

Committee on Health Quality

**Tuesday, January 22, 2008
9:00 AM – 11:20 AM
306 HOB**

**Marco Rubio
Speaker**

**Gayle Harrell
Chair**



House of Representatives

Committee on Health Quality

AGENDA

**January 22, 2008
9:00 AM – 11:20 AM
(306 HOB)**



- I. Opening Remarks**
- II. Consideration of HB 243 by Anderson -- Automated External Defibrillators**
- III. Consideration of HB 341 by Holder -- Treatment Programs for Impaired Practitioners**
- IV. Remarks by the Healthcare Information and Management Systems Society regarding health information technology**
- V. Presentation by the Agency for Health Care Administration regarding recommendations to revise the hospital Code 15 reporting system**
- VI. Presentation by the Department of Health regarding the counter-marketing and advertising campaign for the Comprehensive Statewide Tobacco Education and Use Prevention Program**
- VII. Presentation by the Department of Health regarding the status of electronic tracking of continuing education compliance**
- VIII. Update on 2008 committee interim projects**
- IX. Closing Remarks & Adjournment**

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 243 Automated External Defibrillators

SPONSOR(S): Anderson and others

TIED BILLS: IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) <u>Committee on Health Quality</u>		Owen 	Lowell 
2) <u>Healthcare Council</u>			
3) _____			
4) _____			
5) _____			

SUMMARY ANALYSIS

An Automated External Defibrillator (AED) is a small, lightweight device used to assess a person's heart rhythm and, if necessary, administer an electronic shock to restore a normal heart rhythm in a victim of cardiac arrest.

The bill broadens the scope of those who are required to receive training in the use of an AED by removing provisions requiring a person who uses an AED to obtain proper training that includes demonstrated proficiency in the use of an AED and, instead, requires any "person or entity in possession" of an AED to properly maintain and test the device and provide training to anyone who is expected to be a potential user of the AED.

The bill encourages persons who possess an AED to notify, rather than register with, the local emergency medical services director of the location of the device.

The bill broadens the civil immunity provided under the Cardiac Arrest Survival Act for harm resulting from the use of an AED by removing several provisions which specify instances when a person and an acquirer of the device are not immune from civil liability.

The bill does not appear to have a fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2008.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

This bill does not appear to implicate any of the House Principles.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Use of an AED

The American Heart Association (AHA) describes cardiac arrest as “the sudden, abrupt loss of heart function. The victim may or may not have diagnosed heart disease. It’s also called sudden cardiac arrest or unexpected cardiac arrest. Sudden death (also called sudden cardiac death) occurs within minutes after symptoms appear.”

According to the AHA, brain death and permanent death start to occur within four to six minutes after someone experiences cardiac arrest. Cardiac arrest can be reversed if it is treated within a few minutes with an electric shock to the heart to restore a normal heartbeat - a process called defibrillation. The AHA states that a victim’s chances of survival are reduced by seven to ten percent with every passing minute without cardiopulmonary resuscitation and defibrillation, and few attempts at resuscitation succeed after ten minutes.

An automated external defibrillator (AED) is an electronic device that can shock a person’s heart back into rhythm when he or she is having a cardiac arrest. The AHA estimates that more than 95 percent of cardiac arrest victims die before reaching the hospital. In situations where defibrillation is provided within five to seven minutes, the survival rate from sudden cardiac arrest can be up to 49 percent.

Section 401.2915, Florida Statutes, requires any person who uses an AED to:

- Obtain appropriate training, including completion of a course in cardiopulmonary resuscitation or completion of a basic first aid course that includes cardiopulmonary resuscitation training, and demonstrated proficiency in the use of an AED; and
- Activate the emergency medical services system as soon as possible upon use of the AED.

In addition, this section encourages any person or entity in possession of an AED to register the existence and location of the AED with the local emergency medical services medical director.

Tort Liability

Section 768.13, F.S., the Good Samaritan Act, among other provisions, provides immunity from any civil damages for a person who renders emergency care, without objection of the injured victim, as long as the person has acted as an ordinary reasonably prudent person would have acted under the same or similar circumstances.

Section 768.1325, F.S., the Cardiac Arrest Survival Act, provides immunity from civil liability for a person who uses or attempts to use, without the objection of the victim, an AED in a perceived medical emergency. In addition, any person who acquired the device, including a community association, is immune from civil liability, if the harm was not due to the failure of the acquirer of the AED to:

- Notify the local emergency medical services medical director of the most recent placement of the device within a reasonable period of time after the device was placed;
- Properly maintain and test the device; or

- Provide adequate training in the use of the device to an employee or agent of the acquirer when the employee or agent was the person who used the device on the victim, except that the training requirement does not apply if:
 - The employee or agent was not someone who would have been reasonably expected to use the device.
 - The period of time elapsing between the person's employment date and the occurrence of the harm, or between the acquisition of the AED and the occurrence of the harm was not a reasonably sufficient period in which to provide the training.

However, s. 768.1325(4), F.S., states that the immunity does not apply to a person if:

- The harm was caused by that person's willful or criminal misconduct, gross negligence, reckless disregard or misconduct, or a conscious, flagrant indifference to the rights or safety of the victim who was harmed;
- The person is a licensed or certified health professional who used the AED while acting within the scope of their license or certification and within the scope of their employment or agency;
- The person is a hospital, clinic, or other health care entity, and the harm was caused by an employee or agent of the entity who used the AED while acting within the scope of the employment or agency of the employee or agent;
- The person is an acquirer of the AED who leased the device to a health care entity and the harm was caused by an employee or agent of the entity who used the device while acting within the scope of the employment or agency of the employee or agent; or
- The person is the manufacturer of the device.

Effect of Proposed Changes

House Bill 243 broadens the scope of those who are required to receive training in the use of an AED by removing provisions requiring a person who uses an AED to obtain proper training that includes demonstrated proficiency in the use of an AED and, instead, requiring any "person or entity in possession" of an AED to properly maintain and test the device and provide training in cardiopulmonary resuscitation and AED proficiency from the American Heart Association or the American Red Cross, or a substantially similar program from another provider, to any of its employees or agents who are reasonably expected to be potential users of the AED.

The bill encourages a person or entity in possession of an AED to notify, rather than register with, the local emergency medical services medical director of the location of the device.

The bill broadens the civil immunity provided under the Cardiac Arrest Survival Act, s. 768.1325(3), F.S., by first removing the requirement that the victim of the perceived medical emergency not object to the use of the AED. Second, the bill removes several provisions that specify instances in which the acquirer of the AED is not immune from civil liability. These provisions specify that the harm must not be due to the failure of acquirer of the device to:

- Notify the local emergency medical services director of the most recent placement of the device.
- Properly maintain and test the device; or
- Provide adequate training in the use of the device to an employee or agent of the acquirer when the employee or agent was the person who used the device on the victim, except that such requirement of training does not apply if:
 - The employee or agent was not someone who would have been reasonably expected to use the device.
 - The period of time elapsing between the person's employment date and the occurrence of the harm, or between the acquisition of the AED and the occurrence of the harm was not a reasonably sufficient period in which to provide the training.

However, the bill does not amend s. 768.1325(4), F.S., which, as previously discussed, provides additional instances in which a person is not immune from civil liability.

C. SECTION DIRECTORY:

Section 1. Amends s. 401.2915, F.S., revising provisions relating to maintenance and training requirements and notice to the local emergency medical services medical director.

Section 2. Amends s. 768.1325, F.S., revising requirements for civil immunity for use or attempted use of a defibrillator on a victim of a perceived medical emergency.

Section 3. Provides an effective date of July 1, 2008.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

There is a potential impact to private businesses that possess an AED. The bill requires these entities to provide training to any employees or agents who are reasonably expected to be users of the AED. The exact economic impact to the private sector is unknown.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable because the bill does not appear to require counties or cities to spend funds or take action requiring the expenditure of funds; reduce the authority that cities or counties have to raise revenues in the aggregate; or reduce the percentage of a state tax shared with cities or counties.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

N/A.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

The intention of this bill is to limit liability to Good Samaritans trying to resuscitate individuals using an Automated External Defibrillator (AED) which will encourage more usage, thus saving more lives.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

1 A bill to be entitled
2 An act relating to automated external defibrillators;
3 amending s. 401.2915, F.S.; revising provisions relating
4 to maintenance and training requirements and notice to the
5 local emergency medical services medical director;
6 amending s. 768.1325, F.S.; revising requirements for
7 civil immunity for use or attempted use of a defibrillator
8 on a victim of a perceived medical emergency; providing an
9 effective date.

10

11 Be It Enacted by the Legislature of the State of Florida:

12

13 Section 1. Paragraphs (a) and (b) of subsection (2) of
14 section 401.2915, Florida Statutes, are amended to read:

15 401.2915 Automated external defibrillators.--It is the
16 intent of the Legislature that an automated external
17 defibrillator may be used by any person for the purpose of
18 saving the life of another person in cardiac arrest. In order to
19 achieve that goal, the Legislature intends to encourage training
20 in lifesaving first aid and set standards for and encourage the
21 use of automated external defibrillators.

22 (2) In order to ensure public health and safety:

23 (a) Any person or entity in possession of an automated
24 external defibrillator shall:

25 1. Properly maintain and test the device.

26 2. Provide training in cardiopulmonary resuscitation and
27 automated external defibrillator proficiency from the American

28 Heart Association or the American Red Cross, or a substantially

29 similar program from another provider, to any of its employees
 30 or agents who are reasonably expected to be potential users of
 31 the defibrillator. All persons who use an automated external
 32 ~~defibrillator must obtain appropriate training, to include~~
 33 ~~completion of a course in cardiopulmonary resuscitation or~~
 34 ~~successful completion of a basic first aid course that includes~~
 35 ~~cardiopulmonary resuscitation training, and demonstrated~~
 36 ~~proficiency in the use of an automated external defibrillator.~~

37 (b) Any person or entity in possession of an automated
 38 external defibrillator is encouraged to notify ~~register~~ with the
 39 local emergency medical services medical director of the
 40 ~~existence and~~ location of the automated external defibrillator.

