Committee on Health Quality

Tuesday, March 6, 2007
4:00 PM – 6:00 PM
216 Capitol Building

COMMITTEE MEETING PACKET

Marco Rubio
Speaker

Gayle Harrell
Chair

House of Representatives

Committee on Health Quality

AGENDA

March 6, 2007
4:00 PM – 6:00 PM
(216 Capitol)

I. **Opening Remarks**

II. **Workshop relating to Recommendations on the Department of Health Performance Measures & Standards for FY 2007-2008**

III. **Workshop on the following:**
PCB HCC 07-XX relating to Patient Safety
PCB HCC 07-XX relating to Tobacco Education and Prevention Program

IV. **Closing Remarks & Adjournment**

PCB HCC 07-XX

Relating to Patient Safety

- Redefines "adverse incident" in order to align with "reviewable sentinel event" as defined by the Joint Commission (JCAHO).

- Creates one hospital adverse incident report by deleting the requirement that a facility submit an annual report summarizing the adverse incident reports that have been filed for that year.

- Amends the content of, and procedure for filing, hospital "Code 15" adverse incident reports:
    - When an adverse incident occurs, the facility must file an initial report within 15 days of its occurrence.
    - The facility must additionally file a corrective action plan and a root cause analysis with the Agency for Health Care Administration within 75 days of the occurrence of the incident.

- Requires the agency to quarterly convene an adverse incident review team from a registry of peer experts in order to create a compilation of best practices through a review of root cause analyses submitted by each facility. These best practices must be published on the agency's website.

- Repeals the Patient Safety Corporation effective June 30, 2008.

A bill to be entitled

An act relating to patient safety; amending s. 395.0197, F.S.; repealing ss. 381.0271 and 381.0273, F.S., relating to the Patient Safety Corporation and the public records exemption for patient safety data; providing an effective date.

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

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

395.0197 Internal risk management program.--

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

(5) For purposes of reporting to the agency pursuant to this section, the term "adverse incident" means one of the following events:

(a) Suicide in 24 hour care

(b) Medication error

(c) Procedural complication

(d) Wrong site surgery

(e) Treatment delay

(f) Restraint death

(g) Elopement death

(h) Sexual abuse/rape

(i) Assault/Homicide

(j) Transfusion death

(k) Patient abduction

(l) Unanticipated death of full term infant

(m) Unintended retention of foreign body

(n) Fall related injuries

~~an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which:~~

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

~~1. Death;~~

~~2. Brain or spinal damage;~~

~~3. Permanent disfigurement;~~

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

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

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

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

~~(b) Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;~~

~~(c) Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or~~

~~(d) Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.~~

~~(6)(a) Each licensed facility subject to this section shall submit an annual report to the agency summarizing the incident reports that have been filed in the facility for that year. The report shall include:~~

~~1. The total number of adverse incidents.~~

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

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

~~4. A code number using the health care professional's licensure number and a separate code number identifying all other individuals directly involved in adverse incidents to patients, the relationship of the individual to the licensed facility, and the number of incidents in which each individual has been directly involved. Each licensed facility shall maintain names of the health care professionals and individuals identified by code numbers for purposes of this section.~~

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

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

~~(c) The report submitted to the agency shall also contain the name and license number of the risk manager of the licensed facility, a copy of its policy and procedures which govern the measures taken by the facility and its risk manager to reduce the risk of injuries and adverse incidents, and the results of such measures. The annual report is confidential and is not available~~

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

(6)~~(7)~~ Any of the ~~following~~ adverse incidents listed in subsection (5), whether occurring in the licensed facility or arising from health care prior to admission ~~in~~ to the licensed facility, shall be reported by the facility to the agency within 15 calendar days after its occurrence. ~~:~~ Each initial report shall contain the following information:

(a) The date of the incident;

(b) The name of the patient;

(c) A complete description of the incident including the suspected cause; and

(d) The name, license number, and signature of the risk manager of the reporting facility.

(7) The facility shall determine the root cause of the adverse incident using the Root Cause Analysis Matrix and tools published by the Joint Commission on Accreditation of Health Care Organizations. The root cause analysis, together with a corrective action plan addressing the root cause, shall be

submitted to the agency within 75 days after the occurrence of the adverse incident.

