months after its effective date (by July 3, 2017). The stated purpose of the rules is to ensure the availability and safe use of medical marijuana by qualifying patients. Currently, the DOH has begun the rulemaking process to implement s. 29, Art. X, of the State Constitution and has held several workshops around the state.<sup>43</sup> The DOH is required to adopt rules for:

- Issuing patient and caregiver ID cards;<sup>44</sup>
- Procedures for establishing caregiver qualifications;
- Procedures for registering MMTCs; and
- A regulation that defines the amount of marijuana that could reasonably be presumed to be an adequate supply, based on the best available medical evidence. (This presumption can be overcome on an individual patient basis).

If the DOH does not have rules adopted by the deadline, the amendment creates a cause of action for any Florida citizen to seek judicial relief to compel the DOH's compliance. Additionally, the

<sup>&</sup>lt;sup>43</sup> Rule 64-4.012, rule notice published on Jan. 17, 2017, *available at* <u>https://www.flrules.org/gateway/ruleNo.asp?id=64-4.012</u>, (last visited on Mar. 20, 2017).

<sup>&</sup>lt;sup>44</sup> On Feb. 18, 2017, the DOH adopted Rule 64-4.011, F.A.C., addressing the issuance of Compassionate Use Registry Identification Cards. This rule may bring the DOH into compliance with the requirement to adopt rules for issuing ID cards by July, 3 2017, however the rule may need requiring amending to comply with Constitutional terms and to comply with changes to s. 381.986, F.S., provided in this bill.

DOH is required to begin registering MMTCs and issuing patient and caregiver ID cards within 9 months of the amendment's effective date (October 3, 2017). If the DOH does not comply with this requirement, the amendment states that a physician certification is sufficient for a person to become a qualifying patient without being issued an ID card from the DOH.

The amendment also creates a number of specific restrictions on its exemption from liability and its grants of authority including specifically:

- Not repealing or allowing violations of other laws related to the non-medical use of marijuana;
- Not permitting the operation of any vehicle under the influence of marijuana;
- Not requiring the accommodation of the use of marijuana in specific areas or in any public place;
- Not requiring any health insurance provider to cover the medical use of marijuana; and
- Not affecting laws related to negligence or malpractice on the part of any patient, caregiver, physician, or MMTC agent or employee.

# Medical Marijuana in Florida: The Necessity Defense

Despite the fact that the use, possession, and sale of marijuana are prohibited by state law, Florida courts have found that circumstances can necessitate medical use of marijuana and circumvent the application of criminal penalties. The necessity defense was successfully applied in a marijuana possession case in *Jenks v. State* where the First District Court of Appeal found that "s 893.03, F.S., does not preclude the defense of medical necessity" for the use of marijuana if the defendant:

- Did not intentionally bring about the circumstance which precipitated the unlawful act;
- Could not accomplish the same objective using a less offensive alternative available; and
- The evil sought to be avoided was more heinous than the unlawful act.<sup>45</sup>

In the cited case, the defendants, a married couple, were suffering from uncontrollable nausea due to AIDS treatment and had testimony from their physician that he could find no effective alternative treatment. Under these facts, the court found that the defendants met the criteria to qualify for the necessity defense and ordered an acquittal of the charges of cultivating cannabis and possession of drug paraphernalia.

# Medical Marijuana Laws in Other States

Currently, 28 states, the District of Columbia, and Guam have some form of law that permits the use of marijuana for medicinal purposes.<sup>46</sup> These laws vary widely in detail but most are similar

<sup>&</sup>lt;sup>45</sup> Jenks v. State, 582 So.2d 676, 679 (Fla. 1st DCA 1991), review denied, 589 So.2d 292 (Fla. 1991).

<sup>&</sup>lt;sup>46</sup> These states include: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington. California was the first to establish a medical marijuana program in 1996 and New York was the most recent state to pass medical marijuana legislation in June 2014. Seventeen states allow limited access to marijuana products (low-THC and/or high CBD-cannabidiol). Alabama, Florida, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming. National Conference of State Legislatures, *State Medical Marijuana Laws*,

in that they touch on several recurring themes. For example, most state laws require an identification card and registry for patients and caregivers to use medical marijuana; require the patient to receive certification from up to two physicians that the patient has a qualifying condition before the patient may use medical marijuana; allow a patient to designate a caregiver who can possess the medical marijuana and assist the patient in using the medical marijuana; and provide general restrictions on how medical marijuana can be obtained (self-cultivated or from a dispensary) and where it can be used.<sup>47</sup>

Of the 17 states with low-THC cannabis laws similar to s. 381.986, F.S., most specify that the use of such low-THC cannabis is reserved for patients with epileptic or seizure disorders. Florida allows the treatment of cancer and Georgia allows the treatment of end stage cancer and other specified conditions. Additionally, the definition of low-THC cannabis differs from state to state. The THC level allowed ranges from a high of below 5 percent to less than 0.3 percent; most states restrict the level of THC to below 1 percent. CBD levels are generally required to be high, with most states requiring at least 10 percent.<sup>48</sup>

#### Interaction with the Federal Government

The Federal Controlled Substances Act lists marijuana as a Schedule 1 drug and provides no exceptions for medical uses.<sup>49</sup> Possession, manufacture, and distribution of marijuana is a crime under federal law.<sup>50</sup> Although a state's medical marijuana laws protect patients from prosecution for the legitimate use of marijuana under state law, state medical marijuana laws, or Constitutional provisions, do not protect individuals from prosecution under federal law.

In 2013, the United States Department of Justice (USDOJ) issued statements indicating that the federal government would not pursue cases for low-level drug crimes, leaving such prosecutions largely up to state authorities. The U.S. Attorney General issued a statement that the USDOJ was changing policy such that individuals "who have committed low-level, nonviolent drug offenses, who have no ties to large-scale organizations, gangs, or cartels, will no longer be charged with offenses that impose draconian mandatory minimum sentences... [and] would instead receive sentences better suited to their individual conduct...<sup>51</sup> Further, the USDOJ issued a memorandum clarifying that the department considers small-scale marijuana use to be a state matter which states may choose to punish and certain operations adhering to state laws legalizing marijuana in conjunction with robust state regulatory systems would be far less likely to come under federal scrutiny.<sup>52</sup> In addition, a rider in recent appropriations acts and continuing resolutions has prohibited the USDOJ from using appropriated funds to prevent specified states (including Florida) from implementing the states own medical marijuana

<sup>(</sup>Mar. 16, 2017), available at: <u>http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx</u> (last visited Mar. 20, 2017).

<sup>&</sup>lt;sup>47</sup> Analysis by Senate Health Policy committee staff of *supra* note 49.

<sup>&</sup>lt;sup>48</sup> Supra note 49.

<sup>&</sup>lt;sup>49</sup> 21 U.S.C. s. 812. Note: On August 11, 2016, the Federal Drug Enforcement Administration refused two petitions to reschedule marijuana under the Controlled Substances Act, see <u>https://www.dea.gov/divisions/hq/2016/hq081116.shtml</u>, (last visited on Mar. 20, 2017)

<sup>&</sup>lt;sup>50</sup> The punishments vary depending on the amount of marijuana and the intent with which the marijuana is possessed. *See* 21 U.S.C ss. 841-865.

<sup>&</sup>lt;sup>51</sup> USDOJ, *Smart on Crime: Reforming the Criminal Justice System for the 21<sup>st</sup> Century*, (Aug. 2013), p. 3, *available at* <u>http://www.justice.gov/ag/smart-on-crime.pdf</u> (last visited on Mar. 20, 2017).