41 Section 2. Subsection (3) of section 768.1325, Florida
 42 Statutes, is amended to read:

43 768.1325 Cardiac Arrest Survival Act; immunity from civil
 44 liability.--

45 (3) Notwithstanding any other provision of law to the
 46 contrary, and except as provided in subsection (4), any person
 47 who uses or attempts to use an automated external defibrillator
 48 device on a victim of a perceived medical emergency, ~~without~~
 49 ~~objection of the victim of the perceived medical emergency,~~ is
 50 immune from civil liability for any harm resulting from the use
 51 or attempted use of such device. In addition, any person who
 52 acquired the device, including, but not limited to, a community
 53 association organized under chapter 617, chapter 718, chapter
 54 719, chapter 720, chapter 721, or chapter 723, is immune from
 55 such liability, ~~if the harm was not due to the failure of such~~
 56 ~~acquirer of the device to:~~



57 ~~(a) Notify the local emergency medical services medical~~
 58 ~~director of the most recent placement of the device within a~~
 59 ~~reasonable period of time after the device was placed;~~
 60 ~~(b) Properly maintain and test the device; or~~
 61 ~~(c) Provide appropriate training in the use of the device~~
 62 ~~to an employee or agent of the acquirer when the employee or~~
 63 ~~agent was the person who used the device on the victim, except~~
 64 ~~that such requirement of training does not apply if:~~
 65 ~~1. The employee or agent was not an employee or agent who~~
 66 ~~would have been reasonably expected to use the device; or~~
 67 ~~2. The period of time elapsing between the engagement of~~
 68 ~~the person as an employee or agent and the occurrence of the~~
 69 ~~harm, or between the acquisition of the device and the~~
 70 ~~occurrence of the harm in any case in which the device was~~
 71 ~~acquired after engagement of the employee or agent, was not a~~
 72 ~~reasonably sufficient period in which to provide the training.~~
 73 Section 3. This act shall take effect July 1, 2008.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 341 Treatment Programs for Impaired Practitioners

SPONSOR(S): Holder and others

TIED BILLS: IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) <u>Committee on Health Quality</u>		Owen 	Lowell 
2) <u>Healthcare Council</u>			
3) <u>Policy & Budget Council</u>			
4) _____			
5) _____			

SUMMARY ANALYSIS

HB 341 revises provisions relating to the impaired practitioner program within the Department of Health. The bill authorizes the Department of Health to contract with impaired practitioner program consultants to provide services to students enrolled in schools that provide training for health care practitioners licensed under Chapter 456, F. S., if the school requests such services. The bill provides immunity to the schools from a civil action for the referral of a student to a consultant or for disciplinary actions that adversely affect the status of a student.

The bill grants sovereign immunity to an impaired practitioner consultant, its officers, employees, and persons acting at the direction of the consultant for the limited purpose of an emergency intervention, when the consultant is unable to perform the intervention, for actions taken within the scope of a contract with the Department of Health. The bill specifies contractual conditions that must exist in order for sovereign immunity to be granted.

This bill may implicate Article I, section 21 of the Florida Constitution, the right of access to the courts, by barring a civil recovery against schools that provide training for health care practitioners licensed under chapter 456, F.S., under specific circumstances.

The bill appears to have a significant negative fiscal impact on the Medical Quality Assurance Trust Fund (see fiscal analysis).

The bill provides for an effective date of July 1, 2008.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government – this bill will grant sovereign immunity to contractor consultants for actions taken within the scope of a contract with the Department of Health.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Impaired Practitioner Programs

Healthcare professions are established within individual practice acts and are governed by Chapter 456, Florida Statutes, within the Department of Health (department) in the Division of Medical Quality Assurance (division). Section 456.076, Florida Statutes, authorizes the department to contract with impaired practitioner consultants for services relating to intervention, evaluation, referral, and monitoring of impaired practitioners who have voluntarily agreed to treatment through an impaired practitioner program.¹ Impaired practitioner programs are available to all healthcare practitioners licensed under Chapter 456, F.S. as well as other licensed professionals regulated by the department.

Consultants do not provide medical treatment, nor do they have the authority to render decisions relating to licensure of a particular practitioner. However, the consultant is required to make recommendations to the department regarding a practitioner patient's ability to practice.² Consultants are required by department rules to refer practitioner patients to department-approved treatment programs and providers. They have specified case management duties with regards to practitioner patient progress in a treatment program. Further, the consultant acts as the records custodian for all treatment information on the practitioner patients they are contracted to monitor. A typical contract between a consultant and an impaired practitioner under treatment is 5 years.

Currently, the department contracts with two groups for impaired practitioner consulting services: the Intervention Project for Nurses (IPN) for nurses licensed under Chapter 464, F.S., and the Professionals Resource Network (PRN) for all other licensed health care professionals. According to the department, there are approximately 2,700 participants enrolled in the programs: 1,600 in the IPN and 1,100 in the PRN.

Sovereign Immunity

Sovereign immunity is the legal doctrine which provides that a government may not be sued for a claim without its consent. However, the federal government and most states have waived their immunity from suit in varying degrees in certain cases. Article X, section 13 of the Florida Constitution establishes that laws may be enacted in the statutes for suits to be brought against the state for its liabilities. Accordingly, s. 768.28(1), F.S., provides that the state "waives sovereign immunity for liability for torts, but only to the extent specified in this act."

Specifically, the act provides that the state has limited its financial liability for a tort action by any one person to \$100,000 or to \$200,000 for additional claims and judgments arising from the same incident or occurrence. If a judgment is rendered by a court in excess of those amounts, the plaintiff may pursue a claim bill in the Legislature for the amount in excess of the statutory limit.

¹ Rules 64B31-10.10.001 and 64B31-10.002, F.A.C.

² Section 456.076(5)(a), F.S.

The act further provides that the exclusive remedy for injury or damage suffered as a result of an act, event, or omission of an officer, employee, or agent of the state is an action against the governmental entity, the head of such entity in his or her official capacity, or the constitutional officer of which the officer, employee, or agent is an employee, unless the act or omission was committed in bad faith, with malicious purpose, or in a manner exhibiting wanton and willful disregard of human rights, safety, or property. "Officer, employee or agent" is defined to include any health care provider providing services pursuant to s. 766.1115, F.S.,³ any member of the Florida Health Services Corps, as defined in s. 381.0302, F.S., who provides uncompensated care to medically indigent persons referred by the department, and any public defender or his or her employee or agent, including among others, an assistant public defender and an investigator.

In addition, an officer, employee, or agent of the state or any of its subdivisions may not be held personally liable or named as a defendant for an injury or damage if the act occurred in the scope of his or her employment unless the officer, employee, or agent acted in bad faith, with malicious purpose, or in a manner that exhibited a wanton and willful disregard of human rights, safety, or property.

The Bureau of State Liability Claims within the Department of Financial Services provides protection against general liability claims and suits filed pursuant to Section 768.28, F.S.⁴

Effect of Proposed Changes

The bill increases the qualifications required for impaired practitioner program consultants by requiring that each consultant, instead of at least one, be a practitioner or recovered practitioner licensed under chapters 458, 459, or Part I of 464, or an entity that employs a medical director who is a practitioner or recovered practitioner licensed as an allopathic or osteopathic physician or nurse under chapters 458, 459 or part I of 464, F.S., respectively.

The bill authorizes the department to contract with impaired practitioner program consultants to provide services to students enrolled in schools that provide training for health care practitioners licensed under Chapter 456, F.S.,⁵ if the school requests such services. In addition, the bill provides civil immunity to the schools that refer a student to an impaired practitioner program consultant or take disciplinary actions that adversely affect the status of a student, provided the school adheres to due process procedures adopted by the applicable accreditation entities and does not act with intentional fraud.

The bill provides sovereign immunity to an impaired practitioner consultant, its officers, employees, and persons acting at the direction of the consultant for the limited purpose of an emergency intervention, when the consultant is unable to perform the intervention, for actions taken within the scope of a contract with the Department of Health. The bill specifies contractual conditions that must exist in order for sovereign immunity to be granted.

The bill requires the Department of Financial Services to defend the consultant, its officers, employees, and persons acting at the direction of the consultant for the limited purpose of an emergency intervention, when the consultant is unable to perform the intervention, from any legal action brought as a result of contracted program activities.

C. SECTION DIRECTORY:

Section 1. Amends s. 456.076, F.S., revising provisions relating to treatment for impaired practitioners.

Section 2. Provides an effective date of July 1, 2008.

³ Otherwise known as the "Access to Health Care Act."

⁴ <http://www.fldfs.com/Risk/SLC/index.htm>.

⁵ According to the department, while there are 95 healthcare licenses issued by the department, it is unknown how many educational institutions offer curricula that may lead to licensure in these professions.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

As of 2008, there were 96,423 students enrolled in a health program⁶ within a state community college or state university in Florida.⁷ The Professional Resource Network has determined that approximately 3 percent of currently licensed health practitioners may be eligible for treatment services.⁸ If the assumption is made that the Department of Health enters into contracts with consultants and 3 percent of the student population seeks treatment services provided by either the IPN or PRN program, participation may increase upwards of 2,393 participants annually.

The current contract with IPN and PRN costs \$1,046 per participant annually. However, additional participants may increase the annual contract amount per participant.

<u>Estimated Recurring Expenditures</u>	<u>1st Year</u>	<u>2nd Year</u>
Medical Quality Assurance Trust Fund	\$3,025,754	\$3,025,754

The Medical Quality Assurance (or MQA) Trust Fund is funded by fees collected from all licensed practitioners under chapter 456, F.S. Currently, students do not pay fees until they are licensed. However, the MQA Trust Fund will pay for the consultant/vendor fees associated with providing treatment services to eligible students. As of December 2007, there were 4 medical students receiving services provided by PRN and 14 nursing students receiving services provided by IPN.⁹

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

⁶ Not all enrolled students may be in a health discipline that leads to licensure regulated under chapter 456, F.S.

⁷ 2008 Fact Book Tables 10 and 11 (<http://www.fldoe.org/arm/cctcmis/pubs/factbook/default.asp>) and 2007-08 Baccalaureate Program Enrollment Reports emailed by Dept of Education to House staff on 1/14/08.

⁸ *Impaired Practitioners Program of Florida: Professionals Resource Network, Inc.*, Monthly report prepared for the Department of Health (December 2007).

⁹ *Impaired Practitioners Program of Florida: Professional Resource Network, Inc., and Intervention Project for Nurses* Monthly Reports prepared for the Department of Health (December 2007).

Approved treatment providers may experience an increase in demand for services with the addition of students enrolled in schools that provide training for students licensed under chapter 456, F.S., in impaired practitioner programs.

Students who are found impaired are eligible to enter into a contract to receive services offered by the PRN or IPN program. Based on impairment contracts for licensed practitioners, a student may be required to enter into a contract for up to 5-years. While in an impairment program a student is required to pay for all treatment services such as initial evaluations, urinalysis testing and ongoing psychotherapy. Initial evaluations can range from \$300-\$500 and up to \$1000 if chronic pain evaluation is required. The average cost is \$42 per urinalysis, the number per month varies depending upon the recovery process. The cost of four group therapy meetings per month can range from \$50- \$150 per month. If the impairment is found to be physical, then the cost may be nominal. All participants are required to have a primary care physician, but no visits are required. The PRN program offers a loan forgiveness option to eligible participants. All treatment services are paid directly to the provider or third party administrator and not through the PRN program.

D. FISCAL COMMENTS:

Currently, impaired practitioner consultants are not statutorily designated as agents of the department; rather, they are considered vendors/consultants. Generally, if a claim is brought against a vendor it is currently the responsibility of the vendor/consultant to pay for all costs associated with defending any claim, suit, or proceeding.

The bill will require the Department of Financial Services to defend claims against a vendor/consultant, its officers, employees, and persons acting at the direction of the consultant for the limited purpose of an emergency intervention by making them agents of the department. The potential fiscal impact is indeterminate. The department would be liable for a maximum of \$200,000 per incident unless the Legislature approves a claims bill for the incident.