(8) The agency may grant extensions to the reporting requirements for a maximum of 15 days upon justification submitted in writing by the facility administrator to the agency.

(9) The agency may investigate, as it deems appropriate, any such incident and prescribe measures that must or may be taken in response to the incident.

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

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

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

~~(d) The performance of a wrong-site surgical procedure;~~

~~(e) The performance of a wrong surgical procedure;~~

~~(f) The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition;~~

~~(g) The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage is not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or~~

~~(h) The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure.~~

~~The agency may grant extensions to this reporting requirement for more than 15 days upon justification submitted in writing by the facility administrator to the agency. The agency may require an additional, final report. These reports~~ Reports submitted under subsection (5) shall not be available to the public pursuant to

s. 119.07(1) or any other law providing access to public records, nor be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board, nor shall they be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause. ~~The agency may investigate, as it deems appropriate, any such incident and prescribe measures that must or may be taken in response to the incident. The agency shall review each incident and determine whether it potentially involved conduct by the health care professional who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.~~

(11) ~~(8)~~ The agency shall publish on the agency's website, no less than quarterly, a summary and trend analysis of adverse incident reports received pursuant to this section, which shall not include information that would identify the patient, the reporting facility, or the health care practitioners involved. The agency shall publish on the agency's website an annual summary and trend analysis of all adverse incident reports ~~and malpractice claims information~~ provided by facilities ~~in their annual reports~~, which shall not include information that would identify the patient, the reporting facility, or the practitioners involved. The purpose of the publication of the summary and trend analysis is to promote the rapid dissemination

of information relating to adverse incidents and malpractice claims to assist in avoidance of similar incidents and reduce morbidity and mortality.

(12) Beginning on January 2, 2008, the agency shall maintain a statewide registry of peer experts. The agency shall define by rule the qualifications for serving as a peer expert. The agency shall, at a minimum, quarterly convene an adverse incident review team from the registry and relevant agency staff, which team may vary in size and composition as determined by the agency. The adverse incident review team shall create a compilation of best practices through a systematic review of the root cause analyses developed by each facility in order to improve health care quality and prevent adverse incidents. These best practices shall be maintained on the agency's website.

(13) ~~(9)~~ The internal risk manager of each licensed facility shall:

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

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

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

(d) Report to the Department of Health every allegation of sexual misconduct, as defined in chapter 456 and the respective

practice act, by a licensed health care practitioner that involves a patient.

(15) ~~(10)~~ Any witness who witnessed or who possesses actual knowledge of the act that is the basis of an allegation of sexual abuse shall:

(a) Notify the local police; and

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

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

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

(17) ~~(12)~~ In addition to any penalty imposed pursuant to this section, the agency shall require a written plan of correction from the facility. For a single incident or series of isolated incidents that are nonwillful violations of the

reporting requirements of this section, the agency shall first seek to obtain corrective action by the facility. If the correction is not demonstrated within the timeframe established by the agency or if there is a pattern of nonwillful violations of this section, the agency may impose an administrative fine, not to exceed $5,000 for any violation of the reporting requirements of this section. The administrative fine for repeated nonwillful violations shall not exceed $10,000 for any violation. The administrative fine for each intentional and willful violation may not exceed $25,000 per violation, per day. The fine for an intentional and willful violation of this section may not exceed $250,000. In determining the amount of fine to be levied, the agency shall be guided by s. 395.1065(2)(b).

(18) ~~(13)~~ The agency shall have access to all licensed facility records necessary to carry out the provisions of this section. The records obtained by the agency under subsection (6) or~~,~~ subsection (7)~~, or subsection (9)~~ are not available to the public under s. 119.07(1), nor shall they be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board, nor shall records obtained pursuant to s. 456.071 be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination

of probable cause, except that, with respect to medical review committee records, s. 766.101 controls.

(19) ~~(14)~~ The meetings of the committees and governing board of a licensed facility held solely for the purpose of achieving the objectives of risk management as provided by this section shall not be open to the public under the provisions of chapter 286. The records of such meetings are confidential and exempt from s. 119.07(1), except as provided in subsection (17) ~~(13)~~.