<sup>&</sup>lt;sup>52</sup> USDOJ Memorandum for all U.S. Attorneys, "*Guidance Regarding Marijuana Enforcement*," (August 29, 2013), *available at* <u>http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf</u> (last visited Mar. 20, 2017).

laws.<sup>53</sup> It is worth noting that, with the election of President Trump and changes to the leadership of the USDOJ, the guidance issued by the USDOJ may be amended in the future, however it would require an act of Congress to amend the rider preventing the USDOJ from using funds to prevent specified states from implementing medical marijuana laws.

#### III. Effect of Proposed Changes:

In addition to technical and conforming changes made by the bill to ss. 381.986, 381.987, 385.211, 499.0295, and 1004.441, SB 406 amends s. 381.986, F.S., as follows:

# **Definitions**

The bill:

- Conforms the definitions for "caregiver," "debilitating medical condition," "marijuana," "medical marijuana treatment center" or "MMTC," to the definitions in s. 29, Art. X, of the State Constitution.
- Uses the constitutional definition for "medical use" but amends the definition to restrict:
  - Smoking:
  - The possession, use, or administration of marijuana not purchased from an MMTC;
  - The transfer of marijuana to anyone other than a qualifying patient or his or her caregiver;
  - The use or administration of any type or amount of marijuana not specified on a qualifying patient's physician certification; and
  - The use or administration of marijuana:
    - On any form of public transportation;
    - In any public place;
    - In a qualifying patient's place of employment if restricted by his or her employer;
    - In a state correctional institution;
    - On the grounds of a preschool, primary school, or secondary school; or
    - On a school bus or in a vehicle, aircraft, or motorboat.
- Uses the constitutional definition for "qualifying patient" but also includes "eligible patients" • as defined in the Right to Try Act, patients suffering from a physical medical condition that produces symptoms of seizures or severe and persistent muscle spasms, and patients suffering from chronic nonmalignant pain.
- Adds definitions for: •
  - o "Chronic nonmalignant pain" meaning pain that is caused by a debilitating medical condition or that originates from a debilitating medical condition and persists beyond the usual course of that debilitating medical condition; and
  - "Close relative" meaning a spouse, parent, sibling, grandparent, child, or grandchild, 0 whether related by whole or half-blood, by marriage, or by adoption.

<sup>&</sup>lt;sup>53</sup> See s. 542, Pub. L. No. 114-113 (Consolidated Appropriations Act, 2016). A recent court order by the U.S. District Court for the Northern District of California recently held that a similar provision in the previous appropriations act (s. 538, Pub. L. No. 113-235) does not prohibit the USDOJ from enforcing violations of *federal* marijuana laws by individuals or businesses who are complying with state medical marijuana laws. U.S. v. Marin Alliance for Medical Marijuana and Shaw, Order re: Motion to Dissolve Permanent Injunction, No. C 98-00086 CB, (Oct. 19, 2015), available at

http://www.scribd.com/doc/286089509/US-vs-Marin-Alliance-for-Medical-Marijuana#scribd (last visited Mar. 20, 2017).

#### **Physician Certifications**

The bill allows physicians to issue physician certifications to:

- A patient suffering from a debilitating medical condition;
- A patient suffering from a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms;
  - Such patients may only receive low-THC cannabis if the patient does not meet any of the other qualifications;
- A patient suffering from chronic nonmalignant pain, if the physician has diagnosed an underlying debilitating medical condition as the cause of the pain, which allows the patient to receive marijuana for the patient's medical use to alleviate the patient's pain; or
- An eligible patient as defined in the Right to Try Act.

Before certifying a patient the physician must:

- Be licensed under chs. 458 or 459, F.S.;
- Have successfully completed the required 4-hour course and exam administered by the Florida Medical Association or the Florida Osteopathic Medical Association;<sup>54</sup>
- Have conducted a full assessment of the patient's medical history;
- Have determined that, in the physician's professional opinion, the patient meets one of the criteria specified above;
- Have determined that the medical use of marijuana would likely outweigh the potential health risks to the patient; and
- Have obtained the voluntary written informed consent of the patient or, if the patient is a minor, the patient's parent or legal guardian, after having sufficiently explained the current state of knowledge in the medical community of the effectiveness of treatment of the patient's condition with marijuana and the potential risks and side effects.<sup>55</sup>

The physician must also register as the treating physician with the compassionate use registry and maintain a patient treatment plan that must be submitted to the University of Florida, College of Pharmacy on a quarterly basis. The bill increases the amount of marijuana a physician may certify a patient to receive from a 45-day supply to a 90-day supply and patients must be recertified at least annually. A physician may not issue physician certifications if he or she is a medical director employed by an MMTC.

The bill also grandfathers in all orders for low-THC cannabis issued prior to the effective date of the act as physician certifications and requires the DOH to consider patients with such orders as qualifying patients until the DOH begins issuing compassionate use registry identification cards.

# Penalties

The bill conforms existing penalties to the changes made by the bill and creates two new misdemeanors for a qualifying patient or caregiver who cultivates marijuana or who purchases or

<sup>&</sup>lt;sup>54</sup> Current law requires an 8-hour course and exam, which must be retaken annually.

<sup>&</sup>lt;sup>55</sup> If the patient is an eligible patient, the physician must obtain written informed consent pursuant to s. 499.0295, F.S.

acquires marijuana from any person or entity other than an MMTC<sup>56</sup> and a caregiver who violates any of the applicable provisions of this section or applicable department rules.<sup>57</sup>

#### Caregivers

The bill allows a qualifying patient to designate a caregiver to assist him or her with the medical use of marijuana. The bill requires the DOH to register a caregiver and issue him or her a compassionate use registry identification card if designated by a qualifying patient and the caregiver:

- Is 21 years of age or older, unless the patient is a close relative of the caregiver;
- Agrees in writing to be the qualifying patient's caregiver;
- Does not receive compensation, other than actual expenses incurred, for assisting the qualifying patient with the medical use of marijuana unless the caregiver is acting pursuant to employment in a licensed facility in accordance with subparagraph (c)2.; and
- Passes a level 2 screening pursuant to chapter 435, unless the patient is a close relative of the caregiver.

A qualifying patient may only have one designated caregiver at a time unless all of the patient's caregivers are his or her close relatives or legal representatives. A caregiver may only assist one patient at a time unless:

- All qualifying patients the caregiver is assisting are close relatives of each other and the caregiver is the legal representative of at least one of the patients; or
- All qualifying patients the caregiver is assisting are receiving hospice services, or are residents, in the same assisted living facility, nursing home, or other licensed facility and have requested the assistance of that caregiver with the medical use of marijuana; the caregiver is an employee of the hospice or licensed facility; and the caregiver provides personal care or services directly to clients of the hospice or licensed facility as a part of his or her employment duties at the hospice or licensed facility.

# **Duties of the DOH**

# Compassionate Use Registry

The bill requires the DOH to expand access to the compassionate use registry to:

- Practitioners licensed under chs. 458 or 459, F.S., to ensure proper care for patients requesting physician certifications;
- Practitioners licensed to prescribe prescription drugs, to ensure proper care for patients before prescribing medications that may interact with the medical use of marijuana;

The bill specifies that law enforcement agencies may check the registry to verify the authorization of a qualifying patient or a patient's caregiver to possess marijuana or a cannabis delivery device.

<sup>&</sup>lt;sup>56</sup> A first degree misdemeanor.

<sup>&</sup>lt;sup>57</sup> A second degree misdemeanor on the first offense and a first degree misdemeanor on subsequent offenses.

# Compassionate Use Registry Identification Cards

By July 3, 2017, the bill requires the DOH to adopt rules establishing procedures for the issuance, annual renewal, suspension, and revocation of compassionate use registry identification cards for patients and caregivers who are residents of this state. The bill allows the DOH to charge a reasonable fee for issuing and renewal of identification cards. The bill requires that the DOH begin issuing identification cards to patients and caregivers by October 3, 2017. Minor patients must provide the DOH with written consent from a parent or a legal guardian before being issued an identification card.