The Department of Health has stated that the MQA Trust Fund would have to reimburse the Department of Financial Services for all costs associated with defending any claim, suit, or proceeding against an impaired practitioner consultant.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

This bill may implicate Article I, section 21 of the Florida Constitution, which states that the courts "shall be open to every person for redress of any injury, and justice shall be administered without sale, denial, or delay." The test for ensuring the right of access to the courts was declared in *Kluger v. White*, 281 So.2d 1 (Fla. 1973), in which the Florida Supreme Court held that the Legislature is without power to abolish or otherwise restrict a statutory law right that predated the adoption of the constitution or a common law right without providing a reasonable alternative remedy, unless there is a showing of an overpowering public necessity to limit or abolish such right and no alternative remedy of meeting such public necessity exists.

The Florida Supreme Court refined the *Kluger* test in *Smith v. Department of Ins.*, 507 So.2d 1080 (Fla. 1986). There, comprehensive tort reform legislation capping non-economic damages at \$450,000 was challenged on the basis that it denied claimants access to the courts. In that case, the Court noted the *Kluger* test requires either (1) providing a reasonable alternative remedy or commensurate benefit, or (2) a legislative showing of overpowering public necessity for the abolishment of the right *and* no alternative method of meeting such public necessity. The Court noted that the right to sue and recover non-economic damages of any amount existed at the time the Florida Constitution was adopted. Consequently, the Court found the cap on non-economic damages unconstitutional as the Legislature did not provide an alternative remedy or commensurate benefit and the parties did not assert the existence of an overpowering public necessity.

B. RULE-MAKING AUTHORITY:

No additional rulemaking authority is required as a result of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

It appears that the bill may be overbroad with respect to the extension of sovereign immunity to impaired practitioner consultants' officers, employees, and persons acting at the direction of the consultant for the limited purpose of an emergency intervention, when the consultant is unable to perform the intervention. Extension of sovereign immunity to this degree places the state at risk for the actions of individuals that the state does not have direct control over, such as persons other than a contracted consultant performing emergency interventions.

The Department of Health has recommended three amendments:

- The first amendment is recommended to ensure that the department has sufficient rulemaking authority for all aspects of the impaired practitioner programs.

On lines 30-32, deletes those lines and insert:

treating a professional, and requirements for continued care of impaired professionals by approved treatment providers, continued monitoring by the consultant of the care provided by approved treatment providers regarding the professionals under their care, as well as requirements related to the consultant's expulsion of professionals from the program evaluating and treating a professional, and requirements for the continued care and monitoring of a professional by the consultant by an approved treatment provider.

- The second amendment is recommended to clarify that the treatment of impaired students, who may leave the state after graduation, is the responsibility of the State Board of Education and not the licensed professionals who pay licensing fees.

On lines 45-47, deletes those lines and insert:

practitioner is, in fact, impaired. The department may use a consultant or contract with its consultants, for appropriate compensation from the school or from the State Board of Education, for services to be provided, if requested by a school located in Florida with approval from the State Board of Education, for students

- The third amendment is recommended to require consultants to indemnify the state for liabilities incurred under chapter 768 (sovereign immunity).

On line 73, delete that line and insert:

this section. The contract must provide:

1. For the indemnification of the state by the consultant for any liabilities incurred up to the limits set out in chapter 768.

D. STATEMENT OF THE SPONSOR

I will be introducing a strike all amendment during the Committee meeting that will address the concerns mentioned in the analysis. I look forward to discussing the bill with all of the Committee members.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

1 A bill to be entitled
 2 An act relating to treatment programs for impaired
 3 practitioners; amending s. 456.076, F.S.; revising
 4 requirements for program consultants; authorizing the
 5 Department of Health to contract with consultants to
 6 provide treatment services for allopathic and osteopathic
 7 physician students alleged to be impaired; providing
 8 certain schools with absence of liability in civil actions
 9 when referring students to such consultants or taking
 10 certain actions without intentional fraud; providing
 11 limited sovereign immunity for certain program consultants
 12 under specific contractual conditions; requiring the
 13 Department of Financial Services to defend actions against
 14 program consultants; providing an effective date.

15
 16 Be It Enacted by the Legislature of the State of Florida:

17
 18 Section 1. Subsections (1) and (2) of section 456.076,
 19 Florida Statutes, are amended, and subsection (7) is added to
 20 that section, to read:

21 456.076 Treatment programs for impaired practitioners.--

22 (1) For professions that do not have impaired practitioner
 23 programs provided for in their practice acts, the department
 24 shall, by rule, designate approved impaired practitioner
 25 programs under this section. The department may adopt rules
 26 setting forth appropriate criteria for approval of treatment
 27 providers. The rules may specify the manner in which the
 28 consultant, retained as set forth in subsection (2), works with

29 the department in intervention, requirements for evaluating and
 30 treating a professional, and requirements for the continued care
 31 and monitoring ~~of a professional~~ by the consultant ~~by an~~
 32 ~~approved treatment provider.~~

33 (2) The department shall retain one or more impaired
 34 practitioner consultants. The A consultant shall be a licensee
 35 under the jurisdiction of the Division of Medical Quality
 36 Assurance within the department ~~who, and at least one consultant~~
 37 must be a practitioner or recovered practitioner licensed under
 38 chapter 458, chapter 459, or part I of chapter 464 ~~or shall be~~
 39 an entity that employs a medical director who must be a
 40 practitioner or recovered practitioner licensed under chapter
 41 458, chapter 459, or part I of chapter 464. The consultant shall
 42 assist the probable cause panel and department in carrying out
 43 the responsibilities of this section. This shall include working
 44 with department investigators to determine whether a
 45 practitioner is, in fact, impaired. The department may contract
 46 with the consultant, for appropriate compensation, for services
 47 to be provided, if requested by the school, for students
 48 enrolled in schools for licensure under this chapter who are
 49 alleged to be impaired as a result of the misuse or abuse of
 50 alcohol or drugs, or both, or due to a mental or physical
 51 condition. No school that is governed by accreditation standards
 52 that require notice and the provision of due process procedures
 53 to students shall be held liable in any civil action for
 54 referring a student to the consultant retained by the department
 55 or for disciplinary actions that adversely affect the status of
 56 a student when the disciplinary actions are instituted in

57 reasonable reliance on the recommendations, reports, or
 58 conclusions provided by such consultant, provided that the
 59 school, in referring the student or taking disciplinary action,
 60 adheres to the due process procedures adopted by the applicable
 61 accreditation entities and provided that the school committed no
 62 intentional fraud in carrying out the provisions of this
 63 section.

64 (7) (a) A consultant retained pursuant to subsection (2), a
 65 consultant's officers and employees, and those acting at the
 66 direction of the consultant for the limited purpose of an
 67 emergency intervention on behalf of a licensee or student as
 68 described in subsection (2) when the consultant is unable to
 69 perform such intervention shall be considered agents of the
 70 department for purposes of s. 768.28 while acting within the
 71 scope of the consultant's duties under the contract with the
 72 department if the contract complies with the requirements of
 73 this section. The contract must provide that:

74 1. The consultant establish a quality assurance program to
 75 monitor services delivered under the contract.

76 2. The consultant's quality assurance program, treatment,
 77 and monitoring records be evaluated quarterly.

78 3. The consultant's quality assurance program be subject
 79 to review and approval by the department.

80 4. The consultant operate under policies and procedures
 81 approved by the department.

82 5. The consultant provide to the department for approval a
 83 policy and procedure manual that comports with all statutes,
 84 rules, and contract provisions approved by the department.

85 6. The department be entitled to review the records
 86 relating to the consultant's performance under the contract for
 87 the purpose of management audits, financial audits, or program
 88 evaluation.

89 7. All performance measures and standards be subject to
 90 verification and approval by the department.

91 8. The department be entitled to terminate the contract
 92 with the consultant for noncompliance with the contract.

93 (b) In accordance with s. 284.385, the Department of
 94 Financial Services shall defend any claim, suit, action, or
 95 proceeding against the consultant, the consultant's officers or
 96 employees, or those acting at the direction of the consultant
 97 for the limited purpose of an emergency intervention on behalf
 98 of a licensee or student as described in subsection (2) when the
 99 consultant is unable to perform such intervention brought as a
 100 result of any act or omission of action of any of the
 101 consultant's officers and employees and those acting at the
 102 direction of the consultant for the limited purpose of an
 103 emergency intervention on behalf of a licensee or student as
 104 described in subsection (2) when the consultant is unable to
 105 perform such intervention when such act or omission arises out
 106 of and in the scope of the consultant's duties under its
 107 contract with the department.

108 (c) If the consultant retained pursuant to subsection (2)
 109 is retained by any other state agency, and if the contract
 110 between such state agency and the consultant complies with the
 111 requirements of this section, the consultant, the consultant's
 112 officers and employees, and those acting at the direction of the

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113 consultant for the limited purpose of an emergency intervention
 114 on behalf of a licensee or student as described in subsection
 115 (2) when the consultant is unable to perform such intervention
 116 shall be considered agents of the state for the purposes of this
 117 section while acting within the scope of and pursuant to
 118 guidelines established in the contract between such state agency
 119 and the consultant.

120 Section 2. This act shall take effect July 1, 2008.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1

Bill No. 0341

COUNCIL/COMMITTEE ACTION

ADOPTED _____ (Y/N)
ADOPTED AS AMENDED _____ (Y/N)
ADOPTED W/O OBJECTION _____ (Y/N)
FAILED TO ADOPT _____ (Y/N)
WITHDRAWN _____ (Y/N)
OTHER _____

1 Council/Committee hearing bill: Committee on Health Quality
2 Representative Holder offered the following:

3
4 **Amendment (with title amendment)**

5 Remove everything after the enacting clause and insert:

6 Section 1. Subsections (1) and (2) of section 456.076,
7 Florida Statutes, are amended, and subsection (7) is added to
8 that section, to read:

9 456.076 Treatment programs for impaired practitioners.--

10 (1) For professions that do not have impaired practitioner
11 programs provided for in their practice acts, the department
12 shall, by rule, designate approved impaired practitioner
13 programs under this section. The department may adopt rules
14 setting forth appropriate criteria for approval of treatment
15 providers. The rules may specify the manner in which the
16 consultant, retained as set forth in subsection (2), works with
17 the department in intervention, requirements for evaluating and
18 treating a professional, and requirements for the continued care
19 and monitoring ~~of a professional~~ by the consultant ~~by an~~
20 ~~approved treatment provider.~~

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1

21 (2) The department shall retain one or more impaired
22 practitioner consultants. The A consultant shall be either a
23 licensee under the jurisdiction of the Division of Medical
24 Quality Assurance within the department ~~who, and at least one~~
25 ~~consultant~~ must be a practitioner or recovered practitioner
26 licensed under chapter 458, chapter 459, or part I of chapter
27 464 or an entity that employs a medical director who must be a
28 practitioner or recovered practitioner licensed under chapter
29 458, chapter 459, or part I of chapter 464. The consultant shall
30 assist the probable cause panel and department in carrying out
31 the responsibilities of this section. This shall include working
32 with department investigators to determine whether a
33 practitioner is, in fact, impaired. The department may contract
34 with the consultant, for appropriate compensation, for services
35 to be provided, if requested by the school, for students
36 enrolled in schools in preparation for licensure as allopathic
37 physicians under chapter 458 or osteopathic physicians under
38 chapter 459 who are alleged to be impaired as a result of the
39 misuse or abuse of alcohol or drugs, or both, or due to a mental
40 or physical condition. No medical school accredited by the
41 Liaison Committee on Medical Education or Commission on
42 Osteopathic College Accreditation, or other school that provides
43 for the education of students enrolled in preparation for
44 licensure as allopathic physicians under chapter 458 or
45 osteopathic physicians under chapter 459, which is governed by
46 accreditation standards that require notice and the provision of
47 due process procedures to students shall be held liable in any
48 civil action for referring a student to the consultant retained
49 by the department or for disciplinary actions that adversely
50 affect the status of a student when the disciplinary actions are

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1

51 instituted in reasonable reliance on the recommendations,
52 reports, or conclusions provided by such consultant, provided
53 that the school, in referring the student or taking disciplinary
54 action, adheres to the due process procedures adopted by the
55 applicable accreditation entities and provided that the school
56 committed no intentional fraud in carrying out the provisions of
57 this section.