(20) ~~(15)~~ The agency shall review, as part of its licensure inspection process, the internal risk management program at each licensed facility regulated by this section to determine whether the program meets standards established in statutes and rules, whether the program is being conducted in a manner designed to reduce adverse incidents, and whether the program is appropriately reporting incidents under this section.

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

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

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

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

Section 2. Effective June 30, 2008, ss. 381.0271 and 381.0273 are repealed.

Section 3. This act shall take effect July 1, 2007.

PCB HCC 07-XX

Relating to Tobacco Education and Prevention

- Requires the Department of Health ("department") to conduct a comprehensive, statewide tobacco education and prevention program consistent with the 1999 Best Practices for Comprehensive Tobacco Control Programs developed by the United States Centers for Disease Control and Prevention ("CDC").

- Requires the department to include the following components within the program:
  - An advertising campaign;
  - Cessation programs;
  - Evaluations of community and statewide programs;
  - Evidence-based curricula and programs;
  - Programs of local-community based partnerships; and
  - Training of health care providers and smoking cessation counselors.

- Creates a Tobacco Education and Prevention Oversight Council consisting of 11 members, including:
  - The CEO of the Florida Division of the American Cancer Society;
  - The CEO of the Greater Southeast Affiliate of the American Heart Association;
  - The CEO of the American Lung Association of Florida;
  - Four members appointed by the Governor;
  - Two members appointed by the Speaker of the House; and
  - Two members appointed by the President of the Senate.

- Requires the council to generally advise the Secretary of the department regarding the direction and scope of the program. In addition, the Council is provided a number of specific duties, including:
  - Providing advice on program priorities and emphases;
  - Participating in periodic program evaluation;
  - Recommending meaningful outcome measures; and
  - Recommending policies to encourage a coordinate response to tobacco use in the state.

- Creates a competitive grant and contract award program. Contracts and grants will be awarded by the Secretary of Health, in consultation with the council, on the basis of merit through a competitive, peer review process.

- Restricts the use of grant or contract funds by:
  - Prohibiting the purchase of food and promotional items;
  - Limiting overhead or indirect costs to 7.5 percent; and
  - Limiting advertising commissions to 7.5 percent.

- Requires the department to annually report on the program's effectiveness, including a survey of youth attitudes and behavior towards tobacco.

- Limits the department's administrative expenses to 5 percent of the total appropriation.

A bill to be entitled

An act relating to tobacco prevention; creating s. 381.xx, F.S.; providing an effective date.

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

Section 1. Section 381.xx, Florida Statutes, is created to read:

381.xx Comprehensive Statewide Tobacco Education and Prevention Program.--

(1) DEFINITIONS.--As used in s. 27, Art. X of the State Constitution and this act, the term:

(a) "CDC" means the United States Centers for Disease Control and Prevention.

(b) "Department" means the Department of Health.

(d) "Tobacco" means, without limitation, tobacco itself and tobacco products that include tobacco and are intended or expected for human use or consumption, including, but not limited to, cigarettes, cigars, pipe tobacco, and smokeless tobacco.

(f) "Youth" means minors and young adults.

(2) It is the purpose of this act to implement s. 27, Art. X of the State Constitution. The Legislature finds that this section of the State Constitution is intended to require the department to conduct a statewide tobacco education and prevention program that focuses on youth tobacco use. The Legislature further finds that the primary goals of the program are to reduce the prevalence of tobacco use among youth and adults, reduce per-capita tobacco consumption, and reduce exposure to environmental tobacco smoke.

(3) The department shall conduct a comprehensive, statewide tobacco education and prevention program consistent with the recommendations for effective program components contained in the 1999 Best Practices for Comprehensive Tobacco Control Programs of the CDC, as amended by the CDC. The program must include the following components, each of which must focus on educating people, particularly youth and their parents, about the health hazards of tobacco and discouraging use of tobacco:

(a) An advertising campaign utilizing, at a minimum, internet, print, radio, and television advertising;

(b) Cessation programs, including counseling and treatment;

(c) Evaluation of the effectiveness of community and statewide programs;

(d) Evidence-based curricula and programs, including programs that involve youth, educate youth about the health hazards of tobacco, help youth develop skills to refuse tobacco, and demonstrate to youth how to stop using tobacco;

(e) Programs of local community-based partnerships; and

(f) Training of health care providers and smoking cessation counselors.