The bill specifies that the identification cards must be resistant to counterfeiting and tampering and at a minimum contain:

- The name, address, and date of birth of the patient or caregiver, as appropriate;
- A full-face, passport-type, color photograph of the patient or caregiver, as appropriate, taken within the 90 days immediately preceding registration;
- Designation of the cardholder as a patient or caregiver;
- A unique numeric identifier for the patient or caregiver which is matched to the identifier used for such person in the department's compassionate use registry. A caregiver's identification number and file in the compassionate use registry must be linked to the file of the patient or patients the caregiver is assisting so that the caregiver's status may be verified for each patient individually;
- The expiration date, which shall be 1 year after issuance or the date treatment ends as provided in the patient's physician certification, whichever occurs first; and
- For caregivers who are assisting three or fewer qualifying patients, the names and unique numeric identifiers of the qualifying patient or patients that the caregiver is assisting.

# Dispensing Organization Grandfathering

The bill requires the DOH to grandfather in all existing DOs as MMTCs as soon as practicable.<sup>58</sup> The DOH may not charge the DOs a registration fee and the bill states that, for the purposes of the act, all DOs are deemed to be MMTCs on the effective date of the act. The bill requires that the DOs continue to comply with all representations made in their applications to be dispensing organizations after being registered as MMTCs and allows the DOH to grant variances to those representations.

# Additional MMTCs

The bill requires that, within 6 months of the registration of 250,000 patients in the compassionate use registry, the DOH must register five additional MMTCs including at least one applicant that is a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999) or In re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011) and a member of the Black Farmers and Agriculturalists Association. Afterward, within 6 months after the registration of each of 350,000; 400,000; 500,000; and each additional 100,000 patients above 500,000, the DOH must register an additional five MMTCs. The bill eliminates the requirement that MMTCs possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131, F.S., that is issued for the cultivation of more than 400,000

<sup>&</sup>lt;sup>58</sup> Including DOs that become MMTCs pursuant to the results of litigation (see present situation for details).

plants, be operated by a nurseryman as defined in s. 581.011, and have been operated as a registered nursery in this state for at least 30 continuous years.

#### **MMTC Requirements**

The requirements for MMTCs are substantially similar to the requirements for DOs in current law. The bill amends requirements for MMTCs so that:

- MMTCs are required to maintain compliance with all the representations made to the DOH in the MMTC's application for registration.
  - Upon request, the department may grant an MMTC one or more variances from the representations made in the MMTC's application.
  - Consideration of such a variance shall be based upon the individual facts and circumstances surrounding the request.
  - A variance may not be granted unless the requesting MMTC can demonstrate to the department that it has a proposed alternative to the specific representation made in its application which fulfills the same or a similar purpose as the specific representation in a way that the department can reasonably determine will not be a lower standard than the specific representation in the application.
- MMTCs are required to label all marijuana with the concentration of THC and CBD in the product and with the recommended dose for the qualifying patient receiving it.
- MMTCs are allowed to produce edible products, but may not produce such items that are designed to be attractive to children. Additionally, MMTCs must meet all food safety standards established in state and federal law, including, but not limited to, the identification of the serving size and the amount of THC in each serving.
- When transporting marijuana, a copy of the transportation manifest must be in the vehicle at all times.

The bill also requires the DOH to adopt in rule a process for approving MMTC changes in ownership and changes in an MMTC owner's investment interest.

Additionally, the bill specifies that nothing in the act limits the ability of an employer to establish, continue, or enforce a drug-free workplace program or policy.

The bill's provisions take effect upon becoming law.

# IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

#### D. Other Constitutional Issues:

Section 29, Art. X, of the State Constitution is a unique provision of the Constitution in that it directs a state agency, the DOH, to implement its provisions without requiring implementing legislation. However, s. 29(4)(e), Art. X, of the State Constitution does provide that nothing in that section shall limit the legislature from enacting laws consistent with the section. Given the novelty of the constitutional provision, it is unclear how the courts will interpret its provisions as well as the interaction between its provisions and implementing legislation and rules.

# V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 406 may have a positive fiscal impact on new MMTCs that are registered under its provisions. The bill may have a negative fiscal impact on currently approved DOs due to the increase in number of allowed suppliers of marijuana once the compassionate use registry registers the specified number of patients.

SB 406 may have a negative fiscal impact on patients and caregivers who are required to pay fees for identification cards and on caregivers who are required to pay for background screenings.

# C. Government Sector Impact:

SB 406 may have an indeterminate fiscal impact on the DOH due to increased regulatory activity required by the bill. However, any expenditures required may be offset by fees and fines the DOH is allowed to assess. The DOH estimates that fees and fines may generate between \$6.1 million and \$8.6 million while total expenditures may be between \$6 million and \$8.9 million.<sup>59</sup>

The Florida Department of Law Enforcement (FDLE) estimates that revenues from SB 406 to the FDLE may range from \$9 million to \$18 million generated by fees for criminal history records checks.<sup>60</sup> The FDLE estimates that costs to the department at \$1.278 million.

SB 406 may have a positive fiscal impact on the state as a whole due to an increase in general revenue generated by the collection of sales tax assessed on the sale of marijuana.<sup>61</sup>

<sup>&</sup>lt;sup>59</sup> The DOH states that expenditures are highly dependent on the number of qualifying patients. See DOH analysis of SB 406, Feb. 14, 2017, on file with Senate Health Policy Committee staff.

<sup>&</sup>lt;sup>60</sup> The fee depends on whether or not caregivers are intended to be entered into the Clearinghouse. See FDLE analysis of SB 406, Feb. 15, 2017, (on file with the Senate Committee on Health Policy).

<sup>&</sup>lt;sup>61</sup> See supra, note 36.

SB 406 may have an indeterminate fiscal impact on local governments. Local governments may see a positive fiscal impact from fees associated with licensing and inspecting additional MMTC facilities as permitted by current law and may derive additional tax revenue from the sale of marijuana. Local governments may see a negative fiscal impact due to the expenses associated with implementing ordinances and undertaking regulatory activities required by such ordinances.

#### VI. Technical Deficiencies:

None.

#### VII. Related Issues:

Although SB 406 allows MMTCs to use contractors in general, it is unclear from the text of the bill what limits are placed on how an MMTC may use a contractor. The bill should be clarified to specify the duties a contractor may perform for an MMTC.

#### VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.986, 381.987, 385.211, 499.0295, and 1004.441.

#### IX. Additional Information:

A. Committee Substitute – Statement of Changes: (Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

THE FLORIDA SENATE	
APPEARANCE RECO	ORD
$\frac{3 22}{Meeting Date}$ (Deliver BOTH copies of this form to the Senator or Senate Professional Meeting Date	406
	Bill Number (if applicable)
Topic <u>Compassionale Use of Low THC</u> Cannabis	Amendment Barcode (if applicable)
Name Glen Treadwell	
Job Title Owner, Treadwell Nursery	_
Address PO Box 194	_ Phone 352 357 0888
Street Sorrento FZ 32776 City State Zin	Email
Speaking: For Against Information Waive S	Speaking: In Support Against air will read this information into the record.)
Representing Treadwell Nursery	
	stered with Legislature: 🔲 Yes 🔀 No

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# **APPEARANCE RECORD**

3/77/17 (Deliver BOTH copies of this form to the Senator or Senate Professional S	Staff conducting the meeting)
Meeting Date	Bill Number (if applicable)
Topic Medical Marijnana	Amendment Barcode (if applicable)
Name Ben Pollara	
Job Title Executive Director	
Address 801 Arthur Godfry Rd # 407A	Phone \$ 50 - 364 - 4168
Midmi Beach, FL 33140 City State Zip	Email Ben @ floridator care. org
	beaking: In Support Against ir will read this information into the record.)
Representing Florida For Gare	
Appearing at request of Chair: Yes X No Lobbyist registe	ered with Legislature: 🔀 Yes 🗌 No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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THE FLORIDA SEN	ATE
APPEARANCE R	
March 27, 2017 Meeting Date (Deliver BOTH copies of this form to the Senator or Senate Pro- Meeting Date	ofessional Staff conducting the meeting) $SB 406$ Bill Number (if applicable)
Topic Compassionale use of low-THC Cannas	is + Manjvana Amendment Barcode (if applicable)
Topic <u>Compassionale</u> Use of low-THC Cannab Name <u>Chief Daniel Oates</u>	
Job Title Chief of Police	
Address 2636 Mitcham Drie	Phone 850-219-3631
Tallahaste PL 32308 City State Zip	
Speaking: For Against Information V	Vaive Speaking: In Support Against The Chair will read this information into the record.)
Representing The Florida Police Ch	iefs Association
Appearing at request of Chair: Yes No Lobbyis	t registered with Legislature: Yes 🗹 No

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# THE FLORIDA SENATE APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date	Bill Number (if applicable)
Topic <u>medical mariguana - access</u>	Amendment Barcode (if applicable)
Name Anneluse Clark	
Job Title Parent of a Manor epilep	tic
Address 1336 Hideaway Drs	Phone 904.813.5228
St Johns FL 32259 City State Zip	Email annolise clark og man
Speaking: For Against Information Waive Spe	eaking: In Support Against will read this information into the record.)
Representing	
Appearing at request of Chair: Yes No Lobbyist registe	red with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

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	or Senate Professional Staff conducting the meeting)
Meeting Date	Bill Number (if applicable)
Topic CANMANS is	Amendment Barcode (if applicable
Name Marian BARNHART	·
Job Title 050	
Address 350 WESTFIELD DW	Phone \$13 5501378
City State	<u>Zip</u> Email <u>MoCocannamoms</u> . Com
Speaking: For Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing CAN WAMOMS	
Appearing at request of Chair: Yes No	Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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THE FLORIDA SENATE	
3 22 2017 (Deliver BOTH copies of this form to the Senator or Senate Professional S	RD Staff conducting the meeting)
Meeting Date	Bill Number (if applicable)
Topic Medical Marijugha	Amendment Barcode (if applicable)
Name VINNE Sendety	
Job TitleRealtor	(1) $(2)$
Address 3408 King George Jane	Phone 813)357-75/1
Settner, FL 33584	Email VSEUDATHEGMail.com
City State Zip	
Speaking: For Against Information Waive Speaking:	beaking: In Support Against ir will read this information into the record.)
	essors Distributors Retailer
Appearing at request of Chair: Yes No Lobbyist registed	ered with Legislature: Yes No

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# **APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date	Bill Number (if applicable)
Topic Medical Mening rara	Amendment Barcode (if applicable)
Name_ 202 McCarthy	
Job Title	, ,
Address 1335 Broker Ouk Dr	Phone
Writer Ocrale & 32/787	Email
City State Zip	
	peaking: In Support Against ir will read this information into the record.)
Representing Movites for Medical	Notipora
Appearing at request of Chair: Yes No Lobbyist registe	ered with Legislature: 🗌 Yes 🗌 No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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# **APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

3/22/17	ples of this form to the Sena	nor or Senale Professional S	tan conducting the meeting)	406
Meeting Date				Bill Number (if applicable)
Topic Workshop on SB 406 & ot	her Senate Bills		Ameno	Iment Barcode (if applicable)
Name Michael C. Minardi				,
Job Title Attorney				
Address 11402 Bloomingdale Av	е.	·····	Phone <u>954-729</u>	-9680
Riverview	FL	33511	Email <u>Michael@</u>	MinardiLaw.com
<i>City</i> Speaking: <b>I</b> For Against	<i>State</i> Information			Ipport Against ation into the record.)
Representing Patients and cit	lizens			
Appearing at request of Chair:	Yes 🗹 No	Lobbyist regist	ered with Legislat	ure: Yes 🖌 No
While it is a Senate tradition to encourag meeting. Those who do speak may be a	le public testimony, til sked to limit their rem	me may not permit all arks so that as many	persons wishing to sp persons as possible of	beak to be heard at this can be heard.
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	NCE RECORD or or Senate Professional Staff conducting the meeting) Amanmat 2 Bill Number (if applicable)
Topic Implanentation	Amendment Barcode (if applicable)
Name JARED BAMISIS	
Job Title Self-Employed	
Address 76 E Pensacoli 54	Phone (159) 531-1782
Street TUDASSEE FL City State	8 Email JARED BAMIBIJ (BAMAIL
Speaking: Kror Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing Myself	
Appearing at request of Chair: 🗌 Yes 📉 No	Lobbyist registered with Legislature: Yes 🔀 No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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THE FLO	RIDA SENATE
	<b>NCE RECORD</b> For Senate Professional Staff conducting the meeting) $\frac{SB}{Bill Number (if applicable)}$
Topic Medical Marijuana	Amendment Barcode (if applicable)
Name Jay Czarkowski	
Job Title Partner	
Address 1731 15th Street	Phone <u>303-618-8243</u>
City State	80302 Email jay e think camina com Zip
Speaking: Kor Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing <u>Myself</u>	
Appearing at request of Chair: 🔄 Yes 🖾 No	Lobbyist registered with Legislature: 🗌 Yes 🔀 No

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# THE FLORIDA SENATE APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date	Bill Number (if applicable)
Topic	Amendment Barcode (if applicable)
Name Bill Brothers	
Job Title President - AFS	
Address 3219 & Conclbach Rd	Phone 561 2521194
Street Phoenix Az 85016	Email GM QazFacco
City State Zip	
	eaking: In Support Against ir will read this information into the record.)
Representing <u>AFS</u>	
Appearing at request of Chair: Yes No Lobbyist registe	ered with Legislature: 👘 Yes 📃 No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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3/22/17	(Deliver BOTH copies of thi	is form to the Senato	r or Senate Professional S	taff conducting the meetir	g) 53614
Meeting Date			1135301	PORTOF)	Bill Number (if applicable)
Meeting Date Topic $\underline{AMEPO}$	MENT2 U	PORKSH	10P (53614	Ame	ndment Barcode (if applicable)
Name MARC	RESSLER				
Job Title					
Address <u>176</u> C	ROSSROAD	LAKES	DR.	Phone $904$	-321-7526
Address <u>176</u> Street POPTE M	EDRA BEACH	A	32082	Email MARC	-321-9556 RESELERCAOL, GM
City		State	Zip		
Speaking: For [	Against Info	ormation		peaking: In S	upport Against <i>mation into the record.</i> )
Representing	MISELF		•		
Appearing at reques		No	Lobbyist registe	ered with Legisla	iture: Yes No

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THE FLC	DRIDA SENATE	
APPEARAI		
(Deliver BOTH copies of this form to the Senato	or or Senate Professional S	taff conducting the meeting)
Meeting Date		Bill Number (if applicable)
Topic Medical CAMABIS		Amendment Barcode (if applicable)
Name LOVIS RORNOO		
Job Title		
Address 302 Simestratin Circle		Phone <u>487-699-9361</u>
AltAmonte Spence FC	<u>32714</u> Zip	Email. LCR 5002 Dorde com
Speaking: For Against Information	, Waive Sp	eaking: In Support Against r will read this information into the record.)
Representing		
Appearing at request of Chair: 🦳 Yes 🦳 No	Lobbyist registe	ered with Legislature: Ves No