58 (7)(a) A consultant retained pursuant to subsection (2),
59 and its officers and employees and those acting at the direction
60 of the consultant for the limited purpose of an emergency
61 intervention of a licensee or student as described in subsection
62 (2) when the consultant is unable to perform such intervention,
63 shall be considered agents of the department for purposes of s.
64 768.28 while acting within the scope of the contractor's duties
65 under the contract with the department if the contract complies
66 with the requirements of this section. The contract must
67 provide:

68 1. That the consultant establish a quality assurance
69 program to monitor services delivered under the contract.

70 2. That the consultant's quality assurance program,
71 treatment, and monitoring records be evaluated quarterly.

72 3. That the consultant's quality assurance program be
73 subject to review and approval by the department.

74 4. That the consultant operate under policies and
75 procedures approved by the department.

76 5. That the consultant provide to the department for
77 approval a policy and procedure manual that comports with all
78 statutes, rules, and contract provisions approved by the
79 department.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1

80 6. That the department be entitled to review the records
81 relating to the consultant's performance under the contract for
82 the purpose of management audits, financial audits, or program
83 evaluation.

84 7. That all performance measures and standards be subject
85 to verification and approval by the department.

86 8. That the department be entitled to terminate the
87 contract with the consultant for noncompliance with the
88 contract.

89 (b) In accordance with s. 284.385, the Department of
90 Financial Services shall defend any claim, suit, action, or
91 proceeding against the consultant, or its officers or employees
92 or those acting at the direction of the consultant for the
93 limited purpose of an emergency intervention of a licensee or
94 student as described in subsection (2) when the consultant is
95 unable to perform such intervention, brought as a result of any
96 act or omission of action of any of its officers and employees
97 and those acting at the direction of the consultant for the
98 limited purpose of an emergency intervention of a licensee or
99 student as described in subsection (2) when the consultant is
100 unable to perform such intervention, when such act or omission
101 arises out of and in the scope of the consultant's duties under
102 its contract with the department.

103 (c) If the consultant retained pursuant to subsection (2)
104 is retained by any other state agency, and if the contract
105 between such state agency and the consultant complies with the
106 requirements of this section, then the consultant, and its
107 officers and employees and those acting at the direction of the
108 consultant for the limited purpose of an emergency intervention
109 of a licensee or student as described in subsection (2) when the

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110 consultant is unable to perform such intervention, shall be
111 considered agents of the state for the purposes of this section,
112 while acting within the scope of and pursuant to guidelines
113 established in the contract between such state agency and the
114 consultant.

115 Section 2. This act shall take effect July 1, 2008.

116

117

118 -----

119 **T I T L E A M E N D M E N T**

120 Remove the entire title and insert:

121 A bill to be entitled

122 An act relating to treatment programs for impaired
123 practitioners; amending s. 456.076, F.S.; revising
124 requirements for program consultants; authorizing the
125 Department of Health to contract with consultants to
126 provide treatment services for allopathic and osteopathic
127 physician students alleged to be impaired; providing for
128 absence of liability in civil actions of certain schools
129 for referring students to such consultants or taking
130 certain actions without intentional fraud; providing
131 limited sovereign immunity for certain program consultants
132 under specific contractual conditions; requiring the
133 Department of Financial Services to defend actions against
134 program consultants; providing an effective date.

135

Himss

transforming healthcare through IT

architects of change

Overview of the Healthcare Information and Management Systems Society

Himss

Agenda

- What is HIMSS?
- HIMSS Strategic Direction
- Society History
- Society Today
- Areas of Focus
- Florida Chapters
- Upcoming Events

What is HIMSS?

The Healthcare Information and Management Systems Society (HIMSS) is the healthcare industry's membership organization exclusively focused on providing **global leadership for the optimal use of healthcare information technology (IT) and management systems for the betterment of healthcare.**

HIMSS Strategic Direction

Vision

Advancing the best use of information and management systems for the betterment of health care.

Mission

To lead change in the healthcare information and management systems field through knowledge sharing, advocacy, collaboration, innovation, and community affiliations.

Society Today

- 20,000 Individual Members of which 73% work in the field (non-vendors, non-consultants)
- 330 Corporate Members
- 90+ committees, task forces, & work groups
- 47 Chapters
- 3 corporations, over 175 staff
- Top 5 largest healthcare conference in US
- Top 50 largest conference of any kind in US

Areas of Focus

Subjects

- Interoperability
- IT Adoption
- Privacy & Security
- Quality & P4P
- Financial Systems
- Clinical Informatics
- Patient Safety
- Management Systems
- Standards & Architecture
- PHRs

Settings

- Acute
- Ambulatory
- Life Sciences
- Payer
- Public Health
- Long-Term Care
- Home Health

Upcoming Events

- Florida State HIT Advocacy Day (January 22 – 23, 2008)
- “HIT 101” for State Officials and their Staff (January 24, 2008 / 12:00-1:30pm, Eastern Time)
- 2008 HIMSS Annual Conference and Exhibition USA (Orlando, Florida – February 24 -28, 2008)

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Draft Language to Revise the Hospital Code 15 Reporting System

Product of the Patient Safety Workgroup

Agency for Health Care Administration

January 22, 2008

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1 A bill to be entitled
2 An act relating to quality assurance and incident
3 reporting; amending s. 395.0197, F.S., changing the
4 incident reporting requirements; amending s.408.05 F.S.,
5 creating a new subsection 408.05 (6), F.S., relating to
6 reportable incident collection and reporting; amending s.
7 641.55, F.S., changing the incident reporting
8 requirements; providing an effective date.
9

10 Be It Enacted by the Legislature of the State of Florida:
11

12 Section 1. Section 395.0197, Florida Statutes, is amended
13 to read:

14 395.0197 Internal risk management program.—

15 (1) Every licensed facility shall, as a part of its
16 administrative functions, establish an internal risk management
17 program that includes all of the following components:

18 (a) The investigation and analysis of the frequency and
19 causes of general categories and specific types of reportable
20 ~~adverse~~ incidents, as defined in this section or by federal law,
21 to patients.

22 (b) The development of appropriate measures to minimize the
23 risk of reportable ~~adverse~~ incidents to patients, including, but
24 not limited to:

25 1. Risk management and risk prevention education and
26 training of all nonphysician personnel as follows:

27 a. Such education and training of all nonphysician
28 personnel as part of their initial orientation; and

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29 b. At least 1 hour of such education and training annually
30 for all personnel of the licensed facility working in clinical
31 areas and providing patient care, except those persons licensed
32 as health care practitioners who are required to complete
33 continuing education coursework pursuant to chapter 456 or the
34 respective practice act.

35 2. A prohibition, except when emergency circumstances
36 require otherwise, against a staff member of the licensed
37 facility attending a patient in the recovery room, unless the
38 staff member is authorized to attend the patient in the recovery
39 room and is in the company of at least one other person. However,
40 a licensed facility is exempt from the two-person requirement if
41 it has:

- 42 a. Live visual observation;
- 43 b. Electronic observation; or
- 44 c. Any other reasonable measure taken to ensure patient
45 protection and privacy.

46 3. A prohibition against an unlicensed person from
47 assisting or participating in any surgical procedure unless the
48 facility has authorized the person to do so following a
49 competency assessment, and such assistance or participation is
50 done under the direct and immediate supervision of a licensed
51 physician and is not otherwise an activity that may only be
52 performed by a licensed health care practitioner.

53 4. Development, implementation, and ongoing evaluation of
54 procedures, protocols, and systems to accurately identify
55 patients, planned procedures, and the correct site of the planned
56 procedure so as to minimize the performance of a surgical
57 procedure on the wrong patient, a wrong surgical procedure, a

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58 | wrong-site surgical procedure, or a surgical procedure otherwise
59 | unrelated to the patient's diagnosis or medical condition.

60 | (c) The analysis of patient grievances that relate to
61 | patient care and the quality of medical services.

62 | (d) A system for informing a patient or an individual
63 | identified pursuant to s. 765.401(1) that the patient was the
64 | subject of an reportable ~~adverse~~ incident as defined in
65 | subsection (5). Such notice shall be given by an appropriately
66 | trained person designated by the licensed facility as soon as
67 | practicable to allow the patient an opportunity to minimize
68 | damage or injury. Documentation of the notification should be
69 | placed in the patient's medical record.

70 | (e) The development and implementation of an incident
71 | reporting system based upon the affirmative duty of all health
72 | care providers and all agents and employees of the licensed
73 | health care facility to report on reportable ~~adverse~~ incidents to
74 | the risk manager, or to his or her designee, within 3 business
75 | days after their occurrence.

76 | (2) The internal risk management program is the
77 | responsibility of the governing board of the health care
78 | facility. Each licensed facility shall hire a risk manager,
79 | licensed under s. 395.10974, who is responsible for
80 | implementation and oversight of such facility's internal risk
81 | management program as required by this section. A risk manager
82 | must not be made responsible for more than four internal risk
83 | management programs in separate licensed facilities, unless the
84 | facilities are under one corporate ownership or the risk
85 | management programs are in rural hospitals.