(4) The Tobacco Education and Prevention Oversight Council is created within the department.

(a) The council shall consist of 11 members, including:

1. The chief executive officer of the Florida Division of the American Cancer Society, or a designee;

2. The chief executive officer of the Greater Southeast Affiliate of the American Heart Association, or a designee;

3. The chief executive officer of the American Lung Association of Florida, or a designee;

4. Four members appointed by the Governor, of which two must have expertise in the field of tobacco prevention and education or smoking cessation;

5. Two members appointed by the President of the Senate, of which one must have expertise in the field of tobacco prevention and education or smoking cessation; and

6. Two members appointed by the Speaker of the House of Representatives, of which one must have expertise in the field of tobacco prevention and education or smoking cessation.

(b) The appointments shall be for a 3-year term and shall reflect the diversity of the state's population. A vacancy shall be filled by appointment by the original appointing authority for the unexpired portion of the term.

(c) An appointed member may not serve more than two consecutive terms.

(d) The council shall annually elect from its membership one member to serve as chair of the council and one member to serve as vice chair.

(e) The oversight council shall meet at least quarterly and upon the call of the chairperson.

(f) Members of the council shall serve without compensation but may be reimbursed for per diem and travel expenses pursuant to s. 112.061.

(g) The department shall provide such staff, information, and other assistance as is reasonably necessary to assist the council in carrying out its responsibilities.

(4) The council shall advise the Secretary of Health as to the direction and scope of the Tobacco Education and Prevention

Program. The responsibilities of the council include, but are not limited to:

(a) Providing advice on program priorities and emphases;

(b) Providing advice on the overall program budget;

(c) Participating in periodic program evaluation;

(d) Assisting in the development of guidelines to ensure fairness, neutrality, and adherence to the principles of merit and quality in the conduct of the program;

(e) Developing administrative procedures relating to solicitation, review, and award of contracts and grants, to ensure an impartial, high-quality peer review system;

(f) Developing and supervising peer review panels;

(g) Reviewing reports of peer review panels and making recommendations for contracts and grants;

(h) Recommending meaningful outcome measures through a regular review of tobacco prevention and education strategies and programs of other states and the Federal Government; and

(i) Recommending policies to encourage a coordinated response to tobacco use in this state, focusing specifically on creating partnerships within and between the public and private sectors.

(5) CONTRACT AND GRANT AWARDS.--Contracts and grants for the program components described in subsection (3) shall be awarded by the Secretary of Health, after consultation with the council, on the basis of merit, as determined by an open, competitive, peer review process that ensures objectivity, consistency, and high quality.

(a) To ensure that all proposals for funding are appropriate and are evaluated fairly on the basis of merit, the

Secretary of Health, in consultation with the council, shall appoint a peer review panel of independent, qualified experts in the field of tobacco control to review the content of each proposal and establish its priority score. The priority scores shall be forwarded to the council and must be considered in determining which proposals shall be recommended for funding.

(b) The council and the peer review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest. A member of the council or panel may not participate in any discussion or decision with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee, or with which the member has entered into a contractual arrangement. Meetings of the council and the peer review panels shall be subject to the provisions of chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.

(c) Each contract or grant agreement must prohibit reimbursement of food and promotional items and limit overhead or indirect costs to no more than 7.5 percent of the total cost of the contract or grant.

(d) Each advertising contract must limit the advertising commission to 7.5 percent, with any refunds, rebates, or commissions otherwise awarded by applicable media outlets being reinvested into additional media purchases.

(6) By January 31 of each year, the department must provide to the Legislature and the Governor a report that evaluates the program's effectiveness in reducing and preventing tobacco use and recommends improvements to enhance the program's

effectiveness. The report must contain, at a minimum, an annual survey of youth attitudes and behavior toward tobacco, as well as a description of the progress in reducing the prevalence of tobacco use among youth and adults, reducing per-capita tobacco consumption, and reducing exposure to environmental tobacco smoke.

(7) From the total funds appropriated for the Comprehensive Statewide Tobacco Education and Prevention Program in the General Appropriations Act, up to 5 percent may be used by the department for administrative expenses.

(8) The department may adopt rules necessary to implement this section.

Section 3. This act shall take effect July 1, 2007.