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# **APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional S	taff conducting the meeting)
3/22/2017 Meeting Date	SIS 614 (1388 Bill Number (if applicable)
Topic 56406, 56614, 56 1388, et al	Amendment Barcode (if applicable)
Name ALLISON MAWHINNEY	
Job Title ATTORNEY	
Address 301 S. BRONDIGH ST, SUZTE 600	Phone (850) 577-9090
Tallahussee FL 32301 City State Zip	Email GRAY- ROBINSON. COM
Speaking: For Against Information Waive Sp	eaking: In Support Against r will read this information into the record.)
Representing MODERN CANNA SLIENCE, LLC	
Appearing at request of Chair: Yes No Lobbyist register	ered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

	THE F	LORIDA SENATE			
3/22/17 (Deliver BOT Meeting Date	<b>APPEAR</b> H copies of this form to the Ser	ANCE RECO nator or Senate Professional		<	SB 406 Number (if applicable)
Topic Medical Mari	phane			Amendment	Barcode (if applicable)
Name Chris Mak			_		
Job Title Attorney			_		
Address 2333 Bricke	M Ave., sui	teA-1	Phone		
Mami	FL	33129	Email Cyrra	alekefo	rtemalek. con
City	State	Zip			
Speaking: 🗹 For 🦳 Against	Information		peaking: I		
Representing Florid	a Patients "	First			
Appearing at request of Chair:	Ves No	Lobbyist regist	tered with Leg	islature:	Yes VNo

This form is part of the public record for this meeting.

	THE FLORIDA SENATE
	APPEARANCE RECORD
3-22-17	(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date	Bill Number (if applicable)
Topic <u>Medical Cannabis</u> Name <u>Haren</u> Bass	Amendment Barcode (if applicable)
Job Title Engineer	
Address <u>407 E 9th Auc</u>	Phone 850 - 933 - 505 6
Havana Fl City State	32333 Email tobas Zip Ebass emoore bass
Speaking: For Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing <u>Self</u>	
Appearing at request of Chair: Yes No	Lobbyist registered with Legislature: 🔄 Yes 🔄 No

This form is part of the public record for this meeting.

THE FLORIDA SENATE	
APPEARANCE RECORD	
3-22-74 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meet Meeting Date	ting) Bill Number (if applicable)
Topic <u>Amendment 2</u>	nendment Barcode (if applicable)
Name helly action advell Jacks	
Job Title Mother Grower, Equestrian	
Address Address 14289 Eguestrian Way Sul-	723-3513
Street Wellington FC 33470 Email Kelly City State Zip Email Kelly	csachse me
	Support 🔲 Against
Representing	ermation into the record.)
Appearing at request of Chair: Yes No Lobbyist registered with Legisl	lature: 🦳 Yes 🦳 No

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#### **APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senato	or or Senate Professional Staff conducting the meeting)
Meeting Date	Bill Number (if applicable)
Topic MEDILA CANNABIS	Amendment Barcode (if applicable)
Name Dennis S. PIERE - CHARLES	
Job Title D.R. of Programs	
Address Po Box 38070	Phone 850-445-3189
Tallahassee R City State	32315 Email dennise force, org
Speaking: Kor Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing Flogida Patients	
Appearing at request of Chair: Yes No	Lobbyist registered with Legislature: 🗌 Yes 🦳 No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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		The Flor	IDA SENATE		
		APPEARAN			ι.
3/22/2017	(Daliver BOTH co	ples of this form to the Senator (	or Senate Professional (	Staff conducting the me	eling)
Meeting Date					Bill Number (if applicable)
Topic marijuna				A	mendment Barcode (if applicable)
Name Elaine Geller				_	
Job Title VP legislativ	ve Affasirs			_	
Address 753 S Highl	and Dr			Phone 954-2	260-9159
Street Hollywod		FI	33021		r@belisouth.net
<i>City</i> Speaking: 🗹 For [	Against	State		- Speaking: 🗹 (	n Support Against
Representing saf	e and smart	marijuana laws			and the second

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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Appearing at request of Chair: Ves No

S-001 (10/14/14)

Lobbyist registered with Legislature: Ves No

THE FLORIDA SENATE	
APPEARANCE RECO	RD
$\frac{\partial 3}{\partial \mathcal{R}}$	taff conducting the meeting)
Meeting Date	Bill Number (if applicable)
TOPIC MEDICAL MARITICANA	Amondmont Demode (if a line it)
Name DR. GWAUE FOSU	Amendment Barcode (if applicable)
Job Title_PHARMACIST	
Address 120 CARTER ALVD SWITE 6	Phone 867-874-4835
City EL 33868 Zity State Zip	Email FFOSLOCTAMABALKR.Con
	eaking: In Support Against will read this information into the record.)
Representing OAL ITTON OF CONCERNED PHARMA	CISTS & GTIZENS
Appearing at request of Chair: Yes No Lobbyist registe	ered with Legislature: Yes No

This form is part of the public record for this meeting.

THE FLORIDA SENATE	
APPEARANCE RECO	
22 Mch IT (Deliver BOTH copies of this form to the Senator or Senate Professional	Staff conducting the meeting)
Meeting Date	Bill Number (if applicable)
Topic Medical Marijuana	Amendment Barcode (if applicable)
Name Barney Bishop	_
Job Title Pres & CEO	_
Address 204 5. Monroe	Phone 850.510-9922
Street Tall FL 32301 City State Zip	Email
	peaking: In Support Against air will read this information into the record.)
Representing _ Fla. Smart Justice Allian.	<u> </u>
Appearing at request of Chair: Yes No Lobbyist regist	ered with Legislature: Ves No

This form is part of the public record for this meeting.

THE FLORI	DA SENATE			
(Deliver BOTH copies of this form to the Senator of			the meeting)	
Meeting Date Topic MMT Written to	stamony	Brth	ل	Bill Number (if applicable)
Topic <u>MMJ</u>	Pec	Dron	Amendr	nent Barcode (if applicable)
Name DR MOORE				
Job Title DR of Medicine				
Address 1849 Capital Medica	l Ct	Phone_	850	222-2222
Tallahassee FL City State	32308	Email		
Speaking: For Against Information	Zip Waive Sp <del>(The Chai</del> t		In Sup	port Against tion into the record.)
Representing <u>himself &amp; patient</u>	5			
Appearing at request of Chair: Yes X No	Lobbyist registe	ered with	Legislatu	re: Yes No

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THE FLORIDA SENATE	
	RD
2/22/12 (Deliver BOTH copies of this form to the Senator or Senate Professional	
Meeting Date	Bill Number (if applicable)
Topic COMPASSIONATE USE	 Amendment Barcode (if applicable)
Name DENNIS DECKERHOFF	_
Job Title PATIENT ADVOCATE	_
Address 5704 VICTOR BROWN TRL.	Phone 850-562-0405
TL4 FL 32303	Email dums C deckerhoft cn
City State Zip	
	peaking: In Support Against air will read this information into the record.)
Representing <u>Son</u> BARREN DECKERL	orf
Appearing at request of Chair: Yes No Lobbyist regist	ered with Legislature: Yes VNo

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THE FI	LORIDA SENATE
APPEARA	NCE RECORD
3-22-17 (Deliver BOTH copies of this form to the Sena	ator or Senate Professional Staff conducting the meeting)
Meeting Date	Bill Number (if applicable)
Topic Medical Campobis	Amendment Barcode (if applicable)
Name Fosalyn Peckerhott	
Job Title	
Address 5704 Vitar Bruch	M Phone 567-1503
Street Gall M	323B Email (Dealand Aleckichistican
City State	Zip
Speaking: For Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing <u>MI SAM</u>	
Appearing at request of Chair: 🗌 Yes 🚺 No	Lobbyist registered with Legislature: 🗌 Yes 🗹 No
	x

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THE FLORIDA SENATE	
APPEARANCE RECO	RD
3/22/17 (Deliver BOTH copies of this form to the Senator or Senate Professional S	
Meeting Date	Bill Number (if applicable)
Topic Medical Marijana	Amendment Barcode (if applicable)
Name <u>Sames</u> Horugth	-
Job Title Managing Partner	_
Address 4317 5w 186" Au	Phone 5613062014
MIRAMAR FZ 33024 City State Zip	Email jhor worth a Roychah daing
	peaking: In Support Against ir will read this information into the record.)
Representing	
Appearing at request of Chair: 🗌 Yes 🔀 No 🛛 Lobbyist regist	ered with Legislature: Yes 📈 No

This form is part of the public record for this meeting.