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86 ~~(3) In addition to the programs mandated by this section,~~
87 ~~other innovative approaches intended to reduce the frequency and~~
88 ~~severity of medical malpractice and patient injury claims shall~~
89 ~~be encouraged and their implementation and operation facilitated.~~
90 ~~Such additional approaches may include extending internal risk~~
91 ~~management programs to health care providers' offices and the~~
92 ~~assuming of provider liability by a licensed health care facility~~
93 ~~for acts or omissions occurring within the licensed facility.~~
94 ~~Each licensed facility shall annually report to the agency and~~
95 ~~the Department of Health the name and judgments entered against~~
96 ~~each health care practitioner for which it assumes liability. The~~
97 ~~agency and Department of Health, in their respective annual~~
98 ~~reports, shall include statistics that report the number of~~
99 ~~licensed facilities that assume such liability and the number of~~
100 ~~health care practitioners, by profession, for whom they assume~~
101 ~~liability.~~

102 (4) The agency shall adopt rules to implement the
103 provisions of this section. ~~governing the establishment of~~
104 ~~internal risk management programs to meet the needs of individual~~
105 ~~licensed facilities.~~ Each internal risk management program shall
106 include the use of incident reports to be filed with an
107 individual of responsibility who is competent in risk management
108 techniques in the employ of each licensed facility, such as an
109 insurance coordinator, or who is retained by the licensed
110 facility as a consultant. The individual responsible for the risk
111 management program shall have free access to all medical records
112 of the licensed facility. The incident reports are part of the
113 workpapers of the attorney defending the licensed facility in
114 litigation relating to the licensed facility and are subject to

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115 discovery, but are not admissible as evidence in court. A person
116 filing an incident report is not subject to civil suit by virtue
117 of such incident report. As a part of each internal risk
118 management program, the incident reports shall be used to develop
119 categories of incidents which identify problem areas. Once
120 identified, procedures shall be adjusted to correct the problem
121 areas.

122 (5) For purposes of reporting to the agency and Department
123 of Health, pursuant to this section, the term "reportable
124 incident" means an event which is associated in whole or in part
125 with medical intervention, or lack thereof, rather than the
126 condition for which such intervention occurred, specifically:

127 (a) Surgical Events:

128 1. Surgery performed on the wrong body part, defined as any
129 surgery performed on a body part that is not consistent with the
130 documented informed consent for that patient. Excludes emergency
131 situations that occur in the course of surgery and/or whose
132 exigency precludes obtaining informed consent.

133 2. Surgery performed on the wrong patient, defined as any
134 surgery on a patient that is not consistent with the documented
135 informed consent for that patient.

136 3. Wrong surgical procedure performed on a patient, defined
137 as any procedure performed on a patient that is not consistent
138 with the documented informed consent for that patient. Excludes
139 emergency situations that occur in the course of surgery and/or
140 whose exigency precludes obtaining informed consent.

141 4. Retention of a foreign object in a patient after surgery
142 or other procedure. Excludes objects intentionally implanted as

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143 part of a planned intervention and objects present prior to
 144 surgery that were retained.

145 5. Intraoperative or immediately post-operative death in an
 146 American Society of Anesthesiologist Class I patient, defined as
 147 a normal, healthy patient, including but not limited to, a
 148 patient who has no organic, physiological, biochemical, or
 149 psychiatric disturbance. The pathologic processes for which the
 150 operation is to be performed are localized and do not entail a
 151 systemic disturbance. Includes all American Society of
 152 Anesthesiologists Class I patient deaths in situations where
 153 anesthesia was administered; the planned surgical procedure may
 154 or may not have been carried out.

155 (b) Product or Device Events:

156 1. Patient death or serious disability associated with the
 157 use of contaminated drugs, devices, or biologics provided by the
 158 health care facility. Includes, but is not limited to, generally
 159 detectable contaminants in drugs, devices, or biologics
 160 regardless of the sources of contamination and/or product.

161 2. Patient death or serious disability associated with the
 162 use or function of a device in patient care in which the device
 163 was used for functions other than as intended and in a manner not
 164 consistent with reasonable standards of medical practice.
 165 Includes, but is not limited to, catheters, drains, and other
 166 specialized tubes, infusion pumps, and ventilators.

167 3. Patient death or serious disability associated with
 168 intravascular air embolism that occurs while being cared for in a
 169 health care facility. Excludes deaths associated with
 170 neurosurgical procedures known to be a high risk of intravascular
 171 air embolism.

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- 172 (c) Patient Protection Events:
173 1. Infant discharged to the wrong person.
174 2. Patient death or serious disability associated with
175 patient elopement for more than four hours. Excludes events
176 involving competent adults.
177 3. Patient suicide, or attempted suicide at a health care
178 facility resulting in serious disability.
179 (d) Care Management Events
180 1. Patient death or serious disability associated with a
181 medication error, including but not limited to, errors involving
182 the wrong drug, wrong dose, wrong patient, wrong time, wrong
183 rate, wrong preparation or wrong route of administration.
184 Excludes reasonable differences in clinical judgment on drug
185 selection and dose.
186 2. Patient death or serious disability associated with a
187 hemolytic reaction due to the administration of ABO-incompatible
188 blood or blood products.
189 3. Maternal death or serious disability directly or
190 indirectly associated with labor or delivery in a low-risk
191 pregnancy while being cared for in the hospital. Includes known
192 events that occur within forty-two (42) days post-delivery.
193 Excludes deaths from pulmonary or amniotic fluid embolism, acute
194 fatty liver of pregnancy or cardiomyopathy.
195 4. Death or serious disability (kernicterus) associated
196 with failure to identify and treat hyperbilirubinemia in
197 neonates.
198 5. Stage 2, 3, or 4 pressure ulcers acquired after
199 admission to the hospital. Excludes progression from Stage 1 to
200 Stage 2 if Stage 1 was recognized upon admission and excludes

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201 progression from Stage 2 to Stage 3 if Stage 2 was recognized
202 upon admission.

203 6. Patient death or serious disability due to spinal
204 manipulation therapy performed in the hospital.

205 (e) Environmental Events

206 1. Patient death or serious disability associated with an
207 electric shock while being cared for in the hospital. Excludes
208 events involving planned treatment, such as electrical
209 countershock.

210 2. Any incident in which a line designated for oxygen or
211 other gas to be delivered to a patient contains the wrong gas or
212 is contaminated.

213 3. Patient death or serious disability associated with a
214 burn incurred from any source while being cared for in the
215 hospital.

216 4. Patient death or serious disability associated with a
217 fall while being cared for in the hospital.

218 5. Patient death that occurs while a patient is in
219 seclusion or restraint, patient death and occurs within 24 hours
220 after the patient has been removed from seclusion or restraint,
221 and each patient death known to the facility that occurs within
222 one week after seclusion of restraint use where it is reasonable
223 to assume that it contributed directly or indirectly to a
224 patient's death.

225 (6) For the purposes of this section Serious Disability
226 means:

227 (a) A physical and mental impairment that substantially
228 limits one or more major life activities of an individual;

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229 (b) A loss of bodily function if the impairment or loss
230 lasts more than seven days or is still present at the time of
231 discharge from a hospital or ambulatory surgery center; or
232 (c) The loss of a body part.
233 (7) Reportable incidents, whether occurring in the licensed
234 facility or arising from health care prior to admission in the
235 licensed facility, shall be reported electronically through an
236 online portal by the facility to the agency and Department of
237 Health within 15 calendar days after its occurrence. The
238 reportable incidents will be available immediately to the
239 Department of Health for review through the electronic submission
240 portal. The facilities Chief Executive Officer (CEO) shall
241 certify quarterly, through the electronic submission portal, that
242 all reportable incidents the previous quarter have been reported,
243 and that their reportable incidents submissions are accurate.
244 The agency may grant extensions to this reporting
245 requirement for more than 15 days upon justification submitted in
246 writing by the facility administrator to the agency. These
247 reports are exempt from disclosure under chapter, 119, Florida
248 Statute or any other law providing access to public records, nor
249 be discoverable or admissible in any civil or administrative
250 action, except in disciplinary proceedings by the Department of
251 Health or the appropriate regulatory authority, nor shall they be
252 available to the public as part of the record of investigation
253 for and prosecution in disciplinary proceedings made available to
254 the public by the agency or Department of Health or the
255 appropriate regulatory board. However, the Department of Health
256 or the appropriate regulatory board shall make available, upon
257 written request by a health care professional against whom

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258 probable cause has been found, any such records which form the
259 basis of the determination of probable cause. The agency or
260 Department of Health may investigate any such incident and
261 prescribe measures that must or may be taken in response to the
262 incident. The Department of Health shall review each incident and
263 determine whether it potentially involved conduct by the health
264 care professional regulated by the Department of Health and is
265 subject to disciplinary action, in which case the provisions of
266 s. 456.073 shall apply.

267 (8) Within 60 days of the occurrence of a reportable
268 incident, the Agency shall require the facility to submit a
269 written plan of correction, root cause analysis form, and patient
270 safety lessons learned from the facility.

271 (9) The agency shall do the following:

272 (a) Publish on the agency's website, no less than quarterly,
273 a summary and trend analysis of reportable incidents received
274 pursuant to this section, which shall not include information
275 that would identify the patient, the reporting facility, or the
276 health care practitioners involved.

277 (b) Publish on the agency's website an annual report that
278 shall describe the reported incidents submitted summarized in
279 aggregate form, highlight patient safety lessons learned, common
280 root cause analysis findings, and notable corrective action
281 plans.

282 ~~(5) For purposes of reporting to the agency pursuant to~~
283 ~~this section, the term "adverse incident" means an event over~~
284 ~~which health care personnel could exercise control and which is~~
285 ~~associated in whole or in part with medical intervention, rather~~

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286 ~~than the condition for which such intervention occurred, and~~
287 ~~which:~~

288 ~~(a) Results in one of the following injuries:~~

289 ~~1. Death;~~

290 ~~2. Brain or spinal damage;~~

291 ~~3. Permanent disfigurement;~~

292 ~~4. Fracture or dislocation of bones or joints;~~

293 ~~5. A resulting limitation of neurological, physical, or~~
294 ~~sensory function which continues after discharge from the~~
295 ~~facility;~~

296 ~~6. Any condition that required specialized medical~~
297 ~~attention or surgical intervention resulting from nonemergency~~
298 ~~medical intervention, other than an emergency medical condition,~~
299 ~~to which the patient has not given his or her informed consent;~~
300 ~~or~~

301 ~~7. Any condition that required the transfer of the patient,~~
302 ~~within or outside the facility, to a unit providing a more acute~~
303 ~~level of care due to the adverse incident, rather than the~~
304 ~~patient's condition prior to the adverse incident;~~

305 ~~(b) Was the performance of a surgical procedure on the~~
306 ~~wrong patient, a wrong surgical procedure, a wrong site surgical~~
307 ~~procedure, or a surgical procedure otherwise unrelated to the~~

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308 ~~patient's diagnosis or medical condition;~~
309 ~~(c) Required the surgical repair of damage resulting to a~~
310 ~~patient from a planned surgical procedure, where the damage was~~
311 ~~not a recognized specific risk, as disclosed to the patient and~~
312 ~~documented through the informed consent process; or~~
313 ~~(d) Was a procedure to remove unplanned foreign objects~~
314 ~~remaining from a surgical procedure.~~
315 ~~(6)(a) Each licensed facility subject to this section shall~~
316 ~~submit an annual report to the agency summarizing the incident~~
317 ~~reports that have been filed in the facility for that year. The~~
318 ~~report shall include:~~
319 ~~1. The total number of adverse incidents.~~
320 ~~2. A listing, by category, of the types of operations,~~
321 ~~diagnostic or treatment procedures, or other actions causing the~~
322 ~~injuries, and the number of incidents occurring within each~~
323 ~~category.~~
324 ~~3. A listing, by category, of the types of injuries caused~~
325 ~~and the number of incidents occurring within each category.~~
326 ~~4. A code number using the health care professional's~~
327 ~~licensure number and a separate code number identifying all other~~
328 ~~individuals directly involved in adverse incidents to patients,~~
329 ~~the relationship of the individual to the licensed facility, and~~

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330 | ~~the number of incidents in which each individual has been~~
331 | ~~directly involved. Each licensed facility shall maintain names of~~
332 | ~~the health care professionals and individuals identified by code~~
333 | ~~numbers for purposes of this section.~~

334 | ~~5. A description of all malpractice claims filed against~~
335 | ~~the licensed facility, including the total number of pending and~~
336 | ~~closed claims and the nature of the incident which led to, the~~
337 | ~~persons involved in, and the status and disposition of each~~
338 | ~~claim. Each report shall update status and disposition for all~~
339 | ~~prior reports.~~

340 | ~~(b) The information reported to the agency pursuant to~~
341 | ~~paragraph (a) which relates to persons licensed under chapter~~
342 | ~~458, chapter 459, chapter 461, or chapter 466 shall be reviewed~~
343 | ~~by the agency. The agency shall determine whether any of the~~
344 | ~~incidents potentially involved conduct by a health care~~
345 | ~~professional who is subject to disciplinary action, in which case~~
346 | ~~the provisions of s. 456.073 shall apply.~~

347 | ~~(c) The report submitted to the agency shall also contain~~
348 | ~~the name and license number of the risk manager of the licensed~~
349 | ~~facility, a copy of its policy and procedures which govern the~~
350 | ~~measures taken by the facility and its risk manager to reduce the~~
351 | ~~risk of injuries and adverse incidents, and the results of such~~

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352 ~~measures. The annual report is confidential and is not available~~
353 ~~to the public pursuant to s. 119.07(1) or any other law providing~~
354 ~~access to public records. The annual report is not discoverable~~
355 ~~or admissible in any civil or administrative action, except in~~
356 ~~disciplinary proceedings by the agency or the appropriate~~
357 ~~regulatory board. The annual report is not available to the~~
358 ~~public as part of the record of investigation for and prosecution~~
359 ~~in disciplinary proceedings made available to the public by the~~
360 ~~agency or the appropriate regulatory board. However, the agency~~
361 ~~or the appropriate regulatory board shall make available, upon~~
362 ~~written request by a health care professional against whom~~
363 ~~probable cause has been found, any such records which form the~~
364 ~~basis of the determination of probable cause.~~

365 ~~(7) Any of the following adverse incidents, whether~~
366 ~~occurring in the licensed facility or arising from health care~~
367 ~~prior to admission in the licensed facility, shall be reported by~~
368 ~~the facility to the agency within 15 calendar days after its~~
369 ~~occurrence:~~

370 ~~(a) The death of a patient;~~

371 ~~(b) Brain or spinal damage to a patient;~~

372 ~~(c) The performance of a surgical procedure on the wrong~~
373 ~~patient;~~

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374 ~~(d) The performance of a wrong site surgical procedure;~~
375 ~~(e) The performance of a wrong surgical procedure;~~
376 ~~(f) The performance of a surgical procedure that is~~
377 ~~medically unnecessary or otherwise unrelated to the patient's~~
378 ~~diagnosis or medical condition;~~
379 ~~(g) The surgical repair of damage resulting to a patient~~
380 ~~from a planned surgical procedure, where the damage is not a~~
381 ~~recognized specific risk, as disclosed to the patient and~~
382 ~~documented through the informed consent process; or~~
383 ~~(h) The performance of procedures to remove unplanned~~
384 ~~foreign objects remaining from a surgical procedure.~~
385
386 ~~The agency may grant extensions to this reporting requirement for~~
387 ~~more than 15 days upon justification submitted in writing by the~~
388 ~~facility administrator to the agency. The agency may require an~~
389 ~~additional, final report. These reports shall not be available to~~
390 ~~the public pursuant to s. 119.07(1) or any other law providing~~
391 ~~access to public records, nor be discoverable or admissible in~~
392 ~~any civil or administrative action, except in disciplinary~~
393 ~~proceedings by the agency or the appropriate regulatory board,~~
394 ~~nor shall they be available to the public as part of the record~~
395 ~~of investigation for and prosecution in disciplinary proceedings~~

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396 ~~made available to the public by the agency or the appropriate~~
397 ~~regulatory board. However, the agency or the appropriate~~
398 ~~regulatory board shall make available, upon written request by a~~
399 ~~health care professional against whom probable cause has been~~
400 ~~found, any such records which form the basis of the determination~~
401 ~~of probable cause. The agency may investigate, as it deems~~
402 ~~appropriate, any such incident and prescribe measures that must~~
403 ~~or may be taken in response to the incident. The agency shall~~
404 ~~review each incident and determine whether it potentially~~
405 ~~involved conduct by the health care professional who is subject~~
406 ~~to disciplinary action, in which case the provisions of s.~~
407 ~~456.073 shall apply.~~

408 ~~(8) The agency shall publish on the agency's website, no~~
409 ~~less than quarterly, a summary and trend analysis of adverse~~
410 ~~incident reports received pursuant to this section, which shall~~
411 ~~not include information that would identify the patient, the~~
412 ~~reporting facility, or the health care practitioners involved.~~
413 ~~The agency shall publish on the agency's website an annual~~
414 ~~summary and trend analysis of all adverse incident reports and~~
415 ~~malpractice claims information provided by facilities in their~~
416 ~~annual reports, which shall not include information that would~~
417 ~~identify the patient, the reporting facility, or the~~

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418 ~~practitioners involved. The purpose of the publication of the~~
419 ~~summary and trend analysis is to promote the rapid dissemination~~
420 ~~of information relating to adverse incidents and malpractice~~
421 ~~claims to assist in avoidance of similar incidents and reduce~~
422 ~~morbidity and mortality.~~

423 (10)~~(9)~~ The internal risk manager of each licensed facility
424 shall:

425 (a) Investigate every allegation of sexual misconduct which
426 is made against a member of the facility's personnel who has
427 direct patient contact, when the allegation is that the sexual
428 misconduct occurred at the facility or on the grounds of the
429 facility.

430 (b) Report every allegation of sexual misconduct to the
431 administrator of the licensed facility.

432 (c) Notify the family or guardian of the victim, if a
433 minor, that an allegation of sexual misconduct has been made and
434 that an investigation is being conducted.

435 (d) Report to the Department of Health every allegation of
436 sexual misconduct, as defined in chapter 456 and the respective
437 practice act, by a licensed health care practitioner that
438 involves a patient.

439 (11)~~(10)~~ Any witness who witnessed or who possesses actual

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440 knowledge of the act that is the basis of an allegation of sexual
441 abuse shall:

442 (a) Notify the local police; and

443 (b) Notify the hospital risk manager and the administrator.

444 For purposes of this subsection, "sexual abuse" means acts of a
445 sexual nature committed for the sexual gratification of anyone
446 upon, or in the presence of, a vulnerable adult, without the
447 vulnerable adult's informed consent, or a minor. "Sexual abuse"
448 includes, but is not limited to, the acts defined in s.
449 794.011(1)(h), fondling, exposure of a vulnerable adult's or
450 minor's sexual organs, or the use of the vulnerable adult or
451 minor to solicit for or engage in prostitution or sexual
452 performance. "Sexual abuse" does not include any act intended for
453 a valid medical purpose or any act which may reasonably be
454 construed to be a normal caregiving action.

455 (12)~~(11)~~ A person who, with malice or with intent to
456 discredit or harm a licensed facility or any person, makes a
457 false allegation of sexual misconduct against a member of a
458 licensed facility's personnel is guilty of a misdemeanor of the
459 second degree, punishable as provided in s. 775.082 or s.
460 775.083.

461 ~~(12) In addition to any penalty imposed pursuant to this~~

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462 ~~section, the agency shall require a written plan of correction,~~
463 ~~root cause analysis, and patient safety lessons learned from the~~
464 ~~facility within 45 days of the reportable incident. For a single~~
465 ~~incident or series of isolated incidents that are nonwillful~~
466 ~~violations of the reporting requirements of this section, the~~
467 ~~agency shall first seek to obtain corrective action by the~~
468 ~~facility. If the correction is not demonstrated within the~~
469 ~~timeframe established by the agency or if there is a pattern of~~
470 ~~nonwillful violations of this section, the agency may impose an~~
471 ~~administrative fine, not to exceed \$5,000 for any violation of~~
472 ~~the reporting requirements of this section. The administrative~~
473 ~~fine for repeated nonwillful violations shall not exceed \$10,000~~
474 ~~for any violation. The administrative fine for each intentional~~
475 ~~and willful violation may not exceed \$25,000 per violation, per~~
476 ~~day. The fine for an intentional and willful violation of this~~
477 ~~section may not exceed \$250,000. In determining the amount of~~
478 ~~fine to be levied, the agency shall be guided by s.~~
479 ~~395.1065(2)(b).~~

480 (13) The agency shall have access to all licensed facility
481 records necessary to carry out the provisions of this section.
482 The records obtained by the agency under subsection (6), or
483 subsection (7), ~~or subsection (9)~~ are exempt from disclosure

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484 under chapter, 119, Florida Statute ~~not available to the public~~
485 ~~under s. 119.07(1)~~, nor shall they be discoverable or admissible
486 in any civil or administrative action, except in disciplinary
487 proceedings by the agency or the appropriate regulatory board,
488 nor shall records obtained pursuant to s. 456.071 be available to
489 the public as part of the record of investigation for and
490 prosecution in disciplinary proceedings made available to the
491 public by the agency or the appropriate regulatory board.
492 However, the agency or the appropriate regulatory board shall
493 make available, upon written request by a health care
494 professional against whom probable cause has been found, any such
495 records which form the basis of the determination of probable
496 cause, except that, with respect to medical review committee
497 records, s. 766.101 controls.

498 (14) The meetings of the committees and governing board of
499 a licensed facility held solely for the purpose of achieving the
500 objectives of risk management as provided by this section shall
501 not be open to the public under the provisions of chapter 286.
502 The records of such meetings are confidential and exempt from s.
503 119.07(1), except as provided in subsection (13).

504 (15) The agency may ~~shall~~ review, as part of its licensure
505 inspection process, the internal risk management program at each

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506 licensed facility regulated by this section to determine whether
507 the program meets standards established in statutes and rules,
508 whether the program is being conducted in a manner designed to
509 reduce reportable ~~adverse~~ incidents, and whether the program is
510 appropriately reporting incidents under this section.

511 (16) There shall be no monetary liability on the part of,
512 and no cause of action for damages shall arise against, any risk
513 manager, licensed under s. 395.10974, for the implementation and
514 oversight of the internal risk management program in a facility
515 licensed under this chapter or chapter 390 as required by this
516 section, for any act or proceeding undertaken or performed within
517 the scope of the functions of such internal risk management
518 program if the risk manager acts without intentional fraud.