THE FLORIDA SENATE	
3-21-17 Meeting Date Meeting Date Meeting Date Meeting Date	
Topic Medical Marijuana	Amendment Barcode (if applicable)
Name <u>Noger Drown</u> Job Title <u>President + CEO</u>	
Address <u>Z4Z4 N. Federal Hwy. Suite</u> Street 455 Boca Ration FL 33431	Phone <u>561-367-7997</u> Email rbrown & acs labtest.com
	peaking: In Support Against ir will read this information into the record.)
Representing American Clinical Solutions	5
Appearing at request of Chair: Yes X No Lobbyist regist	ered with Legislature: 🗌 Yes 🔀 No

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THE FLORIDA SENATE	
APPEARANCE RECO	RD
3/22/17 Meeting Date (Deliver BOTH copies of this form to the Senator or Senate Professional S	Staff conducting the meeting) $58614$ Bill Number (if applicable)
Topic Medical Marijuana	Amendment Barcode (if applicable)
Name James Hongath	
Job Title Manggin, Partner	
Address 4317 56 186" Ave	Phone 561 3062017
MIRAMAR FZ 33079 City State Zip	Email for thakey che hilling on
	beaking: In Support Against ir will read this information into the record.)
Representing	
Appearing at request of Chair: Yes No Lobbyist registe	ered with Legislature: 🗌 Yes 🗌 No

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THE FLORIDA SENATE
APPEARANCE RECORD
$\frac{3 - 22 - 11}{1 - 22 - 11}$ (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) $406 + 046$
Meeting Date Bill Number (if applicable)
Topic Medical Marifuana Amendment Barcode (if applicable)
Name Bob Morgan, Former ILLINOIS Med Marijuane Director
Job Title Attorney
Address The Place 191 N. Wacker Dr. Stel8 Phone 3175212474
City State Zin Email RMOrgane Muchshelis
Speaking:       For       Against       Information       Waive Speaking:       In Support       Against         (The Chair will read this information into the record.)
Representing Verde
Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

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THE FLORIDA SENATE
32217 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)
Meeting Date Bill Number (if applicable)
Topic Medical Marijvana Clinical Pharmacy Amendment Barcode (if applicable)
Name Kathleen Vieson Pharmis
Job Title Clinical Pharmacy Specialist
Address 6285 E. FOWER AVE Phone 813-983-600
Street Jampa FL 3347 Email KVRSDnecpshealthe
City State Zip Com
Speaking:       For       Against       Information       Waive Speaking:       In Support       Against         (The Chair will read this information into the record.)
Representing
Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

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Incr	LURIDA JENATE	
(Deliver BOTH conjor of this form to the Sor	ANCE RECO	
3-22-17 Meeting Date		Bill Number (if applicable)
Topic Medica/ Marijuana		Amendment Barcode (if applicable)
Name ZRIK RANGE		
Job Title Chairman of Cha Board		
Address 7501 Citrus Ave.		Phone
Goldenned FL City State	32733	Email
Speaking: For Against Information		eaking: In Support Against r will read this information into the record.)
Representing Minorities 4 Medical	Alarijuana	
Appearing at request of Chair: Yes No	U Lobbyist registe	ered with Legislature: Yes Avo

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While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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### **APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) 04 Meeting Date Number (if applicable) Topic M in cal FLACING DANA Amendment Barcode (if applicable) AMICKA Name Job Title Address Phone \_\_\_\_ JPS Street ,2733 Email H. CAR 071 ae. State Zip Speaking: Information For Against Waive Speaking: | In Support Against (The Chair will read this information into the record.) Representing Medical MARINANA linorities Appearing at request of Chair: Yes NO Lobbyist registered with Legislature: Yes L +No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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	RIDA SENATE
	NCE RECORD r or Senate Professional Staff conducting the meeting)
Meeting Date	Bill Number (if applicable)
Topic <u>Compassionate use of Low-THC can</u>	nnabist Marijuana Amendment Barcode (if applicable)
Name Zachary Davis	
Job Title Legal Countrasel	
Address	Phone 954 319 7868
City State	Zip EmailZachary@nhofl.com
Speaking: For Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing Natural Health Options	
Appearing at request of Chair: 🗌 Yes 🔀 No	Lobbyist registered with Legislature: 🔲 Yes 🔀 No
Mula it is a Canada two differents and an and the state of the state o	

This form is part of the public record for this meeting.

(Deliver BOTH copies of this form to the Senator	NCE RECORD r or Senate Professional Staff conducting the meeting)
Meeting Date	Bill Number (if applicable)
Topic <u>Compassionate use of Iow-THC CA</u>	nnabist Marijuana Amendment Barcode (if applicable)
Name Dr. Jeffrey Postal	
Job Title Senior Partner	
Address	Phone 954 702-9591
	Emaildrieff@nhoft.com
City State	Zip
Speaking: For Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing NATURA HEALTH OPTIONS	
Appearing at request of Chair: 🗌 Yes 🖄 No	Lobbyist registered with Legislature: Yes Xo

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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#### **APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date	Bill Number (if applicable)
Topic MEDICAL CANNADIS	Amendment Barcode (if applicable)
Name OARY STEIN	
Job Title	
Address 7035 Bect Loop	Phone (813) 973.3835
Street <u> WESLEY</u> City City State	33545 Email GJTEINMAN EME. COM
Speaking: For Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
RepresentingS € ωF	
Appearing at request of Chair: Yes Yo	Lobbyist registered with Legislature: Yes ANO

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

	nce Record or or Senate Professional Staff conducting the meeting) <i>40b Worhshop</i>
Meeting Date	Bill Number (if applicable)
Topic Medical MARTJURAS h	Amendment Barcode (if applicable)
Name Jim DEBEAUGNENE	
Job Title CEO, CENTER to Advan	ice Justice
	802 Phone <u>850 - 508 - 8908</u>
City State	Zip Email in _ debeaugnine @
Speaking: For Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing <u>Cercter</u> to Adum.	NEE JUSTICE
Appearing at request of Chair: Yes 🚺 No	Lobbyist registered with Legislature:

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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THE FLORIDA SENA	TE
APPEARANCE R	ECORD
3       22       1       (Deliver BOTH copies of this form to the Senator or Senate Prot         Meeting Date       Meeting Date	fessional Staff conducting the meeting) Bill Number (if applicable)
Topic MEDICAE MARITUANA	Amendment Barcode (if applicable)
Name JEFFREY SHARKEY	
Job Title Mc Partner Capite Alhance G	Long
Address We Ealler Ave Sule 64	D Phone 60 224 460
City City State Zip	35 Email transportation
	Aive Speaking: In Support Against The Chair will read this information into the record.)
Representing MEDICAL MARIJUANA BUSIN	ESS ASSOCIATION of Found
Appearing at request of Chair: Yes No Lobbyist	registered with Legislature: 🗌 Yes 🦳 No

This form is part of the public record for this meeting.