519 (17) A privilege against civil liability is hereby granted
520 to any licensed risk manager or licensed facility with regard to
521 information furnished pursuant to this chapter, unless the
522 licensed risk manager or facility acted in bad faith or with
523 malice in providing such information.

524 (18) The Department of Health shall have access to all
525 identifying information submitted on the reportable incident. The
526 agency and Department of Health shall have access to all facility
527 records relevant to the reportable incident.

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528 ~~(18) If the agency, through its receipt of any reports~~
529 ~~required under this section or through any investigation, has a~~
530 ~~reasonable belief that conduct by a staff member or employee of a~~
531 ~~licensed facility is grounds for disciplinary action by the~~
532 ~~appropriate regulatory board, the agency shall report this fact~~
533 ~~to such regulatory board.~~

534 (19) It shall be unlawful for any person to coerce,
535 intimidate, or preclude a risk manager from lawfully executing
536 his or her reporting obligations pursuant to this chapter. Such
537 unlawful action shall be subject to civil monetary penalties not
538 to exceed \$10,000 per violation.

539 (20) For a single incident or series of isolated incidents
540 that are nonwillful violations of the reporting requirements of
541 this section, the agency shall first seek to obtain corrective
542 action by the facility. If the correction is not demonstrated
543 within the timeframe established by the agency or if there is a
544 pattern of nonwillful violations of this section, the agency may
545 impose an administrative fine, not to exceed \$5,000 for any
546 violation of the reporting requirements of this section. The
547 administrative fine for repeated nonwillful violations shall not
548 exceed \$10,000 for any violation. The administrative fine for
549 each intentional and willful violation may not exceed \$25,000 per

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550 violation, per day. The fine for an intentional and willful
551 violation of this section may not exceed \$250,000. In determining
552 the amount of fine to be levied, the agency shall be guided by s.
553 395.1065 (2) (b) .

554 Section 2. Section 408.05 (2) Florida Center for Health
555 Information and Policy Analysis, is amended to read:--

556 (1) ESTABLISHMENT.--The agency shall establish a Florida
557 Center for Health Information and Policy Analysis. The center
558 shall establish a comprehensive health information system to
559 provide for the collection, compilation, coordination, analysis,
560 indexing, dissemination, and utilization of both purposefully
561 collected and extant health-related data and statistics. The
562 center shall be staffed with public health experts,
563 biostatisticians, information system analysts, health policy
564 experts, patient safety experts, economists, and other staff
565 necessary to carry out its functions.

566 (2) HEALTH-RELATED DATA.--The comprehensive health
567 information system operated by the Florida Center for Health
568 Information and Policy Analysis shall identify the best available
569 data sources and coordinate the compilation of extant health-
570 related data and statistics and purposefully collect data on:

571 (a) The extent and nature of illness and disability of the

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572 | state population, including life expectancy, the incidence of
573 | various acute and chronic illnesses, and infant and maternal
574 | morbidity and mortality.

575 | (b) The impact of illness and disability of the state
576 | population on the state economy and on other aspects of the well-
577 | being of the people in this state.

578 | (c) Environmental, social, and other health hazards.

579 | (d) Health knowledge and practices of the people in this
580 | state and determinants of health and nutritional practices and
581 | status.

582 | (e) Health resources, including physicians, dentists,
583 | nurses, and other health professionals, by specialty and type of
584 | practice and acute, long-term care and other institutional care
585 | facility supplies and specific services provided by hospitals,
586 | nursing homes, home health agencies, and other health care
587 | facilities.

588 | (f) Utilization of health care by type of provider.

589 | (g) Health care costs and financing, including trends in
590 | health care prices and costs, the sources of payment for health
591 | care services, and federal, state, and local expenditures for
592 | health care.

593 | (h) Family formation, growth, and dissolution.

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594 (i) The extent of public and private health insurance
595 coverage in this state.

596 (j) The quality of care provided by various health care
597 providers.

598 (k) Patient safety in health facilities.

599 Section 3. Section 408.05(6) is created to read, The
600 Florida Center shall have responsibility for collecting and
601 analyzing reportable incidents submitted by health facility risk
602 managers under section 395.0197, Florida Statutes. The Florida
603 Center may do a quality assurance review of reportable incidents.
604 Incidents may be reviewed for accuracy, completeness, and
605 compliance. The Florida Center is also responsible for the agency
606 reportable incident reporting requirements, pursuant to section,
607 395.0197, Florida Statutes.

608 Section 4. Section 641.55, Florida Statutes, is amended to
609 read:

610 641.55 Internal risk management program.--

611 (1) Every organization certified under this part shall, as
612 a part of its administrative functions, establish an internal
613 risk management program which shall include the following
614 components:

615 (a) The investigation and analysis of the frequency and

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616 causes of general categories and specific types of reportable
617 ~~adverse~~ incidents causing injury to patients;

618 (b) The development of appropriate measures to minimize the
619 risk of injuries and reportable ~~adverse~~ incidents to patients,
620 including risk management and risk prevention education and
621 training of all nonphysician personnel as follows:

622 1. Such education and training of all nonphysician
623 personnel as part of their initial orientation; and

624 2. At least 1 hour of such education and training annually
625 for all nonphysician personnel of the organization who work in
626 clinical areas and provide patient care;

627 (c) The analysis of patient grievances which relate to
628 patient care and the quality of medical services; and

629 (d) The development and implementation of an incident
630 reporting system based upon the affirmative duty of all providers
631 and all agents and employees of the organization to report
632 injuries and reportable ~~adverse~~ incidents to the risk manager.

633 (2) The risk management program shall be the responsibility
634 of the governing authority or board of the organization. Every
635 organization which has an annual premium volume of \$10 million or
636 more and which directly provides health care in a building owned
637 or leased by the organization shall hire a risk manager,

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638 certified under ss. 395.10971-395.10975, who shall be responsible
639 for implementation of the organization's risk management program
640 required by this section. A part-time risk manager shall not be
641 responsible for risk management programs in more than four
642 organizations or facilities. Every organization which does not
643 directly provide health care in a building owned or leased by the
644 organization and every organization with an annual premium volume
645 of less than \$10 million shall designate an officer or employee
646 of the organization to serve as the risk manager.

647 (3) In addition to the programs mandated by this section,
648 other innovative approaches intended to reduce the frequency and
649 severity of medical malpractice and patient injury claims shall
650 be encouraged and their implementation and operation facilitated.
651 Additional approaches may include extending risk management
652 programs to provider offices or facilities.

653 (4) The Agency for Health Care Administration shall adopt
654 rules necessary to carry out the provisions of this section,
655 including rules governing the establishment of required internal
656 risk management programs to meet the needs of individual
657 organizations and each specific organization type governed by
658 this part. The office shall assist the agency in preparing these
659 rules. Each internal risk management program shall include the

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660 use of incident reports to be filed with the risk manager. The
661 risk manager shall have free access to all organization or
662 provider medical records. The incident reports shall be
663 considered to be a part of the workpapers of the attorney
664 defending the organization in litigation relating thereto and
665 shall be subject to discovery, but not be admissible as evidence
666 in court, nor shall any person filing an incident report be
667 subject to civil suit by virtue of the incident report and the
668 matters it contains. As a part of each internal risk management
669 program, the incident reports shall be utilized to develop
670 categories of incidents which identify problem areas. Once
671 identified, procedures must be adjusted to correct these problem
672 areas.

673 ~~(5) (a) Each organization subject to this section must~~
674 ~~submit an annual report to the agency summarizing the incident~~
675 ~~reports that were filed in the organization during the preceding~~
676 ~~calendar year pertaining to services rendered on the premises of~~
677 ~~the organization. The report must be on a form prescribed by rule~~
678 ~~of the agency and must include, with respect to medical services~~
679 ~~rendered on the premises of the organization:~~

680 ~~1. The total number of adverse incidents causing injury to~~
681 ~~patients.~~

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682 ~~2. A listing, by category, of the types of operations,~~
683 ~~diagnostic or treatment procedures, or other actions causing the~~
684 ~~injuries and the number of incidents occurring within each~~
685 ~~category.~~

686 ~~3. A listing, by category, of the types of injuries caused~~
687 ~~and the number of incidents occurring within each category.~~

688 ~~4. The name of each provider or a code number using each~~
689 ~~health care professional's license number and a separate code~~
690 ~~number identifying all other individuals directly involved in~~
691 ~~adverse incidents causing injury to a patient, the relationship~~
692 ~~of the individual or provider to the organization, and the number~~
693 ~~of incidents with the organization in which each individual or~~
694 ~~provider has been directly involved. Each organization must~~
695 ~~maintain names of the health care professionals and individuals~~
696 ~~identified by code numbers for purposes of this section.~~

697 ~~5. A description of all medical malpractice claims filed~~
698 ~~against the organization or its providers, including the total~~
699 ~~number of pending and closed claims and the nature of the~~
700 ~~incident that led to, the persons involved in, and the status and~~
701 ~~disposition of each claim. Each report must update status and~~
702 ~~disposition for all prior reports.~~

703 ~~6. A report of all disciplinary actions taken against any~~

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704 ~~provider or any medical staff member of the organization,~~
705 ~~including the nature and cause of the action.~~

706 ~~(b) The information reported to the agency under paragraph~~
707 ~~(a) which relates to providers licensed under chapter 458,~~
708 ~~chapter 459, chapter 461, or chapter 466 must also be reported to~~
709 ~~the agency quarterly. The agency shall review the information and~~
710 ~~determine whether any of the incidents potentially involved~~
711 ~~conduct by a licensee that is subject to disciplinary action, in~~
712 ~~which case s. 456.073 applies.~~

713 ~~(c) Except as otherwise provided in this subsection, any~~
714 ~~identifying information contained in the annual report and the~~
715 ~~quarterly reports under paragraphs (a) and (b) is confidential~~
716 ~~and exempt from s. 119.07(1). This information must not be~~
717 ~~available to the public as part of the record of investigation~~
718 ~~for and prosecution in disciplinary proceedings made available to~~
719 ~~the public by the agency or the appropriate regulatory board.~~
720 ~~However, the agency shall make available, upon written request by~~
721 ~~a practitioner against whom probable cause has been found, any~~
722 ~~such information contained in the records that form the basis of~~
723 ~~the determination of probable cause under s. 456.073.~~

724 ~~(d) The annual report shall also contain the name of the~~
725 ~~risk manager of the organization, a copy of its policy and~~

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726 ~~procedures governing the measures taken by the organization and~~
727 ~~its risk manager to reduce the risk of injuries and adverse or~~
728 ~~untoward incidents, and the result of these measures.~~

729 ~~(5)(6)~~ If a reportable ~~n~~ ~~adverse or untoward~~ incident,
730 whether occurring in the facilities of the organization or
731 arising from health care prior to enrollment by the organization
732 or admission to the facilities of the organization or in a
733 facility of one of its providers, results in a reportable
734 incident as defined by section 395.0197

735 ~~(a) The death of a patient;~~

736 ~~(b) Severe brain or spinal damage to a patient;~~

737 ~~(c) A surgical procedure being performed on the wrong~~
738 ~~patient; or~~

739 ~~(d) A surgical procedure unrelated to the patient's~~
740 ~~diagnosis or medical needs being performed on any patient,~~

741
742 the organization must report this incident to the agency within
743 15 ~~3~~ working days after its occurrence. ~~A more detailed follow-up~~
744 ~~report must be submitted to the agency within 10 days after the~~
745 ~~first report.~~ The agency may require ~~an~~ additional information.
746 ~~final report.~~ Reports under this subsection will be available to
747 the Department of Health immediately through electronic means.