THE FLORIDA SE	NATE
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### **APPEARANCE RECORD**

$\frac{3 - 22 - 3617}{Meeting Date}$ (Deliver BOTH copies of this form to the Senator	r or Senate Professional S	taff conducting the meeting) <u> SB406</u> Bill Number (if applicable)
Topic Medical Marijuana		Amendment Barcode (if applicable)
Name Shalah Romine		
Job Title		
Address 608 W 16th St.		Phone 904 651 1306
Street Saint Augustice FL City State	32080 Zip	Email Shalah @ lucalawfirm Sok
Speaking: For Against Information		peaking: In Support Against ir will read this information into the record.)
Representing Luca Law Firm	1, P. A.	
Appearing at request of Chair: 🗌 Yes 🗹 No	Lobbyist registe	ered with Legislature: 🗌 Yes 📶 No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

Beeting Date Appearance Rectors	
Topic Medical Marijuana	Amendment Barcode (if applicable)
Name Ashley French	
Job Title Store Manager	
Address 264 Pradera St Street	_ Phone 904-377-5180
	e Email ashley French 650 ginato
	Speaking: In Support Against hair will read this information into the record.)
Representing Self	
Appearing at request of Chair: Yes Ves No Lobbyist regis	stered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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THE FLORIDA S	SENATE
APPEARANCE	RECORD
$\frac{3 - 22 - 17}{Meeting Date}$ (Deliver BOTH copies of this form to the Senator or Sena	te Professional Staff conducting the meeting) <u>SB406</u>
	Bill Number (if applicable)
Topic Medical Manjuance	Amendment Barcode (if applicable)
Name Deborah Franklin	
Job Title Dr. Director of Quality AF	Faires
Address	Phone <u>\$13679-7533</u>
Street	Email defranklipperfactory
City State	Zip
Speaking: For Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing Florida Health Care	Assoc
Appearing at request of Chair: Yes No Lob	oyist registered with Legislature: 💭 Yes 🥅 No
While it is a Sanata tradition to analyzana nublic testimony, time may	

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	RIDA SENATE
	NCE RECORD r or Senate Professional Staff conducting the meeting) <i>GOA</i> <i>Bill Number (if applicable)</i>
Topic MMT	Amendment Barcode (if applicable)
Name Jodi James	· · · · · · · · · · · · · · · · · · ·
Job Title <u>Executive Director</u>	
Address 1375 Cypress Ave	Phone 321890 7302
City Mulbourne FC	32935 Email James Horida @ GMan
Speaking: For Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing Florida Cannabis	Action Network
Appearing at request of Chair: Yes No	Lobbyist registered with Legislature:

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	RIDA SENATE
	or Senate Professional Staff conducting the meeting) Bill Number (if applicable)
TOPIC MEDICAL MARIJUANA - Name JAMES EATON	- PHYSICIANS Amendment Barcode (if applicable)
Job Title Address P.O. BOX 1713 Street	Phone <u>650 \$12246)89</u> Email <u>JIMEATON 53 E</u>
City State Speaking: For Against Information	Zip Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing THREE BOYS F	ARMS
Appearing at request of Chair: Yes No	Lobbyist registered with Legislature: Yes No

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THE FLORIDA SENATE
APPEARANCE RECORD
3/22/17 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) 406
Meeting Date Bill Number (if applicable)
Topic Medical Cannubis implementation Amendment Barcode (if applicable)
Name Roy Watson
Job Title Labby St
Address 3738 Mundun Way Phone 350 567-1202
Street Tallahusse FL 32304 Email Watson, Anterio CONVert, City State Zip
Speaking: For Against Information Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing <u>AHMed</u> Cannavision + SUGT Inc
Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

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Тне	FLORIDA SENATE
	ANCE RECORD enator or Senate Professional Staff conducting the meeting) SB 406 Bill Number (if applicable)
Topic AMENDMENT Z IMPL	SMENTHTSN Amendment Barcode (if applicable)
Name ADAM ELEND	
Job Title PARTNER, FLORIGROW	N
Address 4501 OLD SAYBROOK	AVE Phone 917 349 1325
TAMPA FL City State	
Speaking: For Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing FLORIGROWN	
Appearing at request of Chair: 🗌 Yes 🔀 No	Lobbyist registered with Legislature: 🔲 Yes 🕅 No
Maile it is a Damate the different and the second s	

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### APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

SB406

Meeting Date

03/22/2017

Bill Number (if applicable)

Topic Implementation of Amendment 2 "Medical Marijuana"		Amendment Barcode (if applicable)	
Name Marlon A. Onias			
Job Title <u>Attorney/Lobbyist</u>			
Address 1825 NW Corporate B	lvd		Phone <u>305-767-9715</u>
<sub>Street</sub> Boca Raton	FL	3343133073	Email marlon.onias@oniaslaw.com
<i>City</i> Speaking: For Against	State	Zip Waive Sp (The Chai	peaking: In Support Against ir will read this information into the record.)
Representing Coalition of C	oncerned Pharmacis	sts and Citizens, I	nc.
Appearing at request of Chair:	Yes 🖌 No	Lobbyist registe	ered with Legislature: 🖌 Yes 🗌 No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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THE FLORIDA SENATE	in Deplicating Med. (upl.
BAPEARANCE RECO (Deliver BOTH copies of this form to the Senator or Senate Professional S Meeting Date Meeting Date	taff conducting the meeting) Workshop
Topic Weekshop Impementation A2	<i>Bill Number (if applicable)</i> <i>Amendment Barcode (if applicable)</i>
Name Melissa Viller	
Job Title President / ED The Holistri Canal	, s Comonling/NORME Tallahors
Address 169 S, relair Rel	Phone (850) 284-2090
Street Tallahestef City State Zip	Email
Speaking: For Against Information Waive Speaking: The Chai	peaking: In Support Against ir will read this information into the record.)
Representing The Holistic Carrubi's Community/	VORML Tallahose
Appearing at request of Chair: Yes No Lobbyist register	ered with Legislature: 🗌 Yes 🎑 No

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THE FLORIDA SENATE	Please	Flower	
APPEARANCE RECOR		Determi	
(Deliver BOTH copies of this form to the Senator or Senate Professional Staff	conducting the meet	ina) an	1

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Bill Number (if applicable)

NOA Topic Amendment Barcode (if applicable) must be open to other Name medical conditions. INC Job Title Address Phone Stree Email Citv State Speaking: Against Information For-Waive Speaking: In Support Against (The Chair will read this information into the record.) reran Representing OWER Lobbyist registered with Legislature: Appearing at request of Chair: Yes No Yes 11% Of Voters think X Flower While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. Vaporized, et This form is part of the public record for this meeting.

	RIDA SENATE
	or Senate Professional Staff conducting the meeting) Bill Number (if applicable)
Topic Medical Marijvana	Amendment Barcode (if applicable)
Name Shalah Romine	
Job Title MMJ Coordinator	
Address 608 W 16th St Street	Phone 904-657-1306
St. Augustine FL City State	32080 Email Shalah @ Weglawfirm.com
Speaking: For Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing Luca Law Firm, P.	A.
Appearing at request of Chair: Yes No	Lobbyist registered with Legislature: 🗌 Yes 🕅 No

This form is part of the public record for this meeting.

	The FL	ORIDA SENATE		Duplicate
	<b>APPEARA</b>	NCE RECO	RD	
03/22/2017 (Deliver BOTH copies	of this form to the Senat	or or Senate Professional S	taff conducting the meeting)	
Meeting Date			Bill Number (if	applicable)
Topic Amendment 2 and related bill	S		Amendment Barcode (ii	f applicable)
Name John Hightower				
Job Title Patient/ paralegal				
Address 128 Salem Ct			Phone	
<sub>Street</sub> Tallahassee	FL	32301	Email johndhightower@gmai	l.com
<i>City</i> Speaking: For Against	<i>State</i> Information	Zip Waive Sp (The Chai		gainst
Representing Self				
Appearing at request of Chair:	′es 🗌 No	Lobbyist registe	ered with Legislature: Yes	No
While it is a Senate tradition to encourage pu meeting. Those who do speak may be asked	រblic testimony, tin d to limit their rema	ne may not permit all arks so that as many	persons wishing to speak to be hear persons as possible can be heard.	d at this

This form is part of the public record for this meeting.

# APPEARANCE RECORD

0.00.117	(Deliver BOTH copies of t	his form to the Senator	or Senate Professional Sta	If conducting the meeting)
3/22/17				Bill Number (if applicable)
Meeting Date				
Medical Can	nabis			Amendment Barcode (if applicable)
· · · · · · · · · · · · · · · · · · ·	annella-Krehl			
	Clinical Social Wor	ker		(050 652 6028
	ntworth Way			Phone
Street Tallahasso	ee	Florida	32311	Email
City Speaking: For	Against	State Information	Zip Waive S (The Cha	peaking: In Support Against ir will read this information into the record.)
Representing _	est of Chair:	es 🗸 No	-	ered with Legislature: Yes Vo
			- may not parmit al	I persons wishing to speak to be heard at this

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

# CourtSmart Tag Report

Room: KN 4 Caption: Se		se No.: Type: Ige:
	22/2017 1:04:13 PM 22/2017 3:29:40 PM Length: 02:	:25:28
1:04:15 PM	Meeting Called to order	
1:04:41 PM	Roll Call	
1:04:44 PM	Quroum present	
1:05:26 PM	Pledge	
1:05:31 PM	Chair explains format of the meetng Tab 1 Presentation on Certified Nurs	Anasthatista
1:06:38 PM 1:07:38 PM	Lori Killinger discusses CRNAs in Flo	
1:16:42 PM	Chair Young introduces next speake	
1:16:44 PM	Dr. Brence Sell Speaker	
1:23:13 PM	Chair calls for questions	
1:23:33 PM	Sen Hutson question	
1:24:03 PM	Dr. Sell	
1:24:11 PM	Sen Hutson	
1:24:16 PM 1:25:28 PM	Dr. Sell Sen Hutson	
1:25:40 PM	Mrs. Killinger comments	
1:26:10 PM	Sen Hutson follow up	
1:26:17 PM	Ms. Killinger	
1:26:33 PM	Sen Benaquissto question	
1:26:48 PM	Dr. Sell response	
1:27:20 PM	Sen Montford question	
1:27:32 PM 1:28:24 PM	Dr. Sell response Sen Montford follow up	
1:28:34 PM	Dr. Sell response	
1:29:28 PM	Chair Young transfers to presentatio	n on Trauma
1:30:51 PM		ves an overview and background on Trauma Systems
1:39:36 PM	Chair Young	
1:40:37 PM	Call to Dr. Robert Winchell via Skype	
1:40:57 PM	Dr. David Ciesla speaks on Regiona	I Trauma Program
1:54:02 PM 1:54:19 PM	Chair Young Dr. Ciesla	
1:54:41 PM	Chair Young connects with Dr. Robe	ert Winchell
2:00:09 PM	Dr. Robert Winchell presents	
2:04:08 PM	Chair Young questions for panelist	
2:04:29 PM	Sen Montford question	
2:05:25 PM	Cindy Dick response	
2:05:31 PM 2:05:47 PM	Sen Montford follow up Dr. Ciesla comment	
2:07:42 PM	Sen Montford question	
2:08:42 PM	Dr. Ciesla response	
2:09:13 PM	Sen Montford question	
2:09:21 PM	Ciesla comments	
2:09:29 PM	Sen Hutson questions	
2:10:04 PM 2:11:18 PM	Dr. Ciesla comments Sen Hutson question	
2:11:56 PM	Cielsa and Sen Huston dialogue	
2:12:11 PM	Sen Hutson question	
2:12:19 PM	Dr. Ciesla response	
2:12:36 PM	Sen Hutson question	
2:12:43 PM	Dr. Ciesla	al Director Day Front -hans - infame - the
2:12:57 PM 2:14:12 PM	Chair Young Tab 3 taken up on Im	al Director Bay Front shares information
2.17.12 F W	Shan roung rab staken up on Imp	

2:15:17 PM	SB for Health Policy Committee
2:16:24 PM	SB 406 Sen Bradley Presents on Medical Marijuana
2:25:50 PM	Chair Young
2:26:53 PM	Sen Bradley
2:27:54 PM	Chair Young
2:28:07 PM	Sen Bradley
2:29:09 PM	Chair Young
2:29:53 PM	Sen Bradley
2:31:35 PM	Chair Young
2:32:27 PM	Sen Benaquisto comments
2:33:07 PM	Chair Young
2:34:04 PM	Sen Benaquisto follow up
2:34:51 PM	Sen Montford question
2:36:31 PM	Sen Bradley response
2:36:39 PM	Sen Montford question
2:37:34 PM	Sen Bradley
2:37:38 PM	Sen Book
2:38:18 PM	Sen Bradley
2:40:31 PM	Chair Young
2:41:45 PM	Sen Powell question
2:42:26 PM	Sen Bradley
2:43:20 PM	Chair Young
2:43:23 PM	Sen Brannen question
2:44:37 PM	Sen Bradley
2:46:05 PM	Chair Young
2:47:16 PM	Sen Bradley
2:48:23 PM	Chair Young
2:49:18 PM	Sen Montford
2:50:10 PM	Sen Bradley
2:50:56 PM	Chair Young
2:51:38 PM	Sen Benaquisto question
2:52:33 PM	Chair Young
2:53:07 PM	Sen Bradley
2:54:32 PM	Sen Benaquisto
2:54:45 PM	Chair Young
2:56:04 PM	Sen Hutson question
2:56:15 PM	Sen Powell
2:56:42 PM	Chair Young
2:56:46 PM	Sen Montford question
2:57:44 PM	Chair Young
2:58:41 PM	Sen Bradley
2:59:20 PM	Chair Young
2:59:52 PM	Sen Montford
3:01:48 PM	Sen Bradley
3:01:51 PM	Chair Young
3:03:05 PM	Sen Bradley
3:03:52 PM	Chair Young
3:06:13 PM	Sen Bradley
3:07:18 PM	Chair Young Sen Montford
3:07:57 PM 3:08:56 PM	
3:08:56 PM 3:09:56 PM	Sen Bradley Sen Montford
3:10:06 PM	Sen Bradley
3:11:15 PM	Chair Young
3:12:06 PM	Sen Hutson
3:12:06 PM	Sen Bradley
3:13:44 PM	Sen Hutson
3:13:54 PM	Sen Bradley
3:14:46 PM	Sen Passidomo
3:16:03 PM	Sen Bradley
3:18:01 PM	Sen Benaquisto
3:19:00 PM	Sen Bradley
5.15.00 I III	Con Bradioy

- 3:19:35 PM
- Sen Powell question Sen Bradley response 3:21:51 PM
- Sen Powell question 3:22:59 PM
- Sen Bradley 3:23:21 PM
- Sen Book question Sen Bradley 3:23:23 PM
- 3:24:08 PM
- Chair Young reads into the record appearance cards names Meeting adjourned 3:25:43 PM
- 3:29:20 PM