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748 ~~must be sent immediately by the agency to the appropriate~~
749 ~~regulatory board whenever they contain references to a provider~~
750 ~~licensed under chapter 458, chapter 459, chapter 461, or chapter~~
751 ~~466.~~ These reports are confidential and are exempt from s.
752 119.07(1). This information is not available to the public as
753 part of the record of investigation for and prosecution in
754 disciplinary proceedings made available to the public by the
755 Department of Health, agency or the appropriate regulatory board.
756 However, the Department of Health agency shall make available,
757 upon written request by a practitioner against whom probable
758 cause has been found, any such information contained in the
759 records that form the basis of the determination of probable
760 cause under s. 456.073. The agency or Department of Health may
761 investigate, as it deems appropriate, any such incident and
762 prescribe measures that must or may be taken by the organization
763 in response to the incident. The Department of Health agency
764 shall review each incident and determine whether it potentially
765 involved conduct by the licensee which is subject to disciplinary
766 action, in which case s. 456.073 applies.

767 (7) In addition to any penalty imposed under s. 641.52, the
768 agency may impose an administrative fine, not to exceed \$5,000,
769 for any violation of the reporting requirements of subsection (5)

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770 ~~or subsection (6).~~

771 (8) The agency, Department of Health and, upon subpoena
772 issued under s. 456.071, the appropriate regulatory board must be
773 given access to all organization records necessary to carry out
774 the provisions of this section. Any identifying information
775 contained in the records obtained under this section is
776 confidential and exempt from s. 119.07(1). The identifying
777 information contained in records obtained under s. 456.071 is
778 exempt from s. 119.07(1) to the extent that it is part of the
779 record of investigation for and prosecution in disciplinary
780 proceedings made available to the public by the Department of
781 Health ~~agency~~ or the appropriate regulatory board. However, the
782 Department of Health ~~agency~~ must make available, upon written
783 request by a practitioner against whom probable cause has been
784 found, any such information contained in the records that form
785 the basis of the determination of probable cause under s.
786 456.073, except that, with respect to medical review committee
787 records, s. 766.101 controls.

788 (9) The agency shall review, no less frequently than
789 annually, the risk management program of each organization
790 regulated by this section to determine whether the program meets
791 standards established in statutes and rules, whether the program

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792 is being conducted in a manner designed to reduce reportable
793 ~~adverse~~ incidents, and whether the program is appropriately
794 reporting incidents under subsections (5) and ~~(6)~~.

795 (10) There shall be no monetary liability on the part of,
796 and no cause of action for damages shall arise against, any risk
797 manager certified under part IX of chapter 626 for the
798 implementation and oversight of the risk management program in an
799 organization authorized under this chapter for any act or
800 proceeding undertaken or performed within the scope of the
801 function of such risk management program if the risk manager acts
802 without intentional fraud.

803 (11) If the agency, ~~through its receipt of the annual~~
804 ~~reports prescribed in subsection (5) or~~ through any
805 investigation, has a reasonable belief that conduct by a
806 provider, staff member, or employee of an organization may
807 constitute grounds for disciplinary action by the appropriate
808 regulatory board, the agency shall report this fact to the
809 regulatory board.

810 ~~(12) The agency shall send information bulletins to all~~
811 ~~organizations as necessary to disseminate trends and preventive~~
812 ~~data derived from its actions under this section or under s.~~
813 ~~395.0197.~~

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815 The gross data compiled under this section or s. 395.0197 shall
816 be furnished by the agency upon request to organizations to be
817 utilized for risk management purposes. The agency shall adopt
818 rules necessary to carry out the provisions of this section.

819 Section 5. This act shall take effect October 1, 2008.

Draft Bill Relating to Quality Assurance and Incident Reporting
Drafted By the Patient Safety Workgroup, Agency for Health Care Administration

- Repeals the requirement that each facility submit an annual report to the Agency for Health Care Administration and the Department of Health that includes the name and judgments entered against each health care practitioner it is liable for.
- Repeals the current definition of “adverse incident” and replaces it with a more prescriptive definition of “reportable event”, which includes the following categories:
 - Surgical events.
 - Product or device events.
 - Patient protection events.
 - Care management events.
 - Environmental events.
- Repeals the requirement that facilities submit an annual report to the agency summarizing the incident reports filed during the year.
- Repeals the current reporting process for adverse incidents and replaces it with a process that includes the following:
 - The facility must electronically provide reportable events to the agency and department within 15 calendar days after its occurrence.
 - The facility’s CEO must electronically certify each quarter that all reportable incidents from the previous quarter have been reported and are accurate.
- Specifies that the department, rather than the agency, must review each incident to determine whether it potentially involved conduct by a health care professional regulated by the department and is subject to disciplinary action.
- Specifies that the facility must submit a written plan of correction, root cause analysis form, and patient safety lessons learned from the hospital within 60 days, rather than 45 days, of the occurrence of the reportable incident.
- Requires the agency to publish an annual report on its website that describes the reported incidents submitted summarized in aggregate form, highlights patient safety lessons learned, common root cause analysis findings, and notable corrective action plans.
- Directs the Florida Center for Health Information and Policy Analysis to collect and analyze reportable incidents submitted by health facility risk managers.
- Repeals the requirement that HMOs and prepaid health clinics submit an annual report to the agency summarizing the incident reports filed during the year.
- Requires the HMO or prepaid health clinic to report all reportable incidents to the agency within 15 days, rather than 3 working days, after its occurrence. Removes the requirement that a more detailed report be submitted to the agency within 10 days of the first report.
- Repeals the requirement that the agency send information bulletins to organizations to disseminate trends and preventative data derived from the reports received.
- Provides an effective date of October 1, 2008.

**Department of Health
Continuing Education Tracking System
January, 2008**

In 2001, the Legislature amended s. 456.025 (7), F.S., to require DOH to integrate the electronic tracking system for continuing education (CE) into the licensure and renewal system. The law also requires all approved continuing education providers to provide DOH with information on course attendance necessary to implement the electronic tracking system. The department must, by rule, specify the form and procedures by which the information is to be submitted.

In the summer of 2002, the Department of Health began implementation of the legislation. Various professional association representatives participated in a work group to design the system with a Request for Proposal issued in the early fall of 2002. After evaluation of the two proposals submitted, Information Systems of Florida, Inc., was selected and the contract was executed in August 2003 after a lengthy bid protest. The contract is at no cost to the state with funding coming from voluntary subscription fees from licensees who want to track and manage compliance with their CE. The system name is CE Broker.

CE Providers must apply for initial approval from DOH. Renewal of that approval can be completed online. CE Providers must register once with basic information of name, address, email address, and contact person. Each course must be registered with four pieces of information: provider name, course title, when offered, and hours approved for. A course number is instantly generated and emailed to the CE Provider. The CE Provider has the option to enter more information for marketing purposes including a course description and website link. CE Providers report attendance in one of four ways:

Excel spreadsheet-electronically; text-file format-electronically; manually by entering it directly into the system; and mailing in scan cards completed by the licensee.

In December 2003, DOH noticed proposed administrative rules to implement the electronic tracking system for continuing education. Rule 64B-5.001, F.A.C, defines “continuing education (CE) tracking system” to mean the designated electronic system through which approved providers submit necessary information on course attendance. Rule 64B-5.002, F.A.C., requires continuing education providers, applying to a board for initial or renewed status as an approved provider or for initial or renewed approval of a continuing education course, to electronically submit their application through the continuing education tracking system. They must also submit specified identifying information, including detailed information on continuing education courses offered by the approved provider. The rule also requires all approved continuing education providers to electronically submit course information by the first day of the renewal period. The rule requires continuing education providers to report continuing education course attendance: (1) in a designated excel format (electronic); (2) in a text file format (electronic); (3) by manual entry of the required data direct to the continuing education system; or (4) by submitting the completed scan cards signed by the licensed health care professional. The rule requires submission of all information and data required by the rule to the CE Broker system.

Currently, there are over 67,000 licensee subscribers to the system with 4,180 active CE Providers who have submitted over 153,000 CE courses to CE Broker. Almost 5 million completed course credit entries have been posted by CE Providers to CE Broker and over 188,000 licensees have self submitted courses to CE Broker for approval by their respective boards. The licensees benefit from having the system because it provides them access to individualized

transcript of CE hours completed which has been designed for the licensees profession; the ability to update his/her file; the ability to search for specific courses by subject, geographic area, dates, and provider; and the ability to create an alert system for renewal dates and credits still lacking from the CE transcript. Licensees have the option to subscribe to CE Broker to manage their compliance with continuing education credits for \$17.50 annually. There is a free licensee limited access registration which allows licensees to self submit courses and to search for providers and courses. A public records request can be submitted to the Department by a licensee at any time to receive a copy of their CE Chronological History that resides on the CE Broker system.

The Department conducts a continuing education audit of all health care practitioners required by statute and rules who are required to complete continuing education credits as part of their license renewal. The Department randomly selects a list of licensees, by profession, for audit and compares the list to the CE Broker database for confirmation of the required continuing education courses and hours. If a licensee has all of their required hours in CE Broker, they will pass the audit and will not receive an audit letter. If the licensee does not have all their required hours in CE Broker, they will receive an audit letter requesting copies of their certificates of completion. Licensees are given 6 weeks to respond to the audit letter. If there is no response within 6 weeks, a second letter is mailed by certified mail. The licensees are then given 3 weeks to respond to the second letter. At the end of the 9 weeks, all incomplete files are determined to be non-compliant and are forwarded to the Consumer Services Unit for further action.

CE Broker Statistics

Number of:	12-7-07	12-14-07	12-21-07	12-28-07	1-4-08	1-11-08
Licensee Full Access Subscriptions	65,520	65,936	66,610	66,847	67,382	67,964
Licensee Course Search Subscriptions (free as of Dec 1, 2007)	6,108	6,122				
Licensee Limited Access Registrations (free to self submit courses and to search for providers and courses)	20,144	20,225	20,368	20,427	20,530	20,701
Active CE Providers with a course input	4,139	4,148	4,159	4,128	4,163	4,180
Courses submitted	150,012	151,091	151,917	152,222	152,638	153,312
Active CE Providers with a published course	3,834	3,844	3,850	3,820	3,848	3,857
Course Publishing's	604,420	613,139	618,388	620,365	625,569	629,099
Completed course credit entries posted by CE Providers	4,790,604	4,848,456	4,886,657	4,901,648	4,928,183	4,959,419
Self-submissions by licensees (number of courses)	180,442	181,991	183,340	184,170	186,091	188,028
Website Weekly Visits	6,028	7,124	6,646	4,267	7,242	9